bioeksen
MOLECULAR DIAGNOSTICS

LETTER OF AUTHORIZATION

By this means, the manufacturer Bioeksen AR GE Teknolojileri A.Ş, located in Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi No:3/31 Sarıyer - İstanbul, authorizes the company SRL SANMEDICO to have a registered office at A. Corobceanu Street 7A, apt. 9, Chişinău MD-2012, Moldova.

As our representative and distributor carry out the necessary procedures in Moldova for the registration, importation, distribution, sales, and promotion of the products manufactured and/or assembled by Bioeksen AR GE Teknolojileri A.Ş in the Country of Moldova.

This authorization is valid for 1 year from the date of signature.

Name: Canan Z. Kotte

Firm: Bioeksen AR GE Teknolojileri A. Ş

Date: 3.02.2023

Position: Executive Manager

BİOEKSEN AR GE TEKNOLOJİLERİ A.Ş.
Huzur Mah. Metin Oktay Cad. Nurol Life D Blok
No: 3/31 Sarıyer / İSTANBUL
Maslak V.D. 176 093 2853 Tic. Sicil No: 904277-0
Mersis No: 0176 0932 8530 0001
info@bioeksen.com.tr - www.bioeksen.com.tr

Digitally signed by Dolgopol Iulian
Date: 2024.03.12 15:32:00 EET
Reason: MoldSign Signature
Location: Moldova

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Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi
D Blok No:3/31 Sarıyer-Istanbul-TURKEY

EC DECLARATION OF CONFORMITY

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Medical Diagnostic Devices

Bioeksen AR GE Teknolojileri A.Ş. hereby declares under its own responsibility that the products covered by this declaration conform with "Essential Requirements" listed in Annex I of EC Directive 98/79/EC (IVD Directive). Supporting documentation (technical documentation) is retained under the premises of the manufacturer.

Manufacturer	: Bioeksen AR GE Teknolojileri Anonim Şirketi
Central Office	: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul TÜRKİYE
Manufacturing Site	: Huzur Mahallesi Metin Oktay Caddesi Nurol Life No:3/10, Sarıyer/İstanbul TÜRKİYE
	Web: www.bioeksen.com.tr, E-mail: info@bioeksen.com.tr
Product(s) Name	: Bio-Speedy® Bordetella pertussis, B.parapertussis, B.bronchiseptica and B.holmesii Real-Time PCR Detection Kit
Description	: Bio-Speedy® Bordetella pertussis, B.parapertussis, B.bronchiseptica and B.holmesii Real-Time PCR Detection Kit
	Ref No: BS-DTC-103-25
	Ref No: BS-DTC-103-100
Classification	: Other (Neither listed in the Annex II, Nor Self-testing device), GMDN code: 50505 - Multiple Bordetella species nucleic acid IVD, kit, nucleic acid technique (NAT)
	Article 9, paragraph 1 of EC Council Directive
	98/79/EC on In Vitro Medical Diagnostic Devices
Conformity Assessment Route	: According to Annex III of the IVD Directive 98/79/EC
	EC declaration of conformity under manufacturer responsibility
Applied Standards	: All standards stated in the annex on the other page are strictly
	implemented in our company.

We hereby declare that the above-mentioned product/s meet the provisions of the EC Council Directive 98/79/EC for in vitro medical diagnostic devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

BİOEKSEN AR GE TEKNOLOJİLERİ A.Ş.
Huzur Mah. Metin Oktay Cad. Nurol Life D Blok
No: 3/31 Sarıyer / İSTANBUL
Maslak V.D. 176 093 2853 Tic. Sicil No: 904277-0
Mersis No: 0176 0932 8530 0001
info@bioeksen.com.tr - www.bioeksen.com.tr

Signature:

Place of Issue: İstanbul

Valid from: 25.05.2022

Authorized Person: Canan Zöhre Ketre Kolukırık

Chairman of the Board

bioeksen

CE IVD

EC DECLARATION OF CONFORMITY

Attachment
List of Applied Standards

No.	Title of standards	Contents
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
3	EN ISO 17511:2020	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
4	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
5	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
6	EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements
7	EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
8	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
9	IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
10	CLSI MM3 A3: 3ED 2015	Molecular Diagnostic Methods for Infectious Diseases
11	CLSI EP17 A2: 2ED 2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
12	CLSI EP07 3ED: 2018	Interference Testing in Clinical Chemistry, 3rd Edition
13	CLSI EP5 A3: 3ED 2014	Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition

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Central Office	: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul TÜRKİYE
Manufacturing Site	: Huzur Mahallesi Metin Oktay Caddesi Nurol Life No:3/10, Sarıyer/İstanbul TÜRKİYE
	Web: www.bioeksen.com.tr, E-mail: info@bioeksen.com.tr
Product(s) Name	: Bio-Speedy® Bacillus anthracis Real-Time PCR Detection Kit
Description	: Bio-Speedy® Bacillus anthracis Real-Time PCR Detection Kit
	Ref No: BS-DTC-V-224-25
	Ref No: BS-DTC-V-224-100
Classification	: Other (Neither listed in the Annex II, Nor Self-testing device), GMDN code: 50432 - Bacillus anthracis nucleic acid IVD, kit, nucleic acid technique (NAT)
	Article 9, paragraph 1 of EC Council Directive
	98/79/EC on In Vitro Medical Diagnostic Devices
Conformity Assessment Route	: According to Annex III of the IVD Directive 98/79/EC
	EC declaration of conformity under manufacturer responsibility
Applied Standards	: All standards stated in the annex on the other page are strictly
	implemented in our company.

We hereby declare that the above-mentioned product/s meet the provisions of the EC Council Directive 98/79/EC for in vitro medical diagnostic devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

Signature:

BİOEKSEN AR GE TEKNOLOJİLERİ A.Ş.
Huzur Mah. Metin Oktay Cad. Nurol Life D Blok
No: 3/31 Sarıyer / İSTANBUL
Maslak V.D. 176 093 2953 Tic. Sicil No: 904277-0
Mersis No: 0176 0932 8530 0001
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Place of Issue: İstanbul

Valid from: 25.05.2022

Authorized Person: Canan Zöhre Ketre Kolukırık

Chairman of the Board

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4	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
5	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
6	EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements
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11	CLSI EP17 A2: 2ED 2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
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Manufacturer	: Bioeksen AR GE Teknolojileri Anonim Şirketi
Central Office	: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul TÜRKİYE
Manufacturing Site	: Huzur Mahallesi Metin Oktay Caddesi Nurol Life No:3/10, Sarıyer/İstanbul TÜRKİYE
	Web: www.bioeksen.com.tr, E-mail: info@bioeksen.com.tr
Product(s) Name	: Bio-Speedy® Measles Virus Real-Time PCR Detection Kit
Description	: Bio-Speedy® Measles Virus Real-Time PCR Detection Kit
	Ref No: BS-MEV-DTC-320-25
	Ref No: BS-MEV-DTC-320-100
Classification	: Other (Neither listed in the Annex II, Nor Self-testing device), GMDN code: 49276 - Measles virus nucleic acid IVD, kit, nucleic acid technique (NAT)
	Article 9, paragraph 1 of EC Council Directive
	98/79/EC on In Vitro Medical Diagnostic Devices
Conformity Assessment Route	: According to Annex III of the IVD Directive 98/79/EC
	EC declaration of conformity under manufacturer responsibility
Applied Standards	: All standards stated in the annex on the other page are strictly
	implemented in our company.

We hereby declare that the above-mentioned product/s meet the provisions of the EC Council Directive 98/79/EC for in vitro medical diagnostic devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

Signature:

BİOEKSEN AR GE TEKNOLOJİLERİ A.Ş.
Huzur Mah. Metin Oktay Cad. Nurol Life D Blok
No: 3/31 Sarıyer/İSTANBUL
Maslak V.D. 176 083 8553 Tic. Sicil No: 904277-0
Mersis No: 0176 0832 8530 0001
info@bioeksen.com.tr - www.bioeksen.com.tr

Place of Issue: İstanbul

Valid from: 25.05.2022

Authorized Person: Canan Zöhre Ketre Kolukırık

Chairman of the Board

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List of Applied Standards

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4	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
5	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
6	EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements
7	EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
8	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
9	IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
10	CLSI MM3 A3: 3ED 2015	Molecular Diagnostic Methods for Infectious Diseases
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Manufacturer	: Bioeksen AR GE Teknolojileri Anonim Şirketi
Central Office	: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul TÜRKİYE
Manufacturing Site	: Huzur Mahallesi Metin Oktay Caddesi Nurol Life No:3/10, Sarıyer/İstanbul TÜRKİYE
	Web: www.bioeksen.com.tr, E-mail: info@bioeksen.com.tr
Product(s) Name	: Bio-Speedy® West Nile Virus Real-Time PCR Detection Kit
Description	: Bio-Speedy® West Nile Virus Real-Time PCR Detection Kit
	Ref No: BS-BNV-DTC-322-25
	Ref No: BS-BNV-DTC-322-100
Classification	: Other (Neither listed in the Annex II, Nor Self-testing device), GMDN code: 49045 - West Nile virus nucleic acid IVD, kit, nucleic acid technique (NAT)
	Article 9, paragraph 1 of EC Council Directive
	98/79/EC on In Vitro Medical Diagnostic Devices
Conformity Assessment Route	: According to Annex III of the IVD Directive 98/79/EC
	EC declaration of conformity under manufacturer responsibility
Applied Standards	: All standards stated in the annex on the other page are strictly
	implemented in our company.

We hereby declare that the above-mentioned product/s meet the provisions of the EC Council Directive 98/79/EC for in vitro medical diagnostic devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

Place of Issue: İstanbul

Valid from: 25.05.2022

Signature:

BİOEKSEN AR GE TEKNOLOJİLERİ A.Ş.
Huzur Mah. Metin Oktay Cad. Nurol Life D Blok
No: 3/31 Sarıyer / İSTANBUL
Maslak V.D. 176 093 2853 Tic. Sicil No: 904277-0
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Authorized Person: Canan Zöhre Ketre Kolukırık

Chairman of the Board

bioeksen

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List of Applied Standards

No.	Title of standards	Contents
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4	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
5	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
6	EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements
7	EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
8	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
9	IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
10	CLSI MM3 A3: 3ED 2015	Molecular Diagnostic Methods for Infectious Diseases
11	CLSI EP17 A2: 2ED 2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
12	CLSI EP07 3ED: 2018	Interference Testing in Clinical Chemistry, 3rd Edition
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EU DECLARATION OF CONFORMITY

2017/746 In Vitro Diagnostic Medical Device Regulation (EU) Declaration of Conformity

Manufacturer	Bioeksen AR GE Teknolojileri A.Ş.
Manufacturer's Address	**Central Office:** Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul TÜRKİYE **Manufacturing Site:** Huzur Mahallesi Metin Oktay Caddesi Nurol Life No:3/10, Sarıyer/İstanbul TÜRKİYE **Web:** www.bioeksen.com.tr, **E-posta:** info@bioeksen.com.tr
Manufacturer Individual Identification Number	TR-MF-000032826
Authorised Representative	-
Authorised Representative's Address	-
Authorized Representative Identification Number	-
Product(s) Name	Bio-Speedy® *ν*NAT® Viral Nucleic Acid Buffer
Product Catalog Number(s)	BS-NA-510-100 BS-NA-510-250 BS-NA-510-500 BS-NA-510-1000
Basic UDI-DI	868187745NAEXB013W
Intended Purpose	The *ν*NAT® Viral Nucleic Acid Buffer is a 10x concentrated viral nucleic acid extractive and preservative liquid for nasopharyngeal swab, oropharyngeal swab, oral/saliva swab samples. The nucleic acid extractive and preservative liquid inactivates all viral, bacterial, or eukaryotic pathogens in the sample within 1 minutes after contact with the clinical specimen. The *ν*NAT® Viral Nucleic Acid Buffer allows from sample to qPCR in a minute.
Technical Documentation Number	TD.016
Risk Classification of Device and Classification Rule	Class A Device according to Annex VIII Article 2.5 (Rule 5) point a of 2017/746 In Vitro Diagnostic Medical Device Regulation (EU)
GMDN Code	52521- Nucleic acid extraction/isolation kit IVD
EMDN Code	-
Conformity Assessment Route	EU Declaration of Conformity, under the responsibility of the manufacturer, according to ANNEX IV (Annex II and Annex III) of 2017/746 In Vitro Diagnostic Medical Device Regulation (EU)

Bioeksen AR GE Teknolojileri A.Ş. declares that the above mentioned device meets the previsions of 2017/746 In Vitro Diagnostic Medical Device Regulation (EU). All supporting documentation is reserved under the premises of the manufacturer and the EU declaration of conformity is issued under sole responsibility of manufacturer.

Authorized Person: Canan Zöhre Ketre Kolukırık

Position: Chairman of the Board

Seal/Signature: BİOEKSEN AR-GE TEKNOLOJİLERİ A.Ş.
Huzur Mah. Metin Oktay Cad. Nurol Life D Blok
No: 3/31 Sarıyer /İSTANBUL
Maslak V.D. 176 093 2858 Tic. Sicil No: 904277-0
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info@bioeksen.com.tr - www.bioeksen.com.tr

Date of Issue: 25.01.2023

Place of Issue: İstanbul

EU DECLARATION OF CONFORMITY

ATTACHMENT
List of Applied Standards

	Standard Title	Content	Scope	Excluded Items
QMS	ISO 9001:2015	Quality management systems — Requirements	Covered	-
Harmonised Standard QMS	EN ISO 13485:2016 EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	Medical devices — Quality management systems — Requirements for regulatory purposes	Partially covered.	– 7.5.5 Special Requirements for Sterile Medical Devices – 7.5.7 Special Requirements for Process Validation for Sterilization and Sterile Barrier Systems – 7.5.9.2 Special requirements for implantable medical devices
Harmonised Standard Risk Management	EN ISO 14971:2019 EN ISO 14971:2019/A11:2021	Medical devices — Application of risk management to medical devices	Covered	-
Risk Management	ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971	Covered	-
Performance Evaluation Metrological Traceability	EN ISO 17511:2020	In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples	Covered	-
Performance Evaluation	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices	Covered	-
Performance Evaluation Stability	EN ISO 23640:2015	In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents	Covered	-
Harmonised Standard Labelling	EN ISO 18113-1:2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements	Covered	-
Harmonised Standard Labelling	EN ISO 18113-2:2012	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use	Covered	-
Harmonised Standard Labelling	EN ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Covered	-
Post-Market Surveillance	ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers	Covered	-
Usability	IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices	Covered	-
Performance Evaluation	ISO 20395:2019	Biotechnology — Requirements for evaluating the performance of quantification methods for nucleic acid target sequences — qPCR and dPCR	Partially covered.	Does not cover dPCR items.

Performance Evaluation	ISO 16142-2:2017	Medical devices — Recognized essential principles of safety and performance of medical devices — Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards	Partially covered.	Table B.1 — General principles for all medical devices 18.3 (l)
Clinical Studies	BS ISO 20916:2019	In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice	Covered	-
Stability	CLSI EP25-A	Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline, CLSI, Wayne, PA, 2009	Covered	-
Stability	ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer	Partially covered.	5.12 Sterile 6.5.3 (c) 6.6.2 (d) (7) 6.6.2 (g) 6.6.2 (h)
Performance Evaluation	MDCG 2021-21	Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices	Covered	-
Performance Evaluation	CLSI MM3 A3: 3ED 2015	Molecular Diagnostic Methods for Infectious Diseases	Covered	-
Performance Evaluation	CLSI EP17 A2: 2ED 2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures	Covered	-
Performance Evaluation	CLSI EP07 3ED: 2018	Interference Testing in Clinical Chemistry, 3rd Edition	Not covered	-
Performance Evaluation	CLSI EP5 A3: 3ED 2014	Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition	Covered	-

EU DECLARATION OF CONFORMITY

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Manufacturing Site	: Huzur Mahallesi Metin Oktay Caddesi Nurol Life No:3/10, Sarıyer/İstanbul TÜRKİYE
	Web: www.bioeksen.com.tr, E-mail: info@bioeksen.com.tr
Product(s) Name	: Bio-Speedy® Respiratory Tract RT-qPCR MX-24T Panel
Description	: Bio-Speedy® Respiratory Tract RT-qPCR MX-24T Panel
	Ref No: BS-SY-MX24T-25
	Ref No: BS-SY-MX24T-100
Classification	: Other (Neither listed in the Annex II, Nor Self-testing device), GMDN code: 61527 - Multiple-type respiratory pathogen nucleic acid IVD, kit, nucleic acid technique (NAT)
	Article 9, paragraph 1 of EC Council Directive
	98/79/EC on In Vitro Medical Diagnostic Devices
Conformity Assessment Route	: According to Annex III of the IVD Directive 98/79/EC
	EC declaration of conformity under manufacturer responsibility
Applied Standards	: All standards stated in the annex on the other page are strictly
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Signature:

BİOEKSEN AR GE TEKNOLOJİLERİ A.Ş.
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Place of Issue: İstanbul

Valid from: 25.05.2022

Authorized Person: Canan Zöhre Ketre Kolukırık

Chairman of the Board

bioeksen

CE IVD

EC DECLARATION OF CONFORMITY

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List of Applied Standards

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Manufacturing Site	: Huzur Mahallesi Metin Oktay Caddesi Nurol Life No:3/10, Sarıyer/İstanbul TÜRKİYE
	Web: www.bioeksen.com.tr, E-mail: info@bioeksen.com.tr
Product(s) Name	: Bio-Speedy® COVID-19/Flu RT-qPCR
Description	: Bio-Speedy® COVID-19/Flu RT-qPCR
	Ref No: BS-SY-SI-100
	Ref No: BS-SY-SI-250
	Ref No: BS-SY-SI-500
	Ref No: BS-SY-SI-1000
Classification	: Other (Neither listed in the Annex II, Nor Self-testing device), GMDN code: 47922- Multiple respiratory virus nucleic acid IVD, kit, nucleic acid technique (NAT)
	Article 9, paragraph 1 of EC Council Directive
	98/79/EC on In Vitro Medical Diagnostic Devices
Conformity Assessment Route	: According to Annex III of the IVD Directive 98/79/EC
	EC declaration of conformity under manufacturer responsibility
Applied Standards	: All standards stated in the annex on the other page are strictly
	implemented in our company.

We hereby declare that the above-mentioned product/s meet the provisions of the EC Council Directive 98/79/EC for in vitro medical diagnostic devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

Signature:

BİOEKSEN AR GE TEKNOLOJİLERİ A.Ş.
Huzur Mah. Metin Oktay Cad. Nurol Life D Blok
No: 3/31 Sarıyer / İSTANBUL
Maslak V.D. 176 [illegible] Ticaret Sicil No: 904277-0
Mersis No: 0176 [illegible] 0001
info@bioeksen.com.tr - www.bioeksen.com.tr

Place of Issue: İstanbul

Valid from: 25.05.2022

Authorized Person: Canan Zöhre Ketre Kolukırık

Chairman of the Board

bioeksen

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EC DECLARATION OF CONFORMITY

Attachment
List of Applied Standards

No.	Title of standards	Contents
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
3	EN ISO 17511:2020	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
4	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
5	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
6	EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements
7	EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
8	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
9	IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
10	CLSI MM3 A3: 3ED 2015	Molecular Diagnostic Methods for Infectious Diseases
11	CLSI EP17 A2: 2ED 2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
12	CLSI EP07 3ED: 2018	Interference Testing in Clinical Chemistry, 3rd Edition
13	CLSI EP5 A3: 3ED 2014	Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition

EC DECLARATION OF CONFORMITY

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Medical Diagnostic Devices

Bioeksen AR GE Teknolojileri A.Ş. hereby declares under its own responsibility that the products covered by this declaration conform with "Essential Requirements" listed in Annex I of EC Directive 98/79/EC (IVD Directive). Supporting documentation (technical documentation) is retained under the premises of the manufacturer.

Manufacturer	: Bioeksen AR GE Teknolojileri Anonim Şirketi
Central Office	: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul TÜRKİYE
Manufacturing Site	: Huzur Mahallesi Metin Oktay Caddesi Nurol Life No:3/10, Sarıyer/İstanbul TÜRKİYE
	Web: www.bioeksen.com.tr, E-mail: info@bioeksen.com.tr
Product(s) Name	: Bio-Speedy® Sepsis qPCR MX-30T Panel
Description	: Bio-Speedy® Sepsis qPCR MX-30T Panel
	Ref No: BS-SE-MX30T-25
	Ref No: BS-SE-MX30T-100
Classification	: Other (Neither listed in the Annex II, Nor Self-testing device), GMDN code: 62484 - Multiple-type bloodstream pathogen nucleic acid IVD, kit, nucleic acid technique (NAT)
	Article 9, paragraph 1 of EC Council Directive
	98/79/EC on In Vitro Medical Diagnostic Devices
Conformity Assessment Route	: According to Annex III of the IVD Directive 98/79/EC
	EC declaration of conformity under manufacturer responsibility
Applied Standards	: All standards stated in the annex on the other page are strictly
	implemented in our company.

We hereby declare that the above-mentioned product/s meet the provisions of the EC Council Directive 98/79/EC for in vitro medical diagnostic devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

Place of Issue: İstanbul

Valid from: 25.05.2022

Signature:

BİOEKSEN AR GE TEKNOLOJİLERİ A.Ş.
Huzur Mah. Metin Oktay Cad. Nurol Life D Blok
No: 3/31 Sarıyer / İSTANBUL
Mersis No: 0176 0932 8530 0001
info@bioeksen.com.tr - www.bioeksen.com.tr

Authorized Person: Canan Zöhre Ketre Kolukırık

Chairman of the Board

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EC DECLARATION OF CONFORMITY

Attachment
List of Applied Standards

No.	Title of standards	Contents
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
3	EN ISO 17511:2020	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
4	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
5	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
6	EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements
7	EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
8	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
9	IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
10	CLSI MM3 A3: 3ED 2015	Molecular Diagnostic Methods for Infectious Diseases
11	CLSI EP17 A2: 2ED 2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
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13	CLSI EP5 A3: 3ED 2014	Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition

EC DECLARATION OF CONFORMITY

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Medical Diagnostic Devices

Bioeksen AR GE Teknolojileri A.Ş. hereby declares under its own responsibility that the products covered by this declaration conform with "Essential Requirements" listed in Annex I of EC Directive 98/79/EC (IVD Directive). Supporting documentation (technical documentation) is retained under the premises of the manufacturer.

Manufacturer	: Bioeksen AR GE Teknolojileri Anonim Şirketi
Central Office	: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul TÜRKİYE
Manufacturing Site	: Huzur Mahallesi Metin Oktay Caddesi Nurol Life No:3/10, Sarıyer/İstanbul TÜRKİYE
	Web: www.bioeksen.com.tr, E-mail: info@bioeksen.com.tr
Product(s) Name	: Bio-Speedy® Meningitis/Encephalitis RT-qPCR MX-17T Panel
Description	: Bio-Speedy® Meningitis/Encephalitis RT-qPCR MX-17T Panel
	Ref No: BS-ME-MX17T-25
	Ref No: BS-ME-MX17T-100
Classification	: Other (Neither listed in the Annex II, Nor Self-testing device), GMDN code: 61043 - Multiple-type meningitis pathogen nucleic acid IVD, kit, nucleic acid technique (NAT)
	Article 9, paragraph 1 of EC Council Directive
	98/79/EC on In Vitro Medical Diagnostic Devices
Conformity Assessment Route	: According to Annex III of the IVD Directive 98/79/EC
	EC declaration of conformity under manufacturer responsibility
Applied Standards	: All standards stated in the annex on the other page are strictly
	implemented in our company.

We hereby declare that the above-mentioned product/s meet the provisions of the EC Council Directive 98/79/EC for in vitro medical diagnostic devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

Place of Issue: İstanbul

Signature:

BİOEKSEN AR GE TEKNOLOJİLERİ A.Ş.
Huzur Mah. Metin Oktay Cad. Nurol Life D Blok
No: 3/31 Sarıyer / İSTANBUL
Maslak V.D. 176 093 2853 Tic. Sicil No: 904277-0
Mersis No: 0176 0932 8530 0001
info@bioeksen.com.tr - www.bioeksen.com.tr

Valid from: 25.05.2022

Authorized Person: Canan Zöhre Ketre Kolukırık

Chairman of the Board

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Attachment
List of Applied Standards

No.	Title of standards	Contents
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
3	EN ISO 17511:2020	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
4	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
5	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
6	EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements
7	EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
8	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
9	IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
10	CLSI MM3 A3: 3ED 2015	Molecular Diagnostic Methods for Infectious Diseases
11	CLSI EP17 A2: 2ED 2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
12	CLSI EP07 3ED: 2018	Interference Testing in Clinical Chemistry, 3rd Edition
13	CLSI EP5 A3: 3ED 2014	Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition

EC DECLARATION OF CONFORMITY

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Medical Diagnostic Devices

Bioeksen AR GE Teknolojileri A.Ş. hereby declares under its own responsibility that the products covered by this declaration conform with "Essential Requirements" listed in Annex I of EC Directive 98/79/EC (IVD Directive). Supporting documentation (technical documentation) is retained under the premises of the manufacturer.

Manufacturer	: Bioeksen AR GE Teknolojileri Anonim Şirketi
Central Office	: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul TÜRKİYE
Manufacturing Site	: Huzur Mahallesi Metin Oktay Caddesi Nurol Life No:3/10, Sarıyer/İstanbul TÜRKİYE
	Web: www.bioeksen.com.tr, E-mail: info@bioeksen.com.tr
Product(s) Name	: Bio-Speedy® Gastroenteritis RT-qPCR MX-24T Panel
Description	: Bio-Speedy® Gastroenteritis RT-qPCR MX-24T Panel
	Ref No: BS-GE-MX24T-25
	Ref No: BS-GE-MX24T-100
Classification	: Other (Neither listed in the Annex II, Nor Self-testing device), GMDN code: 61058 – Multiple-type gastrointestinal pathogen nucleic acid IVD, kit, nucleic acid technique (NAT)
	Article 9, paragraph 1 of EC Council Directive
	98/79/EC on In Vitro Medical Diagnostic Devices
Conformity Assessment Route	: According to Annex III of the IVD Directive 98/79/EC
	EC declaration of conformity under manufacturer responsibility
Applied Standards	: All standards stated in the annex on the other page are strictly
	implemented in our company.

We hereby declare that the above-mentioned product/s meet the provisions of the EC Council Directive 98/79/EC for in vitro medical diagnostic devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

Place of Issue: İstanbul

Signature:

BİOEKSEN AR GE TEKNOLOJİLERİ A.Ş.
Huzur Mah. Metin Oktay Cad. Nurol Life D Blok
No: 3/31 Sarıyer/İSTANBUL
Maslak V.D. 176 093 2853 Tic. Sicil No: 904277-0
Mersis No: 0176 0932 8530 0001
info@bioeksen.com.tr - www.bioeksen.com.tr

Valid from: 25.05.2022

Authorized Person: Canan Zöhre Ketre Kolukırık

Chairman of the Board

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EC DECLARATION OF CONFORMITY

Attachment
List of Applied Standards

No.	Title of standards	Contents
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
3	EN ISO 17511:2020	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
4	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
5	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
6	EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements
7	EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
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9	IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
10	CLSI MM3 A3: 3ED 2015	Molecular Diagnostic Methods for Infectious Diseases
11	CLSI EP17 A2: 2ED 2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
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13	CLSI EP5 A3: 3ED 2014	Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition

EC DECLARATION OF CONFORMITY

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Medical Diagnostic Devices

Bioeksen AR GE Teknolojileri A.Ş. hereby declares under its own responsibility that the products covered by this declaration conform with "Essential Requirements" listed in Annex I of EC Directive 98/79/EC (IVD Directive). Supporting documentation (technical documentation) is retained under the premises of the manufacturer.

Manufacturer	: Bioeksen AR GE Teknolojileri Anonim Şirketi
Central Office	: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul TÜRKİYE
Manufacturing Site	: Huzur Mahallesi Metin Oktay Caddesi Nurol Life No:3/10, Sarıyer/İstanbul TÜRKİYE
	Web: www.bioeksen.com.tr, E-mail: info@bioeksen.com.tr
Product(s) Name	: Bio-Speedy® CCHFV RT-qPCR Detection Kit
Description	: Bio-Speedy® CCHFV RT-qPCR Detection Kit
	Ref No: CCHFVD0125
	Ref No: CCHFVD01100
Classification	: Other (Neither listed in the Annex II, Nor Self-testing device), GMDN code: 49916 - Crimean-Congo hemorrhagic fever (CCHF) virus nucleic acid IVD, kit, nucleic acid technique (NAT)
	Article 9, paragraph 1 of EC Council Directive
	98/79/EC on In Vitro Medical Diagnostic Devices
Conformity Assessment Route	: According to Annex III of the IVD Directive 98/79/EC
	EC declaration of conformity under manufacturer responsibility
Applied Standards	: All standards stated in the annex on the other page are strictly
	implemented in our company.

We hereby declare that the above-mentioned product/s meet the provisions of the EC Council Directive 98/79/EC for in vitro medical diagnostic devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

Signature:

BİOEKSEN AR GE TEKNOLOJİLERİ A.Ş.
Huzur Mah. Metin Oktay Cad. Nurol Life D Blok
No: 3/31 Sarıyer / İSTANBUL
Maslak V.D. 176 093 2853 T.C. Sicil No: 904277-0
Mersis No: 0176 0932 8530 0001
info@bioeksen.com.tr - www.bioeksen.com.tr

Place of Issue: İstanbul

Valid from: 25.05.2022

Authorized Person: Canan Zöhre Ketre Kolukırık

Chairman of the Board

bioeksen

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EC DECLARATION OF CONFORMITY

Attachment
List of Applied Standards

No.	Title of standards	Contents
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
3	EN ISO 17511:2020	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
4	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
5	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
6	EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements
7	EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
8	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
9	IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
10	CLSI MM3 A3: 3ED 2015	Molecular Diagnostic Methods for Infectious Diseases
11	CLSI EP17 A2: 2ED 2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
12	CLSI EP07 3ED: 2018	Interference Testing in Clinical Chemistry, 3rd Edition
13	CLSI EP5 A3: 3ED 2014	Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition

2017/746 In Vitro Diagnostic Medical Device Regulation (EU) Declaration of Conformity

EU DECLARATION OF CONFORMITY

Manufacturer	Bioeksen AR GE Teknolojileri A.Ş.
Manufacturer's Address	**Central Office:** Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul TÜRKİYE **Manufacturing Site:** Huzur Mahallesi Metin Oktay Caddesi Nurol Life No:3/10, Sarıyer/İstanbul TÜRKİYE **Web:** www.bioeksen.com.tr, **E-posta:** info@bioeksen.com.tr
Manufacturer Individual Identification Number	TR-MF-000032826
Authorised Representative	-
Authorised Representative's Address	-
Authorized Representative Identification Number	-
Product(s) Name	**νNAT®** Transfer Tube
Product Catalog Number(s)	BS-NA-513m-100
Basic UDI-DI	868187745NAEXT0672
Intended Purpose	**νNAT®** Transfer Tube, 2 mL of viral nucleic acid extractive and preservative liquid. When clinical specimens suspected of respiratory tract infection are transferred in **νNAT®** Transfer Tube, the liquid inside the tube can be used directly in Real-Time PCR (qPCR) reactions. The nucleic acid extractive and preservative liquid inactivates all viral, bacterial, or eukaryotic pathogens in the sample, 1 minute after contact with the clinical specimen. The **νNAT®** Transfer Tube allows from sample to RT-qPCR in a minute.
Technical Documentation Number	TD.059
Risk Classification of Device and Classification Rule	Class A Device according to Annex VIII Article 2.5 (Rule 5), point c of 2017/746 In Vitro Diagnostic Medical Device Regulation (EU)
GMDN Code	62392- Oral/respiratory tract specimen container IVD, additive/medium
EMDN Code	-
Conformity Assessment Route	EU Declaration of Conformity, under the responsibility of the manufacturer, according to ANNEX IV (Annex II and Annex III) of 2017/746 In Vitro Diagnostic Medical Device Regulation (EU)

Bioeksen AR GE Teknolojileri A.Ş. declares that the above mentioned device meets the previsions of 2017/746 In Vitro Diagnostic Medical Device Regulation (EU). All supporting documentation is reserved under the premises of the manufacturer and the EU declaration of conformity is issued under sole responsibility of manufacturer.

Authorized Person: Canan Zöhre Ketre Kolukırık **Date of Issue:** 25.01.2023

Position: Chairman of the Board **Place of Issue:** İstanbul

Seal/Signature: BİOEKSEN AR-GE TEKNOLOJİLERİ A.Ş.
Huzur Mah. Metin Oktay Cad. Nurol Life D Blok
No:3/31 Sarıyer /İSTANBUL
Maslak V.D. 176 093 3853 Tic. Sicil No: 904277-0
Mersis No: 0176 0932 8530 0001
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EU DECLARATION OF CONFORMITY

ATTACHMENT
List of Applied Standards

	Standard Title	Content	Scope	Excluded Items
QMS	ISO 9001:2015	Quality management systems — Requirements	Covered	-
Harmonised Standard QMS	EN ISO 13485:2016 EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	Medical devices — Quality management systems — Requirements for regulatory purposes	Partially covered.	– 7.5.5 Special Requirements for Sterile Medical Devices – 7.5.7 Special Requirements for Process Validation for Sterilization and Sterile Barrier Systems – 7.5.9.2 Special requirements for implantable medical devices
Harmonised Standard Risk Management	EN ISO 14971:2019 EN ISO 14971:2019/A11:2021	Medical devices — Application of risk management to medical devices	Covered	-
Risk Management	ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971	Covered	-
Performance Evaluation Metrological Traceability	EN ISO 17511:2020	In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples	Covered	-
Performance Evaluation	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices	Covered	-
Performance Evaluation Stability	EN ISO 23640:2015	In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents	Covered	-
Harmonised Standard Labelling	EN ISO 18113-1:2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements	Covered	-
Harmonised Standard Labelling	EN ISO 18113-2:2012	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use	Covered	-
Harmonised Standard Labelling	EN ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Covered	-
Post-Market Surveillance	ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers	Covered	-
Usability	IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices	Covered	-
Performance Evaluation	ISO 20395:2019	Biotechnology — Requirements for evaluating the performance of quantification methods for nucleic acid target sequences — qPCR and dPCR	Partially covered.	Does not cover dPCR items.

Performance Evaluation	ISO 16142-2:2017	Medical devices — Recognized essential principles of safety and performance of medical devices — Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards	Partially covered.	Table B.1 — General principles for all medical devices 18.3 (l)
Clinical Studies	BS ISO 20916:2019	In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice	Covered	-
Stability	CLSI EP25-A	Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline, CLSI, Wayne, PA, 2009	Covered	-
Stability	ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer	Partially covered.	5.12 Sterile 6.5.3 (c) 6.6.2 (d) (7) 6.6.2 (g) 6.6.2 (h)
Performance Evaluation	MDCG 2021-21	Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices	Covered	-
Performance Evaluation	CLSI MM3 A3: 3ED 2015	Molecular Diagnostic Methods for Infectious Diseases	Covered	-
Performance Evaluation	CLSI EP17 A2: 2ED 2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures	Covered	-
Performance Evaluation	CLSI EP07 3ED: 2018	Interference Testing in Clinical Chemistry, 3rd Edition	Not covered	-
Performance Evaluation	CLSI EP5 A3: 3ED 2014	Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition	Covered	-

EU DECLARATION OF CONFORMITY

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Bioeksen AR GE Teknolojileri A.Ş. hereby declares under its own responsibility that the products covered by this declaration conform with "Essential Requirements" listed in Annex I of EC Directive 98/79/EC (IVD Directive). Supporting documentation (technical documentation) is retained under the premises of the manufacturer.

Manufacturer	: Bioeksen AR GE Teknolojileri Anonim Şirketi
Central Office	: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul TÜRKİYE
Manufacturing Site	: Huzur Mahallesi Metin Oktay Caddesi Nurol Life No:3/10, Sarıyer/İstanbul TÜRKİYE
	Web: www.bioeksen.com.tr, E-mail: info@bioeksen.com.tr
Product(s) Name	: Bio-Speedy® Brucella spp. qPCR Kit
Description	: Bio-Speedy® Brucella spp. qPCR Kit
	Ref No: BS-SP-B-12-50
	Ref No: BS-SP-B-12-100
	Ref No: BS-SP-B-12-250
Classification	: Other (Neither listed in the Annex II, Nor Self-testing device), GMDN code: 50605 - Multiple Brucella species nucleic acid IVD, kit, nucleic acid technique (NAT)
	Article 9, paragraph 1 of EC Council Directive
	98/79/EC on In Vitro Medical Diagnostic Devices
Conformity Assessment Route	: According to Annex III of the IVD Directive 98/79/EC
	EC declaration of conformity under manufacturer responsibility
Applied Standards	: All standards stated in the annex on the other page are strictly
	implemented in our company.

We hereby declare that the above-mentioned product/s meet the provisions of the EC Council Directive 98/79/EC for in vitro medical diagnostic devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

Signature:

BİOEKSEN AR GE TEKNOLOJİLERİ A.Ş.
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No: 3/31 Sarıyer/İSTANBUL
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info@bioeksen.com.tr - www.bioeksen.com.tr

Place of Issue: İstanbul

Valid from: 25.05.2022

Authorized Person: Canan Zöhre Ketre Kolukırık

Chairman of the Board

bioeksen

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EC DECLARATION OF CONFORMITY

Attachment
List of Applied Standards

No.	Title of standards	Contents
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9	IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
10	CLSI MM3 A3: 3ED 2015	Molecular Diagnostic Methods for Infectious Diseases
11	CLSI EP17 A2: 2ED 2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
12	CLSI EP07 3ED: 2018	Interference Testing in Clinical Chemistry, 3rd Edition
13	CLSI EP5 A3: 3ED 2014	Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition

EC DECLARATION OF CONFORMITY

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Medical Diagnostic Devices

Bioeksen AR GE Teknolojileri A.Ş. hereby declares under its own responsibility that the products covered by this declaration conform with "Essential Requirements" listed in Annex I of EC Directive 98/79/EC (IVD Directive). Supporting documentation (technical documentation) is retained under the premises of the manufacturer.

Manufacturer	: Bioeksen AR GE Teknolojileri Anonim Şirketi
Central Office	: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul TÜRKİYE
Manufacturing Site	: Huzur Mahallesi Metin Oktay Caddesi Nurol Life No:3/10, Sarıyer/İstanbul TÜRKİYE
	Web: www.bioeksen.com.tr, E-mail: info@bioeksen.com.tr
Product(s) Name	: Bio-Speedy® Tropical Fever RT-qPCR Panel
Description	: Bio-Speedy® Tropical Fever RT-qPCR Panel Ref No: BS-TF-S-25 Ref No: BS-TF-S-100 Ref No: BS-TF-T-25 Ref No: BS-TF-T-100 Ref No: BS-TF-L-25 Ref No: BS-TF-L-100
Classification	: Other (Neither listed in the Annex II, Nor Self-testing device), GMDN code: 61053 - Multiple-type tropical pathogen nucleic acid IVD, kit, nucleic acid technique (NAT) Article 9, paragraph 1 of EC Council Directive 98/79/EC on In Vitro Medical Diagnostic Devices
Conformity Assessment Route	: According to Annex III of the IVD Directive 98/79/EC EC declaration of conformity under manufacturer responsibility
Applied Standards	: All standards stated in the annex on the other page are strictly implemented in our company.

We hereby declare that the above-mentioned product/s meet the provisions of the EC Council Directive 98/79/EC for in vitro medical diagnostic devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

BİOEKSEN AR GE TEKNOLOJİLERİ A.Ş.
Huzur Mah. Metin Oktay Cad. Nurol Life D Blok
No: 3/31 Sarıyer / İSTANBUL
Maslak V.D. 176 093 2853 Ticaret Sicil No: 904277-0
Mersis No: 0176 0932 8530 0001
info@bioeksen.com.tr - www.bioeksen.com.tr

Signature:

Place of Issue: İstanbul
Valid from: 25.05.2022

Authorized Person: Canan Zöhre Ketre Kolukırık
Chairman of the Board

bioeksen

CE IVD

EC DECLARATION OF CONFORMITY

Attachment
List of Applied Standards

No.	Title of standards	Contents
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
3	EN ISO 17511:2020	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
4	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
5	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
6	EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements
7	EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
8	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
9	IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
10	CLSI MM3 A3: 3ED 2015	Molecular Diagnostic Methods for Infectious Diseases
11	CLSI EP17 A2: 2ED 2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
12	CLSI EP07 3ED: 2018	Interference Testing in Clinical Chemistry, 3rd Edition
13	CLSI EP5 A3: 3ED 2014	Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition

EC DECLARATION OF CONFORMITY

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Medical Diagnostic Devices

Bioeksen R&D Technologies Inc. Co. hereby declares under its own responsibility that the products covered by this declaration conform with "Essential Requirements" listed in Annex I of EC Directive 98/79/EC (IVD Directive). Supporting documentation (technical documentation) is retained under the premises of the manufacturer.

Manufacturer	: Bioeksen R&D Technologies Incorporated Company Resitpasa Mh. Katar Cd. No:4/B-105. Sariyer, Istanbul- TURKEY Web: www.bioeksen.com.tr, e-mail: info@bioeksen.com.tr
Product(s) Name	: Bio-Speedy® Legionella pneumophila qPCR Kit
Description	: Bio-Speedy® Legionella pneumophila qPCR Kit Ref No: BS-LP-25 Ref No: BS-LP-100
Classification	: Other (Neither listed in the Annex II, Nor Self-testing device), GMDN code: 51060 - Legionella pneumophila nucleic acid IVD, kit, nucleic acid technique (NAT) Article 9, paragraph 1 of EC Council Directive 98/79/EC on In Vitro Medical Diagnostic Devices
Conformity Assessment Route	: According to Annex III of the IVD Directive 98/79/EC EC declaration of conformity under manufacturer responsibility
Applied Standards	: All standards stated in the annex on the other page are strictly implemented in our company.

We hereby declare that the above-mentioned product/s meet the provisions of the EC Council Directive 98/79/EC for in vitro medical diagnostic devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

Place of Issue: Istanbul

Valid from: 16.05.2022

Signature:

Authorized Person: Canan Zöhre Ketre Kolukırık

Chairman of the Board

bioeksen

CE IVD

EC DECLARATION OF CONFORMITY

Attachment
List of Applied Standards

No.	Title of standards	Contents
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
3	EN ISO 17511:2020	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
4	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
5	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
6	EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements
7	EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
8	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
9	IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
10	CLSI MM3 A3: 3ED 2015	Molecular Diagnostic Methods for Infectious Diseases
11	CLSI EP17 A2: 2ED 2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
12	CLSI EP07 3ED: 2018	Interference Testing in Clinical Chemistry, 3rd Edition
13	CLSI EP5 A3: 3ED 2014	Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition

EC DECLARATION OF CONFORMITY

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Medical Diagnostic Devices

Bioeksen R&D Technologies Inc. Co. hereby declare under own responsibility that the products covered by this declaration conform with "Essential Requirements" listed in Annex I of EC Directive 98/79/EC (IVD Directive). Supporting documentation (technical documentation) is retained under the premises of the manufacturer.

Manufacturer	: Bioeksen R&D Technologies Incorporated Company Resitpasa Mh. Katar Cd. No:4/B-105. Sariyer, Istanbul- TURKEY Web: www.bioeksen.com.tr, e-mail: info@bioeksen.com.tr
Product(s) Name	: Bio-Speedy® Gastroenteritis RT-qPCR MX-5T Viral Panel
Description	: Bio-Speedy® Gastroenteritis RT-qPCR MX-5T Viral Panel Ref No: BS-GE-MX5T-25 Ref No: BS-GE-MX5T-100
Classification	: Other (Neither listed in the Annex II, Nor Self-testing device), GMDN code: 61058 – Multiple-type gastrointestinal pathogen nucleic acid IVD, kit, nucleic acid technique (NAT) Article 9, paragraph 1 of EC Council Directive 98/79/EC on In Vitro Medical Diagnostic Devices
Conformity Assessment Route	: According to Annex III of the IVD Directive 98/79/EC EC declaration of conformity under manufacturer responsibility
Applied Standards	: All standards stated in the annex on the other page are strictly implemented in our company.

We hereby declare that the above-mentioned product/s meet the provisions of the EC Council Directive 98/79/EC for in vitro medical diagnostic devices. All supporting documentation is retained under the premises of the manufacturer and manufacturer is exclusively responsible for the declaration of conformity.

Place of Issue: Istanbul

Signature:

Valid from: 16.05.2022

Authorized Person: Canan Zöhre Ketre Kolukırık

Chairman of the Board

bioeksen

CE IVD

EC DECLARATION OF CONFORMITY

Attachment
List of Applied Standards

No.	Title of standards	Contents
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
3	EN ISO 17511:2020	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
4	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
5	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
6	EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements
7	EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
8	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
9	IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
10	CLSI MM3 A3: 3ED 2015	Molecular Diagnostic Methods for Infectious Diseases
11	CLSI EP17 A2: 2ED 2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
12	CLSI EP07 3ED: 2018	Interference Testing in Clinical Chemistry, 3rd Edition
13	CLSI EP5 A3: 3ED 2014	Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition

For in vitro diagnostic use only.
For professional use only.

Cat No: BS-BNV-DTC-322-25/BS-BNV-DTC-322-100

West Nile Virus Real-Time PCR Detection Kit

Package Insert

Table 1. Kit Content

Component	Intended Use	25 Reactions	100 Reactions
2X Prime Script Mix	Optimized ready-to-use mix for RT-qPCR assay	1 x 125 µL	1 x 500 µL
WNV Oligo Mix	Specific nucleic acid amplification and detection: **FAM:** West Nile virus **HEX:** Human (IC-Internal Control)	1 x 62,5 µL	1 x 250 µL
NTC	Negative Control	1 x 1000 µL	
PC-WNV	Positive Control (PC)	1 x 100 µL	1 x 250 µL

Table 2. Transport Condition, Storage Condition, and Shelf Life of the Components

Component	Transport Condition	Storage Condition*	Shelf Life
2X Prime Script Mix	(-22) – (+8) °C	(-22) – (-18) °C	12 Months
WNV Oligo Mix		(-22) – (-18) °C	
NTC		(+2) – (+8) °C	
PC-WNV		(+2) – (+8) °C	

*Each reagent stored at storage temperature can be used until the expiration date indicated on the tube following the first opening. The kit's expiration date is determined by the expiration date of the reagents.

Table 3. Components Required but Not Included with The Test

Components Required but Not Included with The Test
1. Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS) or/and CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) Real-Time PCR systems
2. Micropipettes and compatible filtered pipette tips (nuclease-free) suitable for transferring 1-10, 10-100, and 100-1000 µL of liquid
3. A centrifuge or Mini-spin
4. Vortex
5. Reaction tubes and caps/films specific to qPCR instruments and compatible with reaction volume

Table 4. Intended Use, Test Principle, and Analytical Specifications

Function	Aid to diagnosis	**Sample Type(s)**	Table 5
Analyte(s)	Table 1	**Nucleic Acid Preparation Method(s)**	Table 5
Qualitative/Quantitative	Qualitative	**Validated PCR Instrument(s)**	Table 3
Test Principle	Reverse transcription and Real-Time PCR (RT-qPCR)	**Results Interpretation and Reporting**	Automated (Sigmoida software)
Automated/Manual	Manual	**Inclusivity and Exclusivity**	Validated on the reference strains and the field isolates
Intended Users	Professional use	**Limit of Detection (LoD)**	Table 5
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	%100.00 and %100.00

Table 5. Collection, Storage, and Transfer of Clinical Specimens / Nucleic Acid Preparation Methods and the Respected LoD Values

Sample Type**	Sample Transfer	Sample Storage	Nucleic Acid Preparation Method	LoD (cp/mL)
Whole blood, serum and plasma	Anti-coagulent treated tube	3 days at (+2) – (+8) °C 1 year at -70 °C	***Zybio EXM3000 Nucleic Acid Isolation System*** (Robot Model No: EXM3000, Kit Cat. No: ZFNAE01) ***RINA™ M14 Nucleic Acid Extraction Device*** (Robot Model No: RINA-M14-01, Kit Cat. No: RN-NA-101)	250

**Clinical specimens should be collected by a healthcare provider in accordance with national/international clinical specimen collection regulations.

1. qPCR Application Protocol

Before starting the assay, please consider the following:

1. The kit was validated only for the template nucleic acid volume which is 25% of the total qPCR volume.
2. The kit cannot be used with real-time PCR instruments without periodic maintenance records.
3. The kit for Bio-Rad Real-Time PCR systems has been validated with white reaction tubes specific to these systems. Clear reaction tubes result in 5-10 times lower fluorescence signal in Bio-Rad instruments compared to white reaction tubes. In addition, device-specific reaction tubes should be used in the BMS device. The kit's stated analytical performance can only be achieved using validated tubes.
4. To test for contamination, a negative control reaction containing NTC (Nuclease-free Water) must be set up in each run.

Program the qPCR device as follows and add the reagents into the qPCR tubes, close the tubes, place them into the qPCR instrument and start the run. (Table 6)

Table 6. qPCR Program Details

Reaction Setup		qPCR Program				QR Code for Thermal Protocol and Plate Setup
		CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) and *Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)*				
Reagent	**Volume/Rxn**	**Step**	**Cycle No.**	**Temperature**	**Duration**	
2X Prime Script Mix	5 µL	**Enzyme Activation**	1 Cycle	52 °C	3 min	
		Pre-Incubation	1 Cycle	95 °C	10 sec	
WNV Oligo Mix	2,5 µL	**Denaturation**	12 Touchdown Cycles: 1 °C decrement in annealing temperature per cycle	95 °C	1 sec	
		Annealing and Extension		67 °C to 56 °C	15 sec	
Template Nucleic Acid/NTC/PC	2,5 µL	**Denaturation**	35 Cycles	95 °C	1 sec	https://www.bioeksen.com.tr/files/BS_TD_3RT153555
		Annealing and Extension		55 °C	15 sec	
Total Reaction Volume	**10 µL**	**Detection (Reading)**		(FAM-Green)/(HEX-Yellow)		

WARNING: The RT-qPCR thermal programs (Bio-Rad and BMS-Mic) and the plate setup (Bio-Rad) file should be downloaded from the QR code or link above.

2. Interpretation of the Assay Results Using The "Sigmoida" Software

The data produced by the instruments must be evaluated and reported using the "**Sigmoida**" software. The result files opened with the "Sigmoida" software will be analyzed automatically. Below are examples of results that can be achieved with the Sigmoida software:

Negative: The sample tested is negative for the tested agent.
Positive: The sample tested is positive for the tested agent.
Contamination: Repeat the analysis paying attention to the "Warnings and Limitations" section.
Invalid: Sampling isn't successfully done, or there is a problem during the sample transportation. A new sample from the same patient should be collected and tested again.
Reagent Problem: Test the "PC-WNV" provided with the kit setting up the PC reaction as shown in Table 6. If the test result is positive, the run is valid. In case the software generates a "Reagent Problem" again, contact the manufacturer.

3. Warnings and Limitations

1. False-negative results may occur if inadequate numbers (lower than the LoD) of organisms are present in the specimen.
2. Mutations within the target regions could affect primer and/or probe binding, resulting in failure to detect the presence of agents.
3. A false-negative result may occur if a specimen is improperly collected, transported, or handled.
4. The clinical specimens shall be collected by a healthcare provider in accordance with the specimen collection guidelines.
5. Test procedures should be performed by personnel trained in the use of the kit.
6. Except for liquid transfers, sample tubes should always be kept closed.
7. Filtered and nuclease-free pipette tips should be used for sample transfer.
8. The components in the kit should not be used together with different lot numbers or chemicals of the same name but from different manufacturers.
9. ***The caps of the reaction tubes must not be opened after the PCR run.*** The PCR tubes should be placed in a bag and thrown away after the bag is tightly closed.
10. The surfaces of the workbenches should be wiped with freshly diluted 10% bleach (0.5% NaClO) at the beginning and end of each day.
11. Disposal of waste must be carried out in accordance with local, state, and federal regulations.

4. Explanation of Symbol

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
CE	European Conformity CE Mark	LOT	Batch code		Keep away from sunlight
IVD	*In vitro* diagnostic *medical device*	REF	Catalogue number		Protect from heat and radioactive sources
	Manufacturer	NON STERILE	Non-*sterile*		Do not use if package is damaged and consult *instructions for use*
	Use-by date		Consult *instructions for use* or consult electronic *instructions for use*		Keep dry
CONTROL -	Negative control		Caution		Keep upright
CONTROL +	Positive control		Temperature limit	Σ	Contains sufficient for *<n>* tests
CONTROL	Control				

5. Manufacturer and Technical Support

Bioeksen AR GE Teknolojileri A.Ş
Address: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul-TÜRKİYE
Phone: +90 (212) 285 10 17, **Fax:** +90 (212) 285 10 18
Web: www.bioeksen.com.tr, **e-mail:** info@bioeksen.com.tr,
Technical Support: support@bioeksen.com.tr

Notice to User: Please inform us about product-related incidents at "**vigilance@bioeksen.com.tr**" within 24 hours.

For in vitro diagnostic use only.
For professional use only.

Cat No: BS-DTC-V-224-25/BS-DTC-V-224-100

Bacillus anthracis Real-Time PCR Detection Kit

Package Insert

Table 1. Kit Content

Component	Intended Use	25 Reactions	100 Reactions
2X qPCR Mix	Optimized ready-to-use mix for qPCR assay	1 x 125 µL	1 x 500 µL
BA Oligo Mix	Specific nucleic acid amplification and detection: **FAM:** *Bacillus anthracis* **HEX:** Human (IC-Internal Control)	1 x 62.5 µL	1 x 250 µL
NTC	Negative Control	1 x 1000 µL	
PC-BA	Positive Control (PC)	1 x 100 µL	1 x 250 µL

Table 2. Transport Condition, Storage Condition, and Shelf Life of the Components

Component	Transport Condition	Storage Condition*	Shelf Life
2X qPCR Mix	(-22) – (+8) °C	(-22) – (-18) °C	12 Months
BA Oligo Mix		(-22) – (-18) °C	
NTC		(+2) – (+8) °C	
PC-BA		(+2) – (+8) °C	

*Each reagent stored at storage temperature can be used until the expiration date indicated on the tube following the first opening. The kit's expiration date is determined by the expiration date of the reagents.

Table 3. Components Required but Not Included with The Test

Components Required but Not Included with The Test
1. Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS) or/and CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) Real-Time PCR systems
2. Micropipettes and compatible filtered pipette tips (nuclease-free) suitable for transferring 1-10, 10-100, and 100-1000 µL of liquid
3. A centrifuge or Mini-spin
4. Vortex
5. Reaction tubes and caps/films specific to qPCR instruments and compatible with reaction volume

Table 4. Intended Use, Test Principle, and Analytical Specifications

Function	Aid to diagnosis	**Sample Type(s)**	Table 5
Analyte(s)	Table 1	**Nucleic Acid Preparation Method(s)**	Table 5
Qualitative/Quantitative	Qualitative	**Validated PCR Instrument(s)**	Table 3
Test Principle	Real-Time PCR (qPCR)	**Results Interpretation and Reporting**	Automated (Sigmoida software)
Automated/Manual	Manual	**Inclusivity and Exclusivity**	Validated on the reference strains and the field isolates
Intended Users	Professional use	**Limit of Detection (LoD)**	Table 5
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	%100.00 and %100.00

Table 5. Collection, Storage, and Transfer of Clinical Specimens / Nucleic Acid Preparation Methods and the Respected LoD Values

Sample Type**	Sample Transfer	Sample Storage	Nucleic Acid Preparation Method	LoD (cp/mL)
Whole blood and serum	Anti-coagulent treated tube	3 days at (+2) – (+8) °C 1 year at -70 °C	***Zybio EXM3000 Nucleic Acid Isolation System*** (Robot Model No: EXM3000, Kit Cat. No: ZFNAE01) ***RINA™ M14 Nucleic Acid Extraction Device*** (Robot Model No: RINA-M14-01, Kit Cat. No: RN-NA-101)	150
Cerebrospinal Fluid (CSF) samples	Preservative-free sterile containers			

**Clinical specimens should be collected by a healthcare provider in accordance with national/international clinical specimen collection regulations.

1. qPCR Application Protocol

Before starting the assay, please consider the following:

1. The kit was validated only for the template nucleic acid volume which is 25% of the total qPCR volume.
2. The kit cannot be used with real-time PCR instruments without periodic maintenance records.
3. The kit for Bio-Rad Real-Time PCR systems has been validated with white reaction tubes specific to these systems. Clear reaction tubes result in 5-10 times lower fluorescence signal in Bio-Rad instruments compared to white reaction tubes. In addition, device-specific reaction tubes should be used in the BMS device. The kit's stated analytical performance can only be achieved using validated tubes.
4. To test for contamination, a negative control reaction containing NTC (Nuclease-free Water) must be set up in each run.

Program the qPCR device as follows and add the reagents into the qPCR tubes, close the tubes, place them into the qPCR instrument and start the run. (Table 6)

Table 6. qPCR Program Details

Reaction Setup		qPCR Program				QR Code for Thermal Protocol and Plate Setup
		CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) and *Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)*				
Reagent	**Volume/Rxn**	**Step**	**Cycle No.**	**Temperature**	**Duration**	
2X qPCR Mix	5 µL	**Enzyme Activation**	1 Cycle	52 °C	3 min	
		Pre-Incubation	1 Cycle	95 °C	10 sec	
Oligo Mix	2.5 µL	**Denaturation**	12 Touchdown Cycles: 1 °C decrement in annealing temperature per cycle	95 °C	1 sec	
		Annealing and Extension		67 °C to 56 °C	15 sec	
Template Nucleic Acid/NTC/PC	2.5 µL	**Denaturation**	35 Cycles	95 °C	1 sec	
		Annealing and Extension		55 °C	15 sec	https://www.bioeksen.com.tr/files/BS_TD_3RT153555
Total Reaction Volume	**10 µL**	**Detection (Reading)**		(FAM-Green)/(HEX-Yellow)		

WARNING: The qPCR thermal programs (Bio-Rad and BMS-Mic) and the plate setup (Bio-Rad) file should be downloaded from the QR code or link above.

2. Interpretation of the Assay Results Using The "Sigmoida" Software

The data produced by the instruments must be evaluated and reported using the "**Sigmoida**" software. The result files opened with the "Sigmoida" software will be analyzed automatically. Below are examples of results that can be achieved with the Sigmoida software:

Negative: The sample tested is negative for the tested agent.
Positive: The sample tested is positive for the tested agent.
Contamination: Repeat the analysis paying attention to the "Warnings and Limitations" section.
Invalid: Sampling isn't successfully done, or there is a problem during the sample transportation. A new sample from the same patient should be collected and tested again.
Reagent Problem: Test the "PC-BA" provided with the kit setting up the PC reaction as shown in Table 6. If the test result is positive, the run is valid. In case the software generates a "Reagent Problem" again, contact the manufacturer.

3. Warnings and Limitations

1. False-negative results may occur if inadequate numbers (lower than the LoD) of organisms are present in the specimen.
2. Mutations within the target regions could affect primer and/or probe binding, resulting in failure to detect the presence of agents.
3. A false-negative result may occur if a specimen is improperly collected, transported, or handled.
4. The clinical specimens shall be collected by a healthcare provider in accordance with the specimen collection guidelines.
5. Test procedures should be performed by personnel trained in the use of the kit.
6. Except for liquid transfers, sample tubes should always be kept closed.
7. Filtered and nuclease-free pipette tips should be used for sample transfer.
8. The components in the kit should not be used together with different lot numbers or chemicals of the same name but from different manufacturers.
9. ***The caps of the reaction tubes must not be opened after the PCR run.*** The PCR tubes should be placed in a bag and thrown away after the bag is tightly closed.
10. The surfaces of the workbenches should be wiped with freshly diluted 10% bleach (0.5% NaClO) at the beginning and end of each day.
11. Disposal of waste must be carried out in accordance with local, state, and federal regulations.

4. Explanation of Symbol

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
CE	European Conformity CE Mark	LOT	Batch code		Keep away from sunlight
IVD	*In vitro* diagnostic *medical device*	REF	Catalogue number		Protect from heat and radioactive sources
	Manufacturer	NON STERILE	Non-*sterile*		Do not use if package is damaged and consult *instructions for use*
	Use-by date		Consult *instructions for use* or consult electronic *instructions for use*		Keep dry
CONTROL -	Negative control		Caution		Keep upright
CONTROL +	Positive control		Temperature limit	Σ	Contains sufficient for *<n>* tests
CONTROL	Control				

5. Manufacturer and Technical Support

Bioeksen AR GE Teknolojileri A.Ş
Address: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul-TÜRKİYE
Phone: +90 (212) 285 10 17, **Fax:** +90 (212) 285 10 18
Web: www.bioeksen.com.tr, **e-mail:** info@bioeksen.com.tr,
Technical Support: support@bioeksen.com.tr

Notice to User: Please inform us about product-related incidents at "**vigilance@bioeksen.com.tr**" within 24 hours.

For in vitro diagnostic use only.
For laboratory professional use only.

Cat No: BS-GE-MX5T-25/BS-GE-MX5T-100

Gastroenteritis RT-qPCR MX-5T Viral Panel

Package Insert

1. Kit Content

Table 1. Kit Content

Oligo Mix Content					Positive Control Content		
Component	**Targets**	**Channel**	**Quantity (20 µL/Rxn) 25 Rxns**	**Quantity (20 µL/Rxn) 100 Rxns**	**Component**	**Quantity (20 µL/Rxn) 25 Rxns**	**Quantity (20 µL/Rxn) 100 Rxns**
SA Oligo Mix	Sapovirus (GI/GII/GIV/GV)	FAM	1 x 125 µL	1 x 500 µL	PC-SA	1 x 100 µL	1 x 100 µL
	Internal Control (Human *RNase P* gene)	HEX					
	-	ROX					
	Adenovirus Type F	CY5					
ANR Oligo Mix	Astrovirus	FAM	1 x 125 µL	1 x 500 µL	PC-ANR	1 x 100 µL	1 x 100 µL
	Norovirus (GI/GII)	HEX					
	Rotavirus (A)	ROX					
	-	CY5					

Component	**Intended Use**	**25 Rxns**	**100 Rxns**
2X Prime Script Mix	Optimized ready-to-use mix for RT-qPCR assay	1 x 500 µL	2 x 1000 µL
NTC	Negative (No template) Control (Nuclease-free Water)	1 x 1000 µL	1 x 1000 µL

Table 2. Storage Requirements and Shelf Life

Component	**Transport Condition**	**Storage Condition**	**Shelf Life**
2X Prime Script Mix	-22 °C to +8 °C	-22 °C to -18 °C	12 Months
Oligo Mix		-22 °C to -18 °C	
NTC		-22 °C to -18 °C / +2°C to +8 °C	
PC		-22 °C to -18 °C before opening, +2°C to +8 °C after first thaw	

! Each reagent stored at storage temperature can be used until the expiration date indicated on the tube following the first opening. The expiration date of the kit is determined by the expiration date of the reagents.

2. Materials Required but Not Provided

Table 3. Components Required but not Included with The Test

Components Required but not Included with The Test	
1. Real-Time instrument with FAM, HEX, ROX, and CY5 channels, Ramp rate ≥3 °C/sec	**7.** Reaction tubes and their caps/seals compatible with the qPCR instruments and the reaction volume
2. Adjustable micropipettes and compatible pipette tips (nuclease-free)	**Extra components recommended to use:**
3. Centrifuge	**8.** Biosafety cabinet for PCR setup
4. Vortex	**9.** Cold tube rack (for microcentrifuge tubes and PCR tubes/strips)
5. Nuclease-free water/viral transport medium/serum physiologic	**10.** PPE (Personal Protective Equipment)
6. 1.5- or 2-mL microcentrifuge tubes (nuclease-free)	

3. Intended Use and Test Principle

Bio-Speedy® Gastroenteritis RT-qPCR MX-5T Viral Panel is a one-step reverse transcription and real-time PCR (RT-qPCR) test intended for the presumptive qualitative detection of the viral agents given in Table 1. The ***Bio-Speedy® Gastroenteritis RT-qPCR MX-5T Viral Panel*** is applied to nucleic acid isolates obtained from the stool and rectal swab samples.

Gastroenteritis is one of the best common health problems, with high morbidity and mortality rates in children and the elderly. Therefore, a rapid and accurate diagnosis of the agent is essential for appropriate treatment.

Detection with the kit is achieved via rapid nucleic acid extraction from the stool and rectal swab samples followed by multiplex RT-qPCR targeting the genomic RNA and DNA regions specific to the target agents in real-time PCR instruments that are equipped with FAM, HEX, ROX, and CY5 detection channels. **The kit allows to achieve RT-qPCR results in 60 minutes (Run time may vary depending on the instrument)**.

The oligonucleotide set targeting the human ***RNase P*** mRNA functions as a control of the sampling, nucleic acid extraction, reverse transcription, and qPCR since the oligonucleotide set targets the exon-exon junction. The kit also contains negative and positive control templates for testing the contamination and the RT-qPCR reagent stability, respectively.

Bio-Speedy® Gastroenteritis RT-qPCR MX-5T Viral Panel is intended for use by laboratory personnel trained in the techniques of RT-qPCR and *in vitro* diagnostic procedures.

4. Analytical Specifications

Bio-Speedy® Gastroenteritis RT-qPCR MX-5T Viral Panel is validated with ***Bio-Speedy® vNAT® Transfer Tube*** (*Catalog No: BS-NA-513-100*), ***vNAT® Transfer Tube*** (*Catalog No: BS-NA-513m-100*) for sample transfer, and ***Zybio EXM3000 Nucleic Acid Isolation System*** (*Robot Model No: EXM3000*) for nucleic acid isolates extracted from the stool and rectal swab samples.

Limit of Detection (LoD) of the ***Bio-Speedy® Gastroenteritis RT-qPCR MX-5T Viral Panel*** is 98 copies/mL for Sapovirus, 62 copies/mL for Adenovirus Type F, 46 copies/mL for Astrovirus, 31 copies/mL for Norovirus, and 24 copies/mL for Rotavirus for stool and rectal swab samples extracted using the ***Zybio EXM3000 Nucleic Acid Isolation System*** *(Robot Model No: EXM3000).*

Table 4. Summary of LoD results based on the specimen type and extraction method.

NO	Specimen Type	Sample Transfer Method		Extraction Method	LOD (cp/mL)
		Sterile Container	*vNAT® Transfer Tube*	*Zybio EXM3000 Nucleic Acid Isolation System*	
1	Rectal swab	-	✓	✓	24-98
2	Stool	✓	-	✓	24-98

The RT-qPCR is carried out in 20 µL reaction volume using the ***CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad)***, and ***Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)*** Real-Time PCR systems equipped with the **FAM**, **HEX**, **ROX**, and **CY5** detection channels.

The exclusivity of the kit was tested on different viral agents. No cross-reaction was observed in analytical specificity studies performed on reference strains and field isolates. The sensitivity and specificity of the kit were determined as 98.93% and 99.14%, respectively.

5. Collection, Storage, and Shipment of Clinical Specimens

Clinical stool samples collected from individuals are transferred into 1-5 mL in a sterile, leak-proof screw cap container. No preservative is required. Clinical rectal swab samples collected from individuals are transferred into a sterile empty tube with a screw cap if the swab is to be processed within 2 hours. If it is to be kept for longer than 2 hours, it should be inoculated into a transport medium. Samples should be stored and transported at 2 °C to 8 °C until they arrive at the laboratory. Samples should be transferred within a maximum of 2 days. Nucleic acid from samples should be extracted and frozen at -70 °C and shipped with dry ice.

6. Warnings

1. Specimen processing should be performed in accordance with national biological safety recommendations.
2. Immediately clean up any spill containing potentially infectious material with 0.5-1% (w/v) sodium hypochlorite (10-20% v/v bleach). Dispose of cleaning materials in a biohazard waste stockpot.
3. All personnel who perform aspects of the testing procedures should be trained to work with PCR and microbiology as appropriate. Sampling should be carried out by personnel with sufficient knowledge and experience.
4. The kit should be stored away from nucleic acid sources and PCR amplicons.
5. Except for fluid transfers, nucleic acid and positive control tubes should always be kept closed.
6. To prevent contamination of the reaction mixture by previously amplified target sequences, maintain separate work areas and dedicated equipment.
7. Different sets of laboratory coats should be worn in pre- and post-PCR areas.
8. The micropipettes used for pipetting PCR mixes and template nucleic acids should be separate. Filtered and nuclease-free tips should be used.
9. Cotton or calcium alginate swabs or swabs with wooden sticks should not be used since they may contain substances that inactivate some pathogens and inhibit PCR.
10. The components in the kit should not be mixed with different lot numbers or chemicals of the same name but from different manufacturers.
11. Master stock reagents should be kept on the cold block during the PCR setup.
12. Kit components should be mixed by gently shaking before use.
13. Maintenance/calibration interval should be determined for all instruments and equipment used with the kit.
14. Immediately after each RT-qPCR run, dispose of the qPCR tubes in closed bags to avoid PCR amplicon contamination in the lab.
15. The wipeable surfaces of the rooms, benches, and devices should be cleaned regularly with freshly diluted 10% bleach solution (0.5% NaClO).
16. Dispose of waste in a designated matter in accordance with local, regional, and federal regulations.

7. RT-qPCR Application Protocol

Before starting the assay, please consider the following:

1. The kit was validated only for the template nucleic acid volume that is 25% of the total RT-qPCR volume.
2. The kit cannot be used with real-time PCR instruments without periodic maintenance records.
3. **It is recommended to use a validated qPCR plate/strip with the kit!** The specified analytical performance of the kit can only be achieved using the validated tubes.
4. **For testing the contamination, set up two different negative control reactions with and without the addition of NTC**.

Program the qPCR device as follows: add the reagents into the qPCR tubes, close the tubes, place them into the qPCR instrument and start the run (Table 5).

Table 5. Real-Time PCR Program

Reaction Setup		RT-qPCR Program				QR Code for Thermal Protocol
		CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) and Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)				
Reagent	**Volume/Rxn**	**Step**	**Cycle No.**	**Temperature**	**Duration**	
2X Prime Script Mix	10 µL	**Reverse Transcription**	1 Cycle	52 °C	5 min	
		Pre-incubation	1 Cycle	95 °C	10 sec	
Oligo Mix	5 µL	**Denaturation**	12 Touchdown Cycles: 1 °C decrement in annealing temperature per cycle	95 °C	1 sec	
		Annealing and Extension		67 °C to 56 °C	30 sec	
Template Nucleic Acid	5 µL	**Denaturation**	35 Cycles	95 °C	1 sec	
		Annealing and Extension		55 °C	30 sec	
Total Reaction Volume	**20 µL**	**Detection (Reading)**		FAM/HEX/ROX/CY5		https://www.bioeksen.com.tr/files/gastroenterit_mx-5t_viral_panel

WARNING: The RT-qPCR program template of the instrument software should be downloaded from the manufacturer's website to avoid errors in manual entry.

8. Interpretation of the Assay Results

- All default analysis options (e.g. **auto-calculated threshold**) in the related software of ***CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad)*** and ***Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)*** instruments should not be changed to calculate Cq values.
- Shape of the amplification curves obtained in the FAM/HEX/ROX/CY5 channels should be examined for all reaction wells returning with Cq values. All the **sigmoidal curves above the threshold** should be recorded as "**positive**" and their Cq values should be recorded. **Non-sigmoidal curves** should be recorded as "**negative**".
- For **samples with a sigmoidal curve below the auto-calculated threshold** for the ***CFX96 Touch™/CFX96™ Dx (Bio-Rad) and CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad)*** instruments, **the threshold level should be manually set to 200 RFU**. **If the sigmoidal curve exceeds the threshold, the Cq value should be recorded as "35,"** and the sample should be reported as "**positive**".
- For **samples with a sigmoidal curve below the auto-calculated threshold** for ***Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)*** should be reported as "**positive**" and **their Cq values should be recorded as "35"**.

Table 6. Expected Performance of the Kit Controls

Control Type	Control Name	Purpose	Expected Results and Cq Values	
			***RNase P* (HEX)**	***Target* (FAM, HEX, ROX, and CY5)**
Negative Control	NTC	Contamination control during RT-qPCR	**Not Detected** (No Cq)	**Not Detected** (No Cq)
No template addition	NRC	Reagent contamination control	**Not Detected** (No Cq)	**Not Detected** (No Cq)
Positive Control	PC	Reagent integrity	**Detected** (Cq≤33)	**Detected** (Cq≤33)
Internal/Extraction Control	IC	To monitor the integrity of nucleic acid extraction and RT-qPCR from each sample	**Detected** (Cq≤33) If IC Cq>33 check the target Cq	If the target Cq≤35, conclude it as IC is valid

If any control does not perform as described above, the run is considered invalid, and the test is repeated.

1. **Invalid PC (Cq>33 in any channel):** It is recommended to contact the manufacturer, renew the reagents, and repeat the reaction.
2. **Invalid NTC (No Cq in any channel):** Repeat the analysis by paying attention to the "**Warnings**" section.
3. **Invalid NRC (No Cq in any channel):** Contact the manufacturer, renew the reagents, and repeat the reaction.
4. **Invalid IC (Cq>33 in HEX channel and no Cq in the other channels):** Repeat the analysis. If the problem continues, then conclude it as an invalid PCR template.

If all the controls are valid, proceed to the interpretation of the results (Table 7).

Table 7. Interpretation of the Patient Results

Target	Internal Control	Report	
Positive (+)	**Positive (+)**	Report it as **POSITIVE** for the target	25≤Cq≤35 = Low positive 18≤Cq<25 = Positive 11≤Cq<18 = High positive Cq<11 = Very high positive
Positive (+)	**Negative (-)**	Report it as **POSITIVE** for the target	
Negative (-)	**Positive (+)**	Report it as **NEGATIVE** for the target	
Negative (-)	**Negative (-)**	**INVALID** Result: Sampling/extraction/inhibition problem Re-extract the specimen and perform testing again. If the result is still invalid, a new specimen should be obtained. If an additional clinical sample is unavailable, report it as **INVALID.**	

WARNING: On the web page linked with the QR code, examples of the sigmoidal amplification curves are given. The results obtained with this kit should NOT be interpreted without examining these samples.

9. Limitations

- ***Bio-Speedy® Gastroenteritis RT-qPCR MX-5T Viral Panel*** is intended for use by laboratory personnel trained in the techniques of RT-qPCR and *in vitro* diagnostic procedures.
- The clinical specimens shall be collected by a healthcare provider in accordance with the specimen collection guidelines.
- A false-negative result may occur if a specimen is improperly collected, transported, or handled.
- The use of cotton or calcium alginate swabs or swabs with wooden sticks can lead to false-negative results since they may contain substances that inactivate some pathogens and inhibit PCR.
- Mutations within the target regions of the ***Bio-Speedy® Gastroenteritis RT-qPCR MX-5T Viral Panel*** could affect primer and/or probe binding resulting in failure to detect the presence of the virus.
- Inhibitors or other types of interference may produce a false-negative result. False-negative results may also occur if inadequate numbers of organisms are present in the specimen.

10. Explanation of Symbol

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
CE	European Conformity CE Mark	LOT	Batch code		Keep away from sunlight
IVD	*In vitro* diagnostic *medical device*	REF	Catalogue number		Protect from heat and radioactive sources
	Manufacturer	NON STERILE	Non-*sterile*		Do not use if package is damaged and consult *instructions for use*
	Use-by date		Consult *instructions for use* or consult electronic *instructions for use*		Keep dry
CONTROL -	Negative control		Caution		Keep upright
CONTROL +	Positive control		Temperature limit	Σ	Contains sufficient for <*n*> tests
CONTROL	Control				

11. Manufacturer and Technical Support

Bioeksen R&D Technologies Incorporated Company
Address: Resitpasa Mh. Katar Cd., 4/B-105. 34467, Sariyer, Istanbul, TURKEY.
Phone: +90 (212) 285 10 17, **Fax:** +90 (212) 285 10 18
Web: www.bioeksen.com.tr, **e-mail:** info@bioeksen.com.tr,
Technical Support: support@bioeksen.com.tr

Notice to User: Please inform us about product-related incidents at " **vigilance@bioeksen.com.tr** " within 24 hours.

For in vitro diagnostic use only.
For laboratory professional use only.

Cat No: BS-DTC-103-25/BS-DTC-103-100

Bordetella pertussis, B.parapertussis, B.bronchiseptica and B.holmesii Real-Time PCR Detection Kit

Package Insert

Table 1. Kit Content

Component	Intended Use	25 Reactions	100 Reactions
2X qPCR Mix	Optimized ready-to-use mix for qPCR assay	1 x 250 µL	1 x 1000 µL
Bor 1-Oligo Mix	Specific nucleic acid amplification and detection: **FAM**: *Bordetella pertussis* **HEX:** Human (IC-Internal Control)	1 x 62.5 µL	1 x 250 µL
Bor 2-Oligo Mix	**FAM:** *Bordetella holmesii* **ROX:** *Bordetella parapertussis* **CY5:** *Bordetella bronchiseptica*	1 x 62.5 µL	1 x 250 µL
NTC	Negative Control	1 x 1000 µL	1 x 1000 µL
PC-Bor 1 / PC-Bor 2	Positive Control (PC)	1 x 100 µL	1 x 100 µL

Table 2. Storage Conditions and Shelf Life

Component	Transport Condition	Storage Condition*	Shelf Life
2X qPCR Mix	(-22) °C – (+8) °C	(-22) °C – (-18) °C	12 Months
Oligo Mix		(-22) °C – (-18) °C	
NTC		(+2) °C – (+8) °C	
PC		(+2) °C – (+8) °C	

*Each reagent stored at storage temperature can be used until the expiration date indicated on the tube following the first opening. The kit's expiration date is determined by the expiration date of the reagents.

Table 3. Components Required but Not Included with The Test

Components Required but Not Included with The Test
1. Micropipettes and compatible filtered pipette tips (nuclease-free) suitable for transferring 1-10, 10-100, and 100-1000 µL of liquid
2. Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS) and/or CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) Real-Time PCR systems
3. A centrifuge or Mini-spin
4. Vortex
5. Reaction tubes and caps/films specific to qPCR instruments and compatible with reaction volume

Table 4. Intended Use, Test Principle, and Analytical Specifications

Function	Aid to diagnosis	**Sample Type(s)**	Table 5
Analyte(s)	Table 1	**Nucleic Acid Preparation Method(s)**	Table 5
Qualitative/Quantitative	Qualitative	**Validated PCR Instrument(s)**	Table 3
Test Principle	Real-Time PCR (qPCR)	**Inclusivity and Exclusivity**	Validated on the reference strains and the field isolates
Automatic/Manual	Manual		
Intended Users	Professional use	**Limit of Detection**	Table 5
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	100.00% and 100.00%

Table 5. Collection, Storage, and Transfer of Clinical Specimens / Nucleic Acid Preparation Methods and the Respected LoD Values

Sample Type**	Sample Transfer	Sample Storage	Nucleic Acid Preparation Method	LoD (cp/mL)
Combined nasopharyngeal and oropharyngeal swabs	***v*NAT® *Transfer Tube*** (Cat. No: BS-NA-513m/BS-NA-513)	3 months at (+2) °C – (+8) °C 1 year at -20 °C	Nucleic acid preparation is not needed, samples can be used directly in qPCR .	250
	Viral Transport Medium (VTM) (CDC SOP#: DSR-052-05 without antibiotics)	3 days at (+2) °C – (+8) °C 1 year at -70 °C	***RINA™ M14 Nucleic Acid Extraction Device*** (Robot Model No: RINA-M14-01, Kit Cat. No: RN-NA-101)	125
Bronchoalveolar lavage, nasopharyngeal aspirate, and sputum	Preservative-free sterile containers	3 days at (+2) °C – (+8) °C 1 year at -70 °C	***Zybio EXM3000 Nucleic Acid Isolation System*** (Robot Model No: EXM3000, Kit Cat. No: ZFNAE01)	500

** Clinical specimens should be collected by a healthcare provider in accordance with national/international clinical specimen collection regulations.

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For in vitro diagnostic use only.
For laboratory professional use only.

1. qPCR Application Protocol

Before starting the assay, please consider the following:

1. The kit was validated only for the template nucleic acid volume which is 25% of the total qPCR volume.
2. The kit cannot be used with real-time PCR instruments without periodic maintenance records.
3. The kit for Bio-Rad Real-Time PCR systems has been validated with white reaction tubes specific to these systems. Clear reaction tubes result in 5-10 times lower fluorescence signal in Bio-Rad instruments compared to white reaction tubes. In addition, device-specific reaction tubes should be used in the BMS device. The kit's stated analytical performance can only be achieved using validated tubes.
4. To test for contamination, a negative control reaction containing NTC (Nuclease-free Water) must be set up in each run.

Program the qPCR device as follows and add the reagents into the qPCR tubes, close the tubes, place them into the qPCR instrument and start the run (Table 6)

Table 6. Reaction Setup and qPCR Program

Reaction Setup		**qPCR Program**				**QR Code for Thermal Protocol and Plate Setup**
		CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) and Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)				
Reagent	**Volume/Rxn**	**Step**	**Cycle No.**	**Temperature**	**Duration**	
2X qPCR Mix	5 µL	**Enzyme Activation**	1 Cycle	52 °C	3 min	
		Pre-Incubation	1 Cycle	95 °C	10 sec	
Oligo Mix	2.5 µL	**Denaturation**	12 Touchdown Cycles: 1 °C decrement in annealing temperature per cycle	95 °C	1 sec	
		Annealing and Extension		67 °C to 56 °C	15 sec	
Template Nucleic Acid/NTC/PC	2.5 µL	**Denaturation**	30 Cycles	95 °C	1 sec	
		Annealing and Extension		55 °C	15 sec	
Total Reaction Volume	**10 µL**	**Detection (Reading)**		(FAM-Green)/(HEX-Yellow) (ROX-Orange)/(CY5-Red)		https://www.bioeksen.com.tr/files/L_TD_43P/

WARNING: The qPCR thermal programs (Bio-Rad and BMS) and the plate setup (Bio-Rad) file should be downloaded from the QR code or link above.

2. Interpretation of the Assay Results

All default analysis options (e.g., auto-calculated threshold) in the MIC and/or Bio-Rad software should not be changed to calculate Cq values.

The shape of the amplification curves should be examined for all reaction wells returning with Cq values. All the sigmoidal curves above the threshold should be recorded as "positive" and their Cq values should be recorded. Non-sigmoidal curves should be recorded as "negative".

Table 7. Expected Performance of Kit Controls

Control Type	**Control Name**	**Purpose**	**Expected Results and Cq Values**	
			IC (HEX)	**Target**
Negative Control	NTC	Contamination control during qPCR	**Not detected** (No Cq)	**Not detected** (No Cq)
Positive Control	PC	Reagent integrity	**Detected** (Cq≤26)	**Detected** (Cq≤26)
Internal/Extraction Control	IC	To monitor the integrity of nucleic acid extraction and qPCR from each sample	**Detected** (Cq≤26) If the IC Cq>26, check the target Cq.	If the target has a valid Cq value according to the result interpretation criteria, IC is valid.

If any control does not work as described above, the run is reported as follows:

1. **Contamination:** If Cq≤26 in any NTC test channel.
   Recommended action: Repeat the analysis paying attention to the "Warnings and Limitations" section.
2. **Reagent Problem**: In case a sigmoidal curve with a Cq≤26 cannot be obtained for any of all the samples tested in the run, including the controls.
   Recommended action: Test the "Positive Control(s)" (Refer to Table 1) provided with the kit according to Table 6. If the test result is positive, the run is valid. In case the software generates a "Reagent Problem" again, contact the manufacturer.
3. **Invalid:** If the sample has a Cq>26 in the HEX (IC) channel of the test tube and no Cq in the other channels.
   Recommended action: Sampling isn't successfully done, or there is a problem during the sample transportation. A new sample from the same patient should be collected and tested again.

If all the controls are valid, the results are interpreted as follows:

Table 8. Interpretation of Patient Results

Target	**Internal Control (IC)**	**Result Interpretation**	
Positive (+)	**Positive (+)** or **Negative (-)**	Results are valid Target is detected	If 26<Cq "Negative" If 16<Cq≤26 "Positive" If Cq≤16 "High Positive"
Negative (-)	**Positive (+)**	Results are valid Target is not detected	

The results produced by the qPCR instrument can manually be reported as described above or can automatically be reported using the "**Sigmoida**" software. To obtain the "Sigmoida" software installer, please send an email to support@bioeksen.com.tr.

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3. Warnings and Limitations

1. False-negative results may occur if inadequate numbers (lower than the LoD) of organisms are present in the specimen.
2. Mutations within the target regions could affect primer and/or probe binding resulting in failure to detect the presence of agents.
3. The use of cotton or calcium alginate swabs or swabs with wooden sticks can lead to false-negative results since they may contain substances that inactivate some pathogens and inhibit PCR.
4. A false-negative result may occur if a specimen is improperly collected, transported, or handled.
5. The clinical specimens shall be collected by a healthcare provider in accordance with the specimen collection guidelines.
6. Test procedures should be performed by personnel trained in the use of the kit.
7. Except for liquid transfers, sample tubes should always be kept closed.
8. Filtered and nuclease-free pipette tips should be used for sample transfer.
9. The components in the kit should not be used together with different lot numbers or chemicals of the same name but from different manufacturers.
10. ***The caps of the reaction tubes must not be opened after the PCR run.*** The PCR tubes should be placed in a bag and thrown away after the bag is tightly closed.
11. The surfaces of the workbenches should be wiped with freshly diluted 10% bleach (0.5% NaClO) at the beginning and end of each day.
12. Disposal of waste must be carried out in accordance with local, state, and federal regulations.

4. Explanation of Symbol

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
CE	European Conformity CE Mark	LOT	Batch code		Keep away from sunlight
IVD	*In vitro* diagnostic *medical device*	REF	Catalogue number		Protect from heat and radioactive sources
	Manufacturer	NON STERILE	Non-*sterile*		Do not use if package is damaged and consult *instructions for use*
	Use-by date		Consult *instructions for use* or consult electronic *instructions for use*		Keep dry
CONTROL -	Negative control		Caution		Keep upright
CONTROL +	Positive control		Temperature limit	Σ	Contains sufficient for <*n*> tests
CONTROL	Control				

5. Manufacturer and Technical Support

Bioeksen AR GE Teknolojileri A.Ş
Address: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul-TÜRKİYE
Phone: +90 (212) 285 10 17, **Fax:** +90 (212) 285 10 18
Web: www.bioeksen.com.tr, **E-mail:** info@bioeksen.com.tr,
Technical Support: support@bioeksen.com.tr

Notice to User: Please inform us about product-related incidents at " **vigilance@bioeksen.com.tr** " within 24 hours.

For in vitro diagnostic use only.
For laboratory professional use only.

For in vitro diagnostic use only.
For professional use only.

Cat No: BS-GE-MX24T-25/BS-GE-MX24T-100

Gastroenteritis RT-qPCR MX-24T Panel

Package Insert

Table 1. Kit Content

Component	Intended Use	25 Reactions	100 Reactions
2X Prime Script Mix	Optimized ready-to-use mix for RT-qPCR assay	2 x 1000 µL	7 x 1250 µL
SA Oligo Mix	Specific nucleic acid amplification and detection **FAM**: Sapovirus (GI/GII/GIV/GV) **HEX:** Human (IC-Internal Control) **CY5:** Adenovirus	1 x 125 µL	1 x 500 µL
GCE Oligo Mix	**FAM**: *Giardia lamblia* **ROX:** *Entamoeba histolytica* **CY5:** *Cryptosporidium* spp.	1 x 125 µL	1 x 500 µL
PCD Oligo Mix	**FAM:** *Clostridium difficile* toxin B **HEX:** *Plesiomonas shigelloides* **ROX:** *Vibrio vulnificus* **CY5:** *Cyclospora cayetanensis*	1 x 125 µL	1 x 500 µL
ANR Oligo Mix	**FAM**: Astrovirus **HEX:** Norovirus (GI/GII) **ROX:** Rotavirus (A)	1 x 125 µL	1 x 500 µL
CVVS Oligo Mix	**FAM:** *Salmonella* spp. **HEX:** *Campylobacter* spp. **ROX:** *Vibrio parahaemolyticus* **CY5:** *Vibrio cholerae*	1 x 125 µL	1 x 500 µL
ET1 Oligo Mix	**FAM:** *Shigella*/Enteroinvasive *E. coli* (EIEC) **ROX:** Enteroaggregative *E. coli* (EAEC) **CY5:** Shiga toxin producing *E. coli* (STEC)	1 x 125 µL	1 x 500 µL
ET2 Oligo Mix	**FAM:** Enteropathogenic *E. coli* (EPEC) **CY5:** Enterotoxigenic *E. coli* (ETEC)	1 x 125 µL	1 x 500 µL
CTXY Oligo Mix	**FAM:** *Yersinia enterocolitica* **ROX:** *Clostridium difficile* toxin A **CY5:** *Clostridium difficile* Binary toxin A/B	1 x 125 µL	1 x 500 µL
PC-SA/PC-GCE/PC-YPC/PC-ANR PC-CVVS/PC-ET1/PC-ET2/PC-CTX	Positive Control (PC)	1 x 100 µL	1 x 100 µL
NTC	Negative Control	1 x 1000 µL	1 x 1000 µL

Table 2. Transport Condition, Storage Condition, and Shelf Life of the Components

Component	Transport Condition	Storage Condition*	Shelf Life
2X Prime Script Mix	(-22) °C – (+8) °C	(-22) °C – (-18) °C	12 Months
Oligo Mix		(-22) °C – (-18) °C	
NTC		(+2) °C – (+8) °C	
PC		(+2) °C – (+8) °C	

*Each reagent stored at storage temperature can be used until the expiration date indicated on the tube following the first opening. The kit's expiration date is determined by the expiration date of the reagents.

Table 3. Components Required but Not Included with The Test

Components Required but Not Included with The Test
1. Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS) or/and CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) Real-Time PCR systems
2. Micropipettes and compatible filtered pipette tips (nuclease-free) suitable for transferring 1-10, 10-100, and 100-1000 µL of liquid
3. A centrifuge or Mini-spin
4. Vortex
5. Reaction tubes and caps/films specific to qPCR instruments and compatible with the reaction volume

Table 4. Intended Use, Test Principle, and Analytical Specifications

Function	Aid to diagnosis	**Sample Type(s)**	Table 5
Analyte	Table 1	**Nucleic Acid Preparation Method(s)**	Table 5
Qualitative/Quantitative	Qualitative	**Validated PCR Instruments**	Table 3
Test Principle	Reverse Transcription and Real-Time PCR (RT-qPCR)	**Inclusivity and Exclusivity**	Validated on the reference strains and the field isolates
Automated/Manual	Manual		
Intended Users	Professional use	**Limit of Detection (LoD)**	Table 5
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	98.93% and 99.14%

Table 5. Collection, Storage and Transfer of Clinical Specimens / Nucleic Acid Preparation Methods and the Respected LoD Values

Sample Type**	Sample Transfer	Sample Storage	Nucleic Acid Preparation Method	LoD (cp/mL)
Stool	Preservative-free sterile containers/tubes	3 days at (+2) °C – (+8) °C 1 year at -70 °C	***RINA™ M14 Nucleic Acid Extraction Device*** (Robot Catalog No: RINA-M14-01, Kit Cat. No: RN-NA-101) ***Zybio EXM3000 Nucleic Acid Isolation System*** (Robot Catalog No: EXM3000, Kit Cat. No: ZFNAE01)	24-98

** Clinical specimens should be collected by a healthcare provider in accordance with national/international clinical specimen collection regulations.

1. RT-qPCR Application Protocol

Before starting the assay, please consider the following:

1. The kit was validated only for the template nucleic acid volume which is 25% of the total RT-qPCR volume.
2. The kit cannot be used with real-time PCR instruments without periodic maintenance records.
3. The kit for Bio-Rad Real-Time PCR systems has been validated with white reaction tubes specific to these systems. Clear reaction tubes result in 5-10 times lower fluorescence signal in Bio-Rad instruments compared to white reaction tubes. In addition, device-specific reaction tubes should be used in the BMS device. The kit's stated analytical performance can only be achieved using validated tubes.
4. To test for contamination, a negative control reaction containing NTC (Nuclease-free Water) must be set up in each run.

Program the qPCR device as follows and add the reagents into the qPCR tubes, close the tubes, place them into the qPCR instrument and start the run (Table 6)

Table 6. Reaction Setup and Real-Time PCR Program

Reaction Setup		RT-qPCR Program				QR Code for Thermal Protocol and Plate Setup
		CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) and ***Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)***				
Reagent	**Volume/Rxn**	**Step**	**Cycle No.**	**Temperature**	**Duration**	
2X Prime Script Mix	10 µL	**Reverse Transcription**	1 Cycle	52 °C	3 min	
		Pre-Incubation	1 Cycle	95 °C	10 sec	
Oligo Mix	5 µL	**Denaturation**	12 Touchdown Cycles: 1 °C decrement in annealing temperature per cycle	95 °C	1 sec	
		Annealing and Extension		67 °C to 56 °C	15 sec	
Template Nucleic Acid/NTC/PC	5 µL	**Denaturation**	30 Cycles	95 °C	1 sec	
		Annealing and Extension		55 °C	15 sec	
Total Reaction Volume	**20 µL**	**Detection (Reading)**		(FAM-Green)/(HEX-Yellow) (ROX-Orange)/(CY5-Red)		https://www.bioeksen.com.tr/files/L_TD_43P/

WARNING: The RT-qPCR thermal programs (Bio-Rad and BMS) and the plate setup (Bio-Rad) file should be downloaded from the QR code or link above.

2. Interpretation of the Assay Results

All default analysis options (e.g., auto-calculated threshold) in the MIC and/or Bio-Rad software should not be changed to calculate Cq values.

The shape of the amplification curves should be examined for all reaction wells returning with Cq values. All the sigmoidal curves above the threshold should be recorded as "positive" and their Cq values should be recorded. Non-sigmoidal curves should be recorded as "negative".

Table 7. Expected Performance of Kit Controls

Control Type	Control Name	Purpose	Expected Results and Cq Values	
			IC (HEX)	Target
Negative Control	NTC	Contamination control during RT-qPCR	**Not detected** (No Cq)	**Not detected** (No Cq)
Positive Control	PC	Reagent integrity	**Detected** (Cq≤26)	**Detected** (Cq≤26)
Internal/Extraction Control	IC	To monitor the integrity of nucleic acid extraction and RT-qPCR from each sample	**Detected** (Cq≤26) If the IC Cq>26, check the target Cq.	If the target has a valid Cq value according to the result interpretation criteria, IC is valid.

If any control does not work as described above, the run is reported as follows:

1. **Contamination:** If Cq≤26 in any NTC test channel.
   Recommended action: Repeat the analysis paying attention to the "Warnings and Limitations" section.

2. **Reagent Problem**: In case a sigmoidal curve with a Cq≤26 cannot be obtained for any of all the samples tested in the run, including the controls.
   Recommended action: Test the **"Positive Control(s)"** (Refer to Table 1) provided with the kit. If the test result is positive, the run is valid. In case the software generates a "Reagent Problem" again, contact the manufacturer.

3. **Invalid:** If the sample has a Cq>26 in the HEX (IC) channel of the test tube and no Cq in the other channels.
   Recommended action: Sampling isn't successfully done, or there is a problem during the sample transportation. A new sample from the same patient should be collected and tested again.

If all the controls are valid, the results are interpreted as follows:

Table 8. Interpretation of Patient Results

Target	Internal Control (IC)	Result Interpretation	
Positive (+)	**Positive (+)** or **Negative (-)**	Results are valid Target is detected	If 26<Cq "Negative" If 16<Cq≤26 "Positive" If Cq≤16 "High Positive"
Negative (-)	**Positive (+)**	Results are valid Target is not detected	

The results produced by the qPCR instrument can manually be reported as described above or can automatically be reported using the "**Sigmoida**" software. To obtain the "Sigmoida" software installer, please send an email to support@bioeksen.com.tr.

3. Warnings and Limitations

1. False-negative results may occur if inadequate numbers (lower than the LoD) of organisms are present in the specimen.
2. Mutations within the target regions could affect primer and/or probe binding, resulting in failure to detect the presence of agents.
3. A false-negative result may occur if a specimen is improperly collected, transported, or handled.
4. The use of cotton or calcium alginate swabs or swabs with wooden sticks can lead to false-negative results since they may contain substances that inactivate some pathogens and inhibit PCR.
5. The clinical specimens shall be collected by a healthcare provider in accordance with the specimen collection guidelines.
6. Test procedures should be performed by personnel trained in the use of the kit.
7. Except for liquid transfers, sample tubes should always be kept closed.
8. Filtered and nuclease-free pipette tips should be used for sample transfer.
9. The components in the kit should not be used together with different lot numbers or chemicals of the same name but from different manufacturers.
10. ***The caps of the reaction tubes must not be opened after the PCR run.*** The PCR tubes should be placed in a bag and thrown away after the bag is tightly closed.
11. The surfaces of the workbenches should be wiped with freshly diluted 10% bleach (0.5% NaClO) at the beginning and end of each day.
12. Disposal of waste must be carried out in accordance with local, state, and federal regulations.

4. Explanation of Symbol

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
CE	European Conformity CE Mark	LOT	Batch code		Keep away from sunlight
IVD	*In vitro* diagnostic *medical device*	REF	Catalogue number		Protect from heat and radioactive sources
	Manufacturer		Non-*sterile*		Do not use if package is damaged and consult *instructions for use*
	Use-by date		Consult *instructions for use* or consult electronic *instructions for use*		Keep dry
CONTROL -	Negative control		Caution		Keep upright
CONTROL +	Positive control		Temperature limit		Contains sufficient for <*n*> tests
CONTROL	Control				

5. Manufacturer and Technical Support

Bioeksen AR GE Teknolojileri A.Ş
Address: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul-TÜRKİYE
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Web: www.bioeksen.com.tr, **e-mail:** info@bioeksen.com.tr,
Technical Support: support@bioeksen.com.tr

Notice to User: Please inform us about product-related incidents at "**vigilance@bioeksen.com.tr**" within 24 hours.

For in vitro diagnostic use only.
For professional use only.

Cat No: BS-LP-25/BS-LP-100

Legionella pneumophila qPCR Kit

Package Insert

Table 1. Kit Content

Component	Intended Use	25 Reactions	100 Reactions
2X qPCR Mix	Optimized ready-to-use mix for qPCR assay	1 x 125 µL	1 x 500 µL
LP Oligo Mix	Specific nucleic acid amplification and detection: **FAM:** *Legionella pneumophila* **HEX:** Human (IC-Internal Control)	1 x 62.5 µL	1 x 250 µL
NTC	Negative Control	1 x 1000 µL	
PC-LP	Positive Control (PC)	1 x 100 µL	1 x 250 µL

Table 2. Transport Condition, Storage Condition, and Shelf Life of the Components

Component	Transport Condition	Storage Condition*	Shelf Life
2X qPCR Mix	(-22) – (+8) °C	(-22) – (-18) °C	12 Months
LP Oligo Mix		(-22) – (-18) °C	
NTC		(+2) – (+8) °C	
PC-LP		(+2) – (+8) °C	

*Each reagent stored at storage temperature can be used until the expiration date indicated on the tube following the first opening. The kit's expiration date is determined by the expiration date of the reagents.

Table 3. Components Required but Not Included with The Test

Components Required but Not Included with The Test
1. Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS) or/and CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) Real-Time PCR systems
2. Micropipettes and compatible filtered pipette tips (nuclease-free) suitable for transferring 1-10, 10-100, and 100-1000 µL of liquid
3. A centrifuge or Mini-spin
4. Vortex
5. Reaction tubes and caps/films specific to qPCR instruments and compatible with reaction volume

Table 4. Intended Use, Test Principle, and Analytical Specifications

Function	Aid to diagnosis	**Sample Type(s)**	Table 5
Analyte(s)	Table 1	**Nucleic Acid Preparation Method(s)**	Table 5
Qualitative/Quantitative	Qualitative	**Validated PCR Instrument(s)**	Table 3
Test Principle	Real-Time PCR (qPCR)	**Results Interpretation and Reporting**	Automated (Sigmoida software)
Automated/Manual	Manual	**Inclusivity and Exclusivity**	Validated on the reference strains and the field isolates
Intended Users	Professional use	**Limit of Detection (LoD)**	Table 5
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	%100.00 and %100.00

Table 5. Collection, Storage, and Transfer of Clinical Specimens / Nucleic Acid Preparation Methods and the Respected LoD Values

Sample Type**	Sample Transfer	Sample Storage	Nucleic Acid Preparation Method	LoD (cp/mL)
Combined nasopharyngeal and oropharyngeal swabs	***v*NAT® *Transfer Tube*** (Cat. No: BS-NA-513m/BS-NA-513)	3 months at (+2) – (+8) °C 1 year at -20 °C	Nucleic acid preparation is not needed, samples can be used directly in qPCR.	500
	Viral Transport Medium (VTM) (CDC SOP#: DSR-052-05 without antibiotics)	3 days at (+2) – (+8) °C 1 year at -70 °C	***RINA™ M14 Nucleic Acid Extraction Device*** (Robot Model No: RINA-M14-01, Kit Cat. No: RN-NA-101) ***Zybio EXM3000 Nucleic Acid Isolation System*** (Robot Model No: EXM3000, Kit Cat. No: ZFNAE01)	250
Bronchoalveolar lavage, nasopharyngeal aspirate, and sputum	Preservative-free sterile containers	3 days at (+2) – (+8) °C 1 year at -70 °C		1000

**Clinical specimens should be collected by a healthcare provider in accordance with national/international clinical specimen collection regulations.

1. qPCR Application Protocol

Before starting the assay, please consider the following:

1. The kit was validated only for the template nucleic acid volume which is 25% of the total qPCR volume.
2. The kit cannot be used with real-time PCR instruments without periodic maintenance records.
3. The kit for Bio-Rad Real-Time PCR systems has been validated with white reaction tubes specific to these systems. Clear reaction tubes result in 5-10 times lower fluorescence signal in Bio-Rad instruments compared to white reaction tubes. In addition, device-specific reaction tubes should be used in the BMS device. The kit's stated analytical performance can only be achieved using validated tubes.

4. To test for contamination, a negative control reaction containing NTC (Nuclease-free Water) must be set up in each run.

Program the qPCR device as follows and add the reagents into the qPCR tubes, close the tubes, place them into the qPCR instrument and start the run. (Table 6)

Table 6. qPCR Program Details

Reaction Setup		qPCR Program				QR Code for Thermal Protocol and Plate Setup
		CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad)* and *Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)				
Reagent	**Volume/Rxn**	**Step**	**Cycle No.**	**Temperature**	**Duration**	
2X qPCR Mix	5 µL	**Enzyme Activation**	1 Cycle	52 °C	3 min	
		Pre-Incubation	1 Cycle	95 °C	10 sec	
Oligo Mix	2.5 µL	**Denaturation**	12 Touchdown Cycles: 1 °C decrement in annealing temperature per cycle	95 °C	1 sec	
		Annealing and Extension		67 °C to 56 °C	15 sec	
Template Nucleic Acid/NTC/PC	2.5 µL	**Denaturation**	35 Cycles	95 °C	1 sec	https://www.bioeksen.com.tr/files/BS_TD_3RT153555
		Annealing and Extension		55 °C	15 sec	
Total Reaction Volume	**10 µL**	**Detection (Reading)**		(FAM-Green)/(HEX-Yellow)		

WARNING: The qPCR thermal programs (Bio-Rad and BMS-Mic) and the plate setup (Bio-Rad) file should be downloaded from the QR code or link above.

2. Interpretation of the Assay Results Using The "Sigmoida" Software

The data produced by the instruments must be evaluated and reported using the Sigmoida software. The result files opened with the "Sigmoida" software will be analyzed automatically. Below are examples of results that can be achieved with the Sigmoida software:

Negative: The sample tested is negative for the tested agent.
Positive: The sample tested is positive for the tested agent.
Contamination: Repeat the analysis paying attention to the "Warnings and Limitations" section.
Invalid: Sampling isn't successfully done, or there is a problem during the sample transportation. A new sample from the same patient should be collected and tested again.
Reagent Problem: Test the "PC-LP" provided with the kit setting up the PC reaction as shown in Table 6. If the test result is positive, the run is valid. In case the software generates a "Reagent Problem" again, contact the manufacturer.

3. Warnings and Limitations

1. False-negative results may occur if inadequate numbers (lower than the LoD) of organisms are present in the specimen.
2. Mutations within the target regions could affect primer and/or probe binding, resulting in failure to detect the presence of agents.
3. Cotton or calcium alginate swabs or swabs with wooden sticks should not be used since they may contain substances that inactivate some pathogens and inhibit PCR.
4. A false-negative result may occur if a specimen is improperly collected, transported, or handled.
5. The clinical specimens shall be collected by a healthcare provider in accordance with the specimen collection guidelines.
6. Test procedures should be performed by personnel trained in the use of the kit.
7. Except for liquid transfers, sample tubes should always be kept closed.
8. Filtered and nuclease-free pipette tips should be used for sample transfer.
9. The components in the kit should not be used together with different lot numbers or chemicals of the same name but from different manufacturers.
10. ***The caps of the reaction tubes must not be opened after the PCR run.*** The PCR tubes should be placed in a bag and thrown away after the bag is tightly closed.
11. The surfaces of the workbenches should be wiped with freshly diluted 10% bleach (0.5% NaClO) at the beginning and end of each day.
12. Disposal of waste must be carried out in accordance with local, state, and federal regulations.

4. Explanation of Symbol

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
CE	European Conformity CE Mark	LOT	Batch code		Keep away from sunlight
IVD	*In vitro* diagnostic *medical device*	REF	Catalogue number		Protect from heat and radioactive sources
	Manufacturer	NON STERILE	Non-*sterile*		Do not use if package is damaged and consult *instructions for use*
	Use-by date		Consult *instructions for use* or consult electronic *instructions for use*		Keep dry
CONTROL -	Negative control		Caution		Keep upright
CONTROL +	Positive control		Temperature limit	Σ	Contains sufficient for *<n>* tests
CONTROL	Control				

5. Manufacturer and Technical Support

Bioeksen AR GE Teknolojileri A.Ş
Address: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul-TÜRKİYE
Phone: +90 (212) 285 10 17, **Fax:** +90 (212) 285 10 18
Web: www.bioeksen.com.tr, **e-mail:** info@bioeksen.com.tr,
Technical Support: support@bioeksen.com.tr

Notice to User: Please inform us about product-related incidents at "**vigilance@bioeksen.com.tr**" within 24 hours.

For in vitro diagnostic use only.
For professional use only.

Cat No: BS-ME-MX17T-25/BS-ME-MX17T-100

Meningitis/Encephalitis RT-qPCR MX-17T Panel

Package Insert

Table 1. Kit Content

Component	Intended Use	25 Reactions	100 Reactions
2X Prime Script Mix	Optimized ready-to-use mix for RT-qPCR assay	2 x 1000 µL	6 x 1000 µL
CNG Oligo Mix	Specific nucleic acid amplification and detection: **HEX:** Human (IC-Internal Control) **CY5:** *Cryptococcus gattii/neoformans*	1 x 125 µL	1 x 500 µL
LNS Oligo Mix	**FAM**: *Listeria monocytogenes* **ROX:** *Neisseria meningitidis* **CY5:** *Streptococcus pneumoniae*	1 x 125 µL	1 x 500 µL
HES Oligo Mix	**FAM**: *Haemophilus influenzae* **ROX:** *Streptococcus agalactiae* **CY5:** *Escherichia coli* K1	1 x 125 µL	1 x 500 µL
CPEV Oligo Mix	**FAM**: Cytomegalovirus **HEX:** Enterovirus **ROX:** Human Parechovirus **CY5:** Varicella Zoster Virus	1 x 125 µL	1 x 500 µL
HSV Oligo Mix	**FAM**: Herpes simplex virus 1 **CY5:** Herpes simplex virus 2	1 x 125 µL	1 x 500 µL
HV Oligo Mix	**FAM**: Human Herpesvirus 6 **ROX:** Human Herpesvirus 7 **CY5:** Human Herpesvirus 8	1 x 125 µL	1 x 500 µL
PC-CNG/PC-LNS/PC-HES/ PC-CPEV/PC-HSV/PC-HV	Positive Control (PC)	1 x 100 µL	1 x 100 µL
NTC	Negative Control	1 x 1000 µL	1 x 1000 µL

Table 2. Transport Condition, Storage Condition, and Shelf Life of the Components

Component	Transport Condition	Storage Condition*	Shelf Life
2X Prime Script Mix	(-22) °C – (+8) °C	(-22) °C – (-18) °C	12 Months
Oligo Mix		(-22) °C – (-18) °C	
NTC		(+2) °C – (+8) °C	
PC		(+2) °C – (+8) °C	

*Each reagent stored at storage temperature can be used until the expiration date indicated on the tube following the first opening. The kit's expiration date is determined by the expiration date of the reagents.

Table 3. Components Required but Not Included with The Test

Components Required but Not Included with The Test
1. Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS) or/and CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) Real-Time PCR systems
2. Micropipettes and compatible filtered pipette tips (nuclease-free) suitable for transferring 1-10, 10-100, and 100-1000 µL of liquid
3. A centrifuge or Mini-spin
4. Vortex
5. Reaction tubes and caps/films specific to qPCR instruments and compatible with the reaction volume

Table 4. Intended Use, Test Principle, and Analytical Specifications

Function	Aid to diagnosis	**Sample Type(s)**	Table 5
Analyte	Table 1	**Nucleic Acid Preparation Method(s)**	Table 5
Qualitative/Quantitative	Qualitative	**Validated PCR Instruments**	Table 3
Test Principle	Reverse Transcription and Real-Time PCR (RT-qPCR)	**Inclusivity and Exclusivity**	Validated on the reference strains and the field isolates
Automated/Manual	Manual		
Intended Users	Professional use	**Limit of Detection (LoD)**	Table 5
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	100.00% and 98.04%

Table 5. Collection, Storage, and Transfer of Clinical Specimens / Nucleic Acid Preparation Methods and the Respected LoD Values

Sample Type**	Sample Transfer	Sample Storage	Nucleic Acid Preparation Method	LoD (cp/mL)
Cerebrospinal Fluid (CSF) samples	Preservative-free sterile containers	3 days at (+2) – (+8) °C 1 year at -70 °C	***RINA™ M14 Nucleic Acid Extraction Device*** (Robot Catalog No: RINA-M14-01, Kit Cat. No: RN-NA-101) ***Zybio EXM3000 Nucleic Acid Isolation System*** (Robot Model No: EXM3000, Kit Cat. No: ZFNAE01)	30-100

** Clinical specimens should be collected by a healthcare provider in accordance with national/international clinical specimen collection regulations.

For in vitro diagnostic use only.
For professional use only.

1. RT-qPCR Application Protocol

Before starting the assay, please consider the following:

1. The kit was validated only for the template nucleic acid volume which is 25% of the total RT-qPCR volume.
2. The kit cannot be used with real-time PCR instruments without periodic maintenance records.
3. The kit for Bio-Rad Real-Time PCR systems has been validated with white reaction tubes specific to these systems. Clear reaction tubes result in 5-10 times lower fluorescence signal in Bio-Rad instruments compared to white reaction tubes. In addition, device-specific reaction tubes should be used in the BMS device. The kit's stated analytical performance can only be achieved using validated tubes.
4. To test for contamination, a negative control reaction containing NTC (Nuclease-free Water) must be set up in each run.

Program the qPCR device as follows and add the reagents into the qPCR tubes, close the tubes, place them into the qPCR instrument and start the run (Table 6)

Table 6. Reaction Setup and Real-Time PCR Program

Reaction Setup		**RT-qPCR Program**				**QR Code for Thermal Protocol and Plate Setup**
		CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) and ***Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)***				
Reagent	**Volume/Rxn**	**Step**	**Cycle No.**	**Temperature**	**Duration**	
2X Prime Script Mix	10 µL	**Reverse Transcription**	1 Cycle	52 °C	3 min	
		Pre-Incubation	1 Cycle	95 °C	10 sec	
Oligo Mix	5 µL	**Denaturation**	12 Touchdown Cycles: 1 °C decrement in annealing temperature per cycle	95 °C	1 sec	
		Annealing and Extension		67 °C to 56 °C	15 sec	
Template Nucleic Acid/NTC/PC	5 µL	**Denaturation**	30 Cycles	95 °C	1 sec	
		Annealing and Extension		55 °C	15 sec	
Total Reaction Volume	**20 µL**	**Detection (Reading)**		(FAM-Green)/(HEX-Yellow) (ROX-Orange)/(CY5-Red)		https://www.bioeksen.com.tr/files/L_TD_43P/

WARNING: The RT-qPCR thermal programs (Bio-Rad and BMS) and the plate setup (Bio-Rad) file should be downloaded from the QR code or link above.

2. Interpretation of the Assay Results

All default analysis options (e.g., auto-calculated threshold) in the qPCR instrument software should not be changed to calculate Cq values.

The shape of the amplification curves should be examined for all reaction wells returning with Cq values. All the sigmoidal curves above the threshold should be recorded as "positive" and their Cq values should be recorded. Non-sigmoidal curves should be recorded as "negative".

Table 7. Expected Performance of Kit Controls

Control Type	**Control Name**	**Purpose**	**Expected Results and Cq Values**	
			IC (HEX)	**Target**
Negative Control	NTC	Contamination control during RT-qPCR	**Not detected** (No Cq)	**Not detected** (No Cq)
Positive Control	PC	Reagent integrity	**Detected** (Cq≤26)	**Detected** (Cq≤26)
Internal/Extraction Control	IC	To monitor the integrity of nucleic acid extraction and RT-qPCR from each sample	**Detected** (Cq≤26) If the IC Cq>26, check the target Cq.	If the target has a valid Cq value according to the result interpretation criteria, IC is valid.

If any control does not work as described above, the run is reported as follows:

1. **Contamination:** If Cq≤26 in any NTC test channel.
   Recommended action: Repeat the analysis paying attention to the "Warnings and Limitations" section.
2. **Reagent Problem**: In case a sigmoidal curve with a Cq≤26 cannot be obtained for any of all the samples tested in the run, including the controls.
   Recommended action: Test the "PC"s (Refer to Table 1) provided with the kit. If the test result is positive, the run is valid. In case the software generates a "Reagent Problem" again, contact the manufacturer.
3. **Invalid:** If the sample has a Cq>26 in the HEX (IC) channel of the test tube and no Cq in the other channels.
   Recommended action: Sampling isn't successfully done, or there is a problem during the sample transportation. A new sample from the same patient should be collected and tested again.

If all the controls are valid, the results are interpreted as follows:

Table 8. Interpretation of Patient Results

Target	**Internal Control (IC)**	**Result Interpretation**	
Positive (+)	**Positive (+)** or **Negative (-)**	Results are valid Target is detected	If 26<Cq "Negative" If 16<Cq≤26 "Positive" If Cq≤16 "High Positive"
Negative (-)	**Positive (+)**	Results are valid Target is not detected	

The results produced by the qPCR instrument can manually be reported as described above or can automatically be reported using the "**Sigmoida**" software. To obtain the "Sigmoida" software installer, please send an email to support@bioeksen.com.tr.

3. Warnings and Limitations

1. False-negative results may occur if inadequate numbers (lower than the LoD) of organisms are present in the specimen.
2. Mutations within the target regions could affect primer and/or probe binding, resulting in failure to detect the presence of agents.
3. A false-negative result may occur if a specimen is improperly collected, transported, or handled.
4. The clinical specimens shall be collected by a healthcare provider in accordance with the specimen collection guidelines.
5. Test procedures should be performed by personnel trained in the use of the kit.
6. Except for liquid transfers, sample tubes should always be kept closed.
7. Filtered and nuclease-free pipette tips should be used for sample transfer.
8. The components in the kit should not be used together with different lot numbers or chemicals of the same name but from different manufacturers.
9. ***The caps of the reaction tubes must not be opened after the PCR run.*** The PCR tubes should be placed in a bag and thrown away after the bag is tightly closed.
10. The surfaces of the workbenches should be wiped with freshly diluted 10% bleach (0.5% NaClO) at the beginning and end of each day.
11. Disposal of waste must be carried out in accordance with local, state, and federal regulations.

4. Explanation of Symbol

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
CE	European Conformity CE Mark	LOT	Batch code		Keep away from sunlight
IVD	*In vitro* diagnostic *medical device*	REF	Catalogue number		Protect from heat and radioactive sources
	Manufacturer	NON STERILE	Non-*sterile*		Do not use if package is damaged and consult *instructions for use*
	Use-by date		Consult *instructions for use* or consult electronic *instructions for use*		Keep dry
CONTROL -	Negative control		Caution		Keep upright
CONTROL +	Positive control		Temperature limit	Σ	Contains sufficient for *<n>* tests
CONTROL	Control				

5. Manufacturer and Technical Support

Bioeksen AR GE Teknolojileri A.Ş
Address: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul-TÜRKİYE
Phone: +90 (212) 285 10 17, **Fax:** +90 (212) 285 10 18
Web: www.bioeksen.com.tr, **e-mail:** info@bioeksen.com.tr,
Technical Support: support@bioeksen.com.tr

Notice to User: Please inform us about product-related incidents at "**vigilance@bioeksen.com.tr**" within 24 hours.

For in vitro diagnostic use only.
For laboratory professional use only.

Cat No: BS-MEV-DTC-320-25/BS-MEV-DTC-320-100

Measles Virus Real-Time PCR Detection Kit

Package Insert

Table 1. Kit Content

Component	Intended Use	25 Reactions	100 Reactions
2X Prime Script Mix	Optimized ready-to-use mix for RT-qPCR assay	1 x 125 µL	1 x 500 µL
MeV Oligo Mix	Specific nucleic acid amplification and detection: **FAM**: Measles Virus **HEX:** *Human* (*IC-Internal Control*)	1 x 62.5 µL	1 x 250 µL
NTC	Negative Control	1 x 1000 µL	
PC-MeV	Positive Control (PC)	1 x 100 µL	1 x 250 µL

Table 2. Storage Conditions and Shelf Life

Component	Transport Condition	Storage Condition*	Shelf Life
2X Prime Script Mix	(-22) – (+8) °C	(-22) – (-18) °C	12 Months
MeV Oligo Mix		(-22) – (-18) °C	
NTC		(+2) – (+8) °C	
PC-MeV		(+2) – (+8) °C	

*Each reagent stored at storage temperature can be used until the expiration date indicated on the tube following the first opening. The kit's expiration date is determined by the expiration date of the reagents.

Table 3. Components Required but Not Included with The Test

Components Required but Not Included with The Test
1. Micropipettes and filtered pipette tips (nuclease-free) suitable for transferring 1-10, 10-100, and 100-1000 µL of liquid
2. Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS) and CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) Real-Time PCR systems
3. A centrifuge or Mini-spin
4. Vortex
5. Reaction tubes and caps/films specific to qPCR instruments and compatible with reaction volume

Table 4. Intended Use, Test Principle and Analytical Specifications

Function	Aid to diagnosis	**Sample Type(s)**	Table 5
Analyte(s)	Table 1	**Nucleic Acid Preparation Method(s)**	Table 5
Qualitative/Quantitative	Qualitative	**Validated PCR Instrument(s)**	Table 3
Test Principle	Reverse Transcription and Real-Time PCR (RT-qPCR)	**Results Interpretation and Reporting**	Automated (Sigmoida software)
Automated/Manual	Manual	**Inclusivity and Exclusivity**	Validated on the reference strains and the field isolates
Intended Users	Professional use	**Limit of Detection**	Table 5
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	100.00% and 100.00%

Table 5. Collection, Storage, and Transfer of Clinical Specimens / Nucleic Acid Preparation Methods and the Respected LoD Values

Sample Type**	Sample Transfer	Sample Storage	Nucleic Acid Preparation Method	LoD (cp/mL)
Combined nasopharyngeal and oropharyngeal swabs	***vNAT® Transfer Tube*** (Cat. No: BS-NA-513m/BS-NA-513)	3 months at (+2) – (+8) °C 1 year at -20 °C	Nucleic acid preparation is not needed, samples can be used directly in qPCR.	250
	Viral Transport Medium (VTM) (CDC SOP#: DSR-052-05)	3 days at (+2) – (+8) °C 1 year at -70 °C	***Zybio EXM3000 Nucleic Acid Isolation System*** (Robot Model No: EXM3000, Kit Cat. No: ZFNAE01) ***RINA™ M14 Nucleic Acid Extraction Device*** (Robot Catalog No: RINA-M14-01, Kit Cat. No: RN-NA-101)	125
Urine samples	Preservative-free sterile containers	3 days at (+2) – (+8) °C 1 year at -70 °C		1000

**Clinical specimens should be collected by a healthcare provider in accordance with national/international clinical specimen collection regulations.

Revision Date: 2023-03-22/Rev.03
Published Date: 2020-07-22

For in vitro diagnostic use only.
For laboratory professional use only.

1. RT-qPCR Application Protocol

Before starting the assay, please consider the following:

1. The kit was validated only for the template nucleic acid volume which is 25% of the total qPCR volume.
2. The kit cannot be used with real-time PCR instruments without periodic maintenance records.
3. The kit for Bio-Rad Real-Time PCR systems has been validated with white reaction tubes specific to these systems. Clear reaction tubes result in 5-10 times lower fluorescence signal in Bio-Rad instruments compared to white reaction tubes. In addition, device-specific reaction tubes should be used in the BMS device. The kit's stated analytical performance can only be achieved using validated tubes.
4. To test for contamination, a negative control reaction containing NTC (Nuclease-free Water) must be set up in each run.

Program the qPCR device as follows and add the reagents into the qPCR tubes, close the tubes, place them into the qPCR instrument and start the run (Table 6)

Table 6. Reaction Setup and RT-qPCR Program

Reaction Setup		**RT-qPCR Program**				**QR Code for Thermal Protocol and Plate Setup**
		CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) and Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)				
Reagent	**Volume/Rxn**	**Step**	**Cycle No.**	**Temperature**	**Duration**	
2X Prime Script Mix	5 µL	**Reverse Transcription**	1 Cycle	52 °C	3 min	
		Pre-Incubation	1 Cycle	95 °C	10 sec	
Oligo Mix	2.5 µL	**Denaturation**	12 Touchdown Cycles: 1 °C decrement in annealing temperature per cycle	95 °C	1 sec	
		Annealing and Extension		67 °C to 56 °C	15 sec	
Template Nucleic Acid/NTC/PC	2.5 µL	**Denaturation**	35 Cycles	95 °C	1 sec	
		Annealing and Extension		55 °C	15 sec	
Total Reaction Volume	**10 µL**	**Detection (Reading)**		(FAM-Green)/(HEX-Yellow)		https://www.bioeksen.com.tr/files/BS_TD_3RT153555

WARNING: The RT-qPCR thermal programs (Bio-Rad and BMS) and the plate setup (Bio-Rad) file should be downloaded from the QR code or link above.

2. Interpretation of the Assay Results Using The "Sigmoida" Software

Result files must be opened with the "**Sigmoida**" software provided by the manufacturer, and the analysis must be performed automatically by the software. Below are examples of results that can be achieved with the Sigmoida software. Below are examples of results that can be achieved with the Sigmoida software;

Negative: The sample tested is negative for the tested agent.
Positive: The sample tested is positive for the tested agent.
Contamination: Repeat the analysis paying attention to the "Warnings and Limitations" section.
Invalid: Sampling isn't successfully done, or there is a problem during the sample transportation. A new sample from the same patient should be collected and tested again.
Reagent Problem: Test the "PC-MeV" provided with the kit setting up the PC-MeV reaction, as shown in Table 6. If the test result is positive, the run is valid. In case the software generates a "Reagent Problem" again, contact the manufacturer.

3. Warnings and Limitations

1. False-negative results may occur if inadequate numbers (lower than the LoD) of organisms are present in the specimen.
2. Mutations within the target regions could affect primer and/or probe binding resulting in failure to detect the presence of agents.
3. The use of cotton or calcium alginate swabs or swabs with wooden sticks can lead to false-negative results since they may contain substances that inactivate some pathogens and inhibit PCR.
4. A false-negative result may occur if a specimen is improperly collected, transported, or handled.
5. The clinical specimens shall be collected by a healthcare provider in accordance with the specimen collection guidelines.
6. Test procedures should be performed by personnel trained in the use of the kit.
7. Except for liquid transfers, sample tubes should always be kept closed.
8. Filtered and nuclease-free pipette tips should be used for sample transfer.
9. The components in the kit should not be used together with different lot numbers or chemicals of the same name but from different manufacturers.
10. ***The caps of the reaction tubes must not be opened after the PCR run.*** The PCR tubes should be placed in a bag and thrown away after the bag is tightly closed.
11. The surfaces of the workbenches should be wiped with freshly diluted 10% bleach (0.5% NaClO) at the beginning and end of each day.
12. Disposal of waste must be carried out in accordance with local, state, and federal regulations.

For in vitro diagnostic use only.
For laboratory professional use only.

4. Explanation of Symbol

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
CE	European Conformity CE Mark	LOT	Batch code		Keep away from sunlight
IVD	*In vitro* diagnostic *medical device*	REF	Catalogue number		Protect from heat and radioactive sources
	Manufacturer		Non-*sterile*		Do not use if package is damaged and consult *instructions for use*
	Use-by date		Consult *instructions for use* or consult electronic *instructions for use*		Keep dry
CONTROL -	Negative control		Caution		Keep upright
CONTROL +	Positive control		Temperature limit		Contains sufficient for *<n>* tests
CONTROL	Control				

5. Manufacturer and Technical Support

Bioeksen AR GE Teknolojileri A.Ş
Address: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul-TÜRKİYE
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Web: www.bioeksen.com.tr, **E-mail:** info@bioeksen.com.tr,
Technical Support: support@bioeksen.com.tr

Notice to User: Please inform us about product-related incidents at " **vigilance@bioeksen.com.tr** " within 24 hours.

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For professional use only.

Cat No: BS-SE-MX30T-25/BS-SE-MX30T-100

Sepsis qPCR MX-30T Panel

Package Insert

Table 1. Kit Content

Component	Target	25 Reactions	100 Reactions
2X qPCR Mix	Optimized ready-to-use mix for qPCR assay	2 x 1000 µL	7 x 1250 µL
SPVC Oligo Mix	**FAM:** *Staphylococcus aureus* **HEX:** *Pseudomonas* spp. **ROX**: VanA-Vancomycin resistance **CY5:** *Candida krusei*	1 x 125 µL	1 x 500 µL
CRVS Oligo Mix	**FAM:** *Candida glabrata* **HEX:** Human (IC-Internal Control) **ROX**: VanB-Vancomycin resistance **CY5:** *Staphylococcus* spp.	1 x 125 µL	1 x 500 µL
KPAC Oligo Mix	**FAM:** *Pseudomonas aeruginosa* **HEX:** *Candida albicans* **ROX**: *Klebsiella pneumoniae* **CY5:** *Acinetobacter baumannii*	1 x 125 µL	1 x 500 µL
HKOC Oligo Mix	**FAM:** *Haemophilus influenzae* **HEX:** *Klebsiella oxytoca* **ROX**: *Candida parapsilosis* **CY5:** OXA-48-Carbapenem resistance	1 x 125 µL	1 x 500 µL
CRE Oligo Mix	**FAM:** KPC-Carbapenem resistance **HEX:** NDM-Carbapenem resistance **ROX**: VIM-Carbapenem resistance **CY5:** IMP-Carbapenem resistance	1 x 125 µL	1 x 500 µL
LEMC Oligo Mix	**FAM:** *Listeria monocytogenes* **HEX:** *Enterococcus faecalis* **ROX**: mecA/mecC-Methicillin resistance **CY5:** *Candida tropicalis*	1 x 125 µL	1 x 500 µL
SES Oligo Mix	**FAM:** *Stenotrophomonas maltophilia* **ROX**: *Enterobacteriaceae* **CY5:** *Streptococcus* spp.	1 x 125 µL	1 x 500 µL
ENES Oligo Mix	**FAM:** *Enterococcus faecium* **HEX:** *Escherichia coli* **ROX**: *Neisseria meningitidis* **CY5:** *Streptococcus pneumoniae*	1 x 125 µL	1 x 500 µL
PC-SPVC / PC-CRVS / PC-KPAC / PC-HKOC PC-CRE / PC-LEMC / PC-SES / PC-ENES	Positive Control (PC)	1 x 100 µL	1 x 100 µL
NTC	Negative Control	1 x 1000 µL	1 x 1000 µL

Table 2. Transport Condition, Storage Condition and Shelf Life of The Components

Component	Transport Condition	Storage Condition*	Shelf Life
2X qPCR Mix	(-22) °C – (+8) °C	(-22) °C – (-18) °C	12 Months
Oligo Mix		(-22) °C – (-18) °C	
NTC		(+2) °C – (+8) °C	
PC		(+2) °C – (+8) °C	

*Each reagent stored at storage temperature can be used until the expiration date indicated on the tube following the first opening. The kit's expiration date is determined by the expiration date of the reagents

Table 3. Components Required but Not Included with The Test

Components Required but Not Included with The Test
1. Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS) and CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) Real-Time PCR systems
2. Micropipettes and compatible filtered pipette tips (nuclease-free) suitable for transferring 1-10, 10-100, 100-1000 µL of liquid
3. A centrifuge or Mini-spin
4. Vortex
5. Reaction tubes and caps/films specific to qPCR instruments and compatible with reaction volume

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Table 4. Intended Use, Test Principle and Analytical Specifications

Function	Aid to diagnosis	**Sample Type(s)**	Table 5
Analyte	Table 1	**Nucleic Acid Preparation Method(s)**	Table 5
Qualitative/Quantitative	Qualitative	**Validated PCR Instruments**	Table 3
Test Principle	Real-Time PCR (qPCR)	**Inclusivity and Exclusivity**	Validated on the reference strains and the field isolates
Automated/Manual	Manual		
Intended Users	Professional use	**Limit of Detection (LoD)**	Table 5
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	Whole blood; 82.00% and 98.30% Positive blood culture; 97.10% and 99.30%

Table 5. Collection, Storage and Transfer of Clinical Specimens / Nucleic Acid Preparation Methods and the Respected LoD Values

Sample Type**	Sample Transfer	Sample Storage	Nucleic Acid Preparation Method	LoD (cfu/mL)
Whole blood	EDTA-treated tube	3 days at (+2) – (+8) °C 1 year at -70 °C	***RINA™ M14 Nucleic Acid Extraction Device*** (Robot Model No: RINA-M14-01, Kit Cat. No: RN-NA-101)	500-1000
Positive blood culture	Blood culture bottle	Room temperature	***Zybio EXM3000 Nucleic Acid Isolation System*** (Robot Model No: EXM3000, Kit Cat. No: ZFNAE01)	100-500

** Clinical specimens should be collected by a healthcare provider in accordance with national/international clinical specimen collection regulations.

1. qPCR Application Protocol

Before starting the assay, please consider the following:

1. The kit was validated only for the template nucleic acid volume which is 25% of the total qPCR volume.
2. The kit cannot be used with real-time PCR instruments without periodic maintenance records.
3. The kit for Bio-Rad Real-Time PCR systems has been validated with white reaction tubes specific to these systems. Clear reaction tubes result in 5-10 times lower fluorescence signal in Bio-Rad instruments compared to white reaction tubes. In addition, device-specific reaction tubes should be used in the BMS device. The kit's stated analytical performance can only be achieved using validated tubes.
4. To test for contamination, a negative control reaction containing NTC (Nuclease-free Water) must be set up in each run.

Program the qPCR device as follows and add the reagents into the qPCR tubes, close the tubes, place them into the qPCR instrument and start the run (Table 6)

Table 6. Reaction Setup and Real-Time PCR Program

Reaction Setup		qPCR Program				QR Code for Thermal Protocol and Plate Setup
		CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) and Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)				
Reagent	**Volume/Rxn**	**Step**	**Cycle No.**	**Temperature**	**Duration**	
2X qPCR Mix	10 µL	**Enzyme Activation**	1 Cycle	52 °C	3 min	
		Pre-Incubation	1 Cycle	95 °C	10 sec	
Oligo Mix	5 µL	**Denaturation**	12 Touchdown Cycles: 1 °C decrement in annealing temperature per cycle	95 °C	1 sec	
		Annealing and Extension		67 °C to 56 °C	15 sec	
Template Nucleic Acid/NTC/PC	5 µL	**Denaturation**	30 Cycles	95 °C	1 sec	https://www.bioeksen.com.tr/files/L_TD_43P/
		Annealing and Extension		55 °C	15 sec	
Total Reaction Volume	**20 µL**	**Detection (Reading)**		(FAM-Green)/(HEX-Yellow) (ROX-Orange)/(CY5-Red)		

WARNING: The qPCR thermal programs (Bio-Rad and BMS-Mic) and the plate setup (Bio-Rad) file should be downloaded from the QR code or link above.

2. Interpretation of the Assay Results

All default analysis options (e.g., auto-calculated threshold) in the MIC and/or Bio-Rad software should not be changed to calculate Cq values.

The shape of the amplification curves should be examined for all reaction wells returning with Cq values. All the sigmoidal curves above the threshold should be recorded as "positive" and their Cq values should be recorded. Non-sigmoidal curves should be recorded as "negative".

Table 7. Expected Performance of Kit Controls

Control Type	Control Name	Purpose	Expected Results and Cq Values	
			IC (HEX)	Target
Negative Control	NTC	Contamination control during RT-qPCR	**Not detected** (No Cq)	**Not detected** (No Cq)
Positive Control	PC	Reagent integrity	**Detected** (Cq≤26)	**Detected** (Cq≤26)
Internal/Extraction Control	IC	To monitor the integrity of nucleic acid extraction and qPCR from each sample	**Detected** (Cq≤26) If the IC Cq>26, check the target Cq.	If the target has a valid Cq value according to the result interpretation criteria, IC is valid.

If any control does not work as described above, the run is reported as follows:

1. **Contamination:** If Cq≤26 in any NTC test channel.
   Recommended action: Repeat the analysis paying attention to the "Warnings and Limitations" section.
2. **Reagent Problem**: In case a sigmoidal curve with a Cq≤26 cannot be obtained for any of all the samples tested in the run, including the controls.
   Recommended action: Test the "**Positive Control(s)**" (Refer to Table 1) provided with the kit. If the test result is positive, the run is valid. In case the software generates a "Reagent Problem" again, contact the manufacturer.
3. **Invalid:** If the sample has a Cq>26 in the HEX (IC) channel of the test tube and no Cq in the other channels.
   Recommended action: Sampling isn't successfully done, or there is a problem during the sample transportation. A new sample from the same patient should be collected and tested again.

If all the controls are valid, the results are interpreted as follows:

For positive blood culture samples:

If **more than one parameter (except drug resistance genes)** gives positive results in positive blood culture sample, the final reporting is performed after the following evaluation process:

1. The parameter giving the lowest Cq is determined = Min Cq
2. (Cq value of other parameter) – (Min Cq) If <7, a **positive** result is given for other parameter
3. (Cq value of other parameter) – (Min Cq) If ≥7, a **negative** result is given for other parameter

For drug resistance gene targets (VanA, and VanB-Vancomycin resistance, OXA-48, KPC, NDM, VIM, IMP-Carbapenem resistance, mecA/mecC-Methicillin resistance) and *Candida krusei*, *Candida glabrata, Candida albicans, Candida parapsilosis, Candida tropicalis* gene targets:

- If the Cq value is **≤26**, it is reported as **positive.**
- If the Cq value is **>26**, it is reported as **negative**.

For all other gene targets:

- If the Cq value is **≤23**, it is reported as **positive.**
- If the Cq value is **>23**, it is reported as **negative.**

Table 8. Interpretation of Patient Results

Target	Internal Control (IC)	Result Interpretation	
Positive (+)	**Positive (+)** or **Negative (-)**	Results are valid Target is detected	If 26<Cq "Negative" If 16<Cq≤26 "Positive" If Cq≤16 "High Positive"
Negative (-)	**Positive (+)**	Results are valid Target is not detected	

The results produced by the qPCR instrument can manually be reported as described above or can automatically be reported using the "**Sigmoida**" software. To obtain the "Sigmoida" software installer, please send an email to support@bioeksen.com.tr.

3. Warnings and Limitations

1. False-negative results may occur if inadequate numbers (lower than the LoD) of organisms are present in the specimen.
2. Mutations within the target regions could affect primer and/or probe binding resulting in failure to detect the presence of agents.
3. A false-negative result may occur if a specimen is improperly collected, transported, or handled.
4. The clinical specimens shall be collected by a healthcare provider in accordance with the specimen collection guidelines.
5. Test procedures should be performed by personnel trained in the use of the kit.
6. Except for liquid transfers, sample tubes should always be kept closed.
7. Filtered and nuclease-free pipette tips should be used for sample transfer.
8. The components in the kit should not be used together with different lot numbers or chemicals of the same name but from different manufacturers.
9. ***The caps of the reaction tubes must not be opened after the PCR run.*** The PCR tubes should be placed in a bag and thrown away after the bag is tightly closed.
10. The surfaces of the workbenches should be wiped with freshly diluted 10% bleach (0.5% NaClO) at the beginning and end of each day.
11. Disposal of waste must be carried out in accordance with local, state and federal regulations.

4. Explanation of Symbol

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
CE	European Conformity CE Mark	LOT	Batch code		Keep away from sunlight
IVD	*In vitro* diagnostic *medical device*	REF	Catalogue number		Protect from heat and radioactive sources
	Manufacturer	NON STERILE	Non-*sterile*		Do not use if package is damaged and consult *instructions for use*
	Use-by date		Consult *instructions for use* or consult electronic *instructions for use*		Keep dry
CONTROL -	Negative control		Caution		Keep upright
CONTROL +	Positive control		Temperature limit	Σ	Contains sufficient for <*n*> tests
CONTROL	Control				

5. Manufacturer and Technical Support

Bioeksen AR GE Teknolojileri A.Ş
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Web: www.bioeksen.com.tr, **e-mail:** info@bioeksen.com.tr,
Technical Support: support@bioeksen.com.tr

Notice to User: Please inform us about product-related incidents at "**vigilance@bioeksen.com.tr**" within 24 hours.

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For professional use only.

Cat No: BS-SP-B-12-50/BS-SP-B-12-100/BS-SP-B-12-250

Brucella spp. qPCR Kit

Package Insert

Table 1. Kit Content

Component	Intended Use	50 Reactions	100 Reactions	250 Reactions
2X qPCR Mix	Optimized ready-to-use mix for qPCR assay	1 x 250 µL	1 x 500 µL	1 x 1250 µL
Brucella spp. Oligo Mix	Specific nucleic acid amplification and detection: **FAM:** *Brucella* spp. **HEX:** Human (IC-Internal Control)	1 x 125 µL	1 x 250 µL	1 x 625 µL
NTC	Negative Control	1 x 1000 µL	1 x 1000 µL	1 x 1000 µL
PC-Brucella spp.	Positive Control (PC)	1 x 250 µL	1 x 250 µL	1 x 250 µL

Table 2. Transport Condition, Storage Condition, and Shelf Life of the Components

Component	Transport Condition	Storage Condition*	Shelf Life
2X qPCR Mix	(-22) – (+8) °C	(-22) – (-18) °C	12 Months
Brucella spp. Oligo Mix		(-22) – (-18) °C	
PC-Brucella spp.		(+2) – (+8) °C	
NTC		(+2) – (+8) °C	

*Each reagent stored at storage temperature can be used until the expiration date indicated on the tube following the first opening. The kit's expiration date is determined by the expiration date of the reagents.

Table 3. Components Required but Not Included with The Test

Components Required but Not Included with The Test
1. Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS) or/and CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) Real-Time PCR systems
2. Micropipettes and compatible filtered pipette tips (nuclease-free) suitable for transferring 1-10, 10-100, and 100-1000 µL of liquid
3. A centrifuge or Mini-spin
4. Vortex
5. Reaction tubes and caps/films specific to qPCR instruments and compatible with reaction volume

Table 4. Intended Use, Test Principle, and Analytical Specifications

Function	Aid to diagnosis	**Sample Type(s)**	Table 5
Analyte(s)	Table 1	**Nucleic Acid Preparation Method(s)**	Table 5
Qualitative/Quantitative	Qualitative	**Validated PCR Instrument(s)**	Table 3
Test Principle	Real-Time PCR (qPCR)	**Inclusivity and Exclusivity**	Validated on the reference strains and the field isolates
Automated/Manual	Manual		
Intended Users	Professional use	**Limit of Detection (LoD)**	Table 5
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	Whole blood; 83.00% and 98.40% Positive blood culture; 97.20% and 99.10%

Table 5. Collection, Storage, and Transfer of Clinical Specimens / Nucleic Acid Preparation Methods and the Respected LoD Values

Sample Type**	Sample Transfer	Sample Storage	Nucleic Acid Preparation Method	LoD (cp/mL)
Positive blood culture	Blood culture bottle	Room temperature	***RINA™ M14 Nucleic Acid Extraction Device*** (Robot Cat. No: RINA-M14-01, Kit Cat. No: RN-NA-101) ***Zybio EXM3000 Nucleic Acid Isolation System*** (Robot Model No: EXM3000, Kit Cat. No: ZFNAE01)	100
Whole blood	EDTA-treated blood tube	3 days at (+2) – (+8) °C 1 year at -70 °C		250
Synovial fluid	Preservative-free sterile tubes/containers	3 days at (+2) – (+8) °C 1 year at -70 °C		250

**Clinical specimens should be collected by a healthcare provider in accordance with national/international clinical specimen collection regulations.

1. RT-qPCR Application Protocol

Before starting the assay, please consider the following:

1. The kit was validated only for the template nucleic acid volume which is 25% of the total qPCR volume.
2. The kit cannot be used with real-time PCR instruments without periodic maintenance records.
3. The kit for Bio-Rad Real-Time PCR systems has been validated with white reaction tubes specific to these systems. Clear reaction tubes result in 5-10 times lower fluorescence signal in Bio-Rad instruments compared to white reaction tubes. In addition, device-specific reaction tubes should be used in the BMS device. The kit's stated analytical performance can only be achieved using validated tubes.
4. To test for contamination, a negative control reaction containing NTC (Nuclease-free Water) must be set up in each run.

Program the qPCR device as follows and add the reagents into the qPCR tubes, close the tubes, place them into the qPCR instrument and start the run (Table 6)

Table 6. qPCR Program Details

Reaction Setup		qPCR Program				QR Code for Thermal Protocol and Plate Setup
		CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) and *Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)*				
Reagent	**Volume/Rxn**	**Step**	**Cycle No.**	**Temperature**	**Duration**	
2X qPCR Mix	5 µL	**Enzyme Activation**	1 Cycle	52 °C	3 min	
		Pre-Incubation	1 Cycle	95 °C	10 sec	
Oligo Mix	2,5 µL	**Denaturation**	12 Touchdown Cycles: 1 °C decrement in annealing temperature per cycle	95 °C	1 sec	
		Annealing and Extension		67 °C to 56 °C	15 sec	
Template Nucleic Acid/NTC/PC	2,5 µL	**Denaturation**	30 Cycles	95 °C	1 sec	
		Annealing and Extension		55 °C	15 sec	
Total Reaction Volume	**10 µL**	**Detection (Reading)**		(FAM-Green)/(HEX-Yellow)		

https://www.bioeksen.com.tr/files/L_TD_43P

WARNING: The qPCR thermal programs (Bio-Rad and BMS-Mic) and the plate setup (Bio-Rad) file should be downloaded from the QR code or link above.

2. nterpretation of the Assay Results

All default analysis options (e.g., auto-calculated threshold) in the software of the qPCR instrument should not be changed to calculate Cq values.

The shape of the amplification curves should be examined for all reaction wells returning with Cq values. All the sigmoidal curves above the threshold should be recorded as "positive" and their Cq values should be recorded. Non-sigmoidal curves should be recorded as "negative".

Table 7. Expected Performance of Kit Controls

Control Type	Control Name	Purpose	Expected Results and Cq Values	
			IC (HEX)	Target
Negative Control	NTC	Contamination control during RT-qPCR	**Not detected** (No Cq)	**Not detected** (No Cq)
Positive Control	PC	Reagent integrity	**Detected** (Cq≤26)	**Detected** (Cq≤26)
Internal/Extraction Control	IC	To monitor the integrity of nucleic acid extraction and RT-qPCR from each sample	**Detected** (Cq≤26) If the IC Cq>26, check the target Cq.	If the target has a valid Cq value according to the result interpretation criteria, IC is valid.

If any control does not work as described above, the run is reported as follows:

1. **Contamination:** If Cq≤26 in any NTC test channel.
   Recommended action: Repeat the analysis paying attention to the "Warnings and Limitations" section.
2. **Reagent Problem**: In case a sigmoidal curve with a Cq≤26 cannot be obtained for any of all the samples tested in the run, including the controls.
   Recommended action: Test the "**PC-Brucella spp.**" provided with the kit. If the test result is positive, the run is valid. In case the software generates a "Reagent Problem" again, contact the manufacturer.
3. **Invalid:** If the sample has a Cq>26 in the HEX channel of the test tube and no Cq in the other channels.
   Recommended action: Sampling isn't successfully done, or there is a problem during the sample transportation. A new sample from the same patient should be collected and tested again.

If all the controls are valid, the results are interpreted as follows:

Table 8. Interpretation of Patient Results

Target	IC	Result Interpretation
Positive (+)	**Positive (+)** or **Negative (-)**	Results are valid Target is detected
Negative (-)	**Positive (+)**	Results are valid, Target is not detected.

For positive blood culture samples:

Set the threshold level to **1500 RFU** for **CFX96 Touch™ /CFX96™ Dx/CFX Opus 96™ /CFX Opus 96™ Dx (Bio-Rad)** Real-Time PCR systems to calculate Cq values and does not change any other analysis options.

All default analysis options (e.g., auto-calculated threshold) in the **Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)** software should not be changed to calculate Cq values.

If the Cq value is **≤23**, it is reported as **positive.**

If the Cq value is **>23**, it is reported as **negative.**

The results produced by the qPCR instrument can manually be reported as described above or can automatically be reported using the "**Sigmoida**" software.

3. Warnings and Limitations

1. False-negative results may occur if inadequate numbers (lower than the LoD) of organisms are present in the specimen.
2. Mutations within the target regions could affect primer and/or probe binding resulting in failure to detect the presence of agents.
3. Cotton or calcium alginate swabs or swabs with wooden sticks should not be used since they may contain substances that inactivate some pathogens and inhibit PCR.
4. A false-negative result may occur if a specimen is improperly collected, transported, or handled.
5. The clinical specimens shall be collected by a healthcare provider in accordance with the specimen collection guidelines.
6. Test procedures should be performed by personnel trained in the use of the kit.
7. Except for liquid transfers, sample tubes should always be kept closed.
8. Filtered and nuclease-free pipette tips should be used for sample transfer.
9. The components in the kit should not be used together with different lot numbers or chemicals of the same name but from different manufacturers.
10. ***The caps of the reaction tubes must not be opened after the PCR run.*** The PCR tubes should be placed in a bag and thrown away after the bag is tightly closed.
11. The surfaces of the workbenches should be wiped with freshly diluted 10% bleach (0.5% NaClO) at the beginning and end of each day.
12. Disposal of waste must be carried out in accordance with local, state, and federal regulations.

4. Explanation of Symbol

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
CE	European Conformity CE Mark	LOT	Batch code		Keep away from sunlight
IVD	*In vitro* diagnostic *medical device*	REF	Catalogue number		Protect from heat and radioactive sources
	Manufacturer	NON STERILE	Non-*sterile*		Do not use if package is damaged and consult *instructions for use*
	Use-by date		Consult *instructions for use* or consult electronic *instructions for use*		Keep dry
CONTROL -	Negative control		Caution		Keep upright
CONTROL +	Positive control		Temperature limit	Σ	Contains sufficient for *<n>* tests
CONTROL	Control				

5. Manufacturer and Technical Support

Bioeksen AR GE Teknolojileri A.Ş
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Technical Support: support@bioeksen.com.tr

Notice to User: Please inform us about product-related incidents at "**vigilance@bioeksen.com.tr**" within 24 hours.

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Cat No: BS-SY-MX24T-25/BS-SY-MX24T-100

Respiratory Tract RT-qPCR MX-24T Panel

Package Insert

Table 1. Kit Content

Component	Intended Use	25 Reactions	100 Reactions
COVID/Flu Oligo Mix	Specific nucleic acid amplification and detection: **FAM**: SARS-CoV-2 **HEX:** Human (IC-Internal Control) **ROX:** Influenza B **CY5:** Influenza A	1 x 125 µL	1 x 500 µL
COR Oligo Mix	**FAM**: Human Coronavirus 229E **HEX:** Human Coronavirus OC43 **ROX:** Human Coronavirus NL63 **CY5:** Human Coronavirus HKU1	1 x 125 µL	1 x 500 µL
PAR Oligo Mix	**FAM:** Human Parainfluenza 1 **HEX:** Human Parainfluenza 2 **ROX:** Human Parainfluenza 3 **CY5:** Human Parainfluenza 4	1 x 125 µL	1 x 500 µL
MEA Oligo Mix	**FAM:** Human Metapneumovirus **HEX:** Human Enterovirus/Human Rhinovirus Oligo Set 1 **CY5:** Human Adenovirus	1 x 125 µL	1 x 500 µL
BPR Oligo Mix	**FAM:** Human Bocavirus **ROX:** Human Parechovirus **CY5:** Human Enterovirus/Human Rhinovirus Oligo Set 2	1 x 125 µL	1 x 500 µL
LMC Oligo Mix	**FAM:** *Legionella pneumophila* **ROX:** *Mycoplasma pneumoniae* **CY5:** *Chlamydophila pneumoniae*	1 x 125 µL	1 x 500 µL
HBS Oligo Mix	**FAM:** *Haemophilus influenzae* **ROX:** *Bordetella pertussis* **CY5:** *Streptococcus pneumoniae*	1 x 125 µL	1 x 500 µL
RSV Oligo Mix	**FAM:** Respiratory syncytial virus A/B	1 x 125 µL	1 x 500 µL
2X Prime Script Mix	Optimized ready-to-use mix for RT-qPCR assay	2 x 1000 µL	7 x 1250 µL
PC-COVID/FLU / PC-COR / PC-PAR / PC-MEA / PC-BPR / PC-LMC / PC-HBS / PC-RSV	Positive Control (PC)	1 x 100 µL	
NTC	Negative Control	1 x 1000 µL	

Table 2. Transport Condition, Storage Condition, and Shelf Life of the Components

Component	Transport Condition	Storage Condition*	Shelf Life
2X Prime Script Mix	(-22) °C – (+8) °C	(-22) °C – (-18) °C	12 Months
Oligo Mix		(-22) °C – (-18) °C	
NTC		(+2) °C – (+8) °C	
PC		(+2) °C – (+8) °C	

*Each reagent stored at storage temperature can be used until the expiration date indicated on the tube following the first opening. The kit's expiration date is determined by the expiration date of the reagents

Table 3. Components Required but Not Included with The Test

Components Required but Not Included with The Test
1. Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS) or/and CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) Real-Time PCR systems
2. Micropipettes and compatible filtered pipette tips (nuclease-free) suitable for transferring 1-10, 10-100, and 100-1000 µL of liquid
3. A centrifuge or Mini-spin
4. Vortex
5. Reaction tubes and caps/films specific to qPCR instruments and compatible with reaction volume

Revision Date: 2023-03-22/Rev.17
Published Date: 2021-02-23

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For professional use only.

Table 4. Intended Use, Test Principle, and Analytical Specifications

Function	Aid to diagnosis	**Sample Type(s)**	Table 5
Analyte(s)	Table 1	**Nucleic Acid Preparation Method(s)**	Table 5
Qualitative/Quantitative	Qualitative	**Validated PCR Instrument(s)**	Table 3
Test Principle	Reverse transcription and Real-Time PCR (RT-qPCR)	**Results Interpretation and Reporting**	Automated (Sigmoida software)
Automated/Manual	Manual	**Inclusivity and Exclusivity**	Validated on the reference strains and the field isolates
Intended Users	Professional use	**Limit of Detection (LoD)**	Table 5
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	98.95% and 99.13%

Table 5. Collection, Storage, and Transfer of Clinical Specimens / Nucleic Acid Preparation Methods and the Respected LoD Values

Sample Type**	Sample Transfer	Sample Storage	Nucleic Acid Preparation Method	LoD (cp/mL)
Combined nasopharyngeal and oropharyngeal swabs	***v*NAT® *Transfer Tube*** (Cat. No: BS-NA-513m/BS-NA-513)	3 months at (+2) – (+8) °C 1 year at -20 °C	Nucleic acid preparation is not needed, samples can be used directly in RT-qPCR.	250
	Viral Transport Medium (VTM) (CDC SOP#: DSR-052-05 without antibiotics)	3 days at (+2) – (+8) °C 1 year at -70 °C	***RINA™ M14 Nucleic Acid Extraction Device*** (Robot Model No: RINA-M14-01, Kit Cat. No: RN-NA-101) ***Zybio EXM3000 Nucleic Acid Isolation System*** (Robot Model No: EXM3000, Kit Cat. No: ZFNAE01)	125
Bronchoalveolar lavage, nasopharyngeal aspirate, and sputum	Preservative-free sterile containers	3 days at (+2) – (+8) °C 1 year at -70 °C		500

**Clinical specimens should be collected by a healthcare provider in accordance with national/international clinical specimen collection regulations.

1. RT-qPCR Application Protocol

Before starting the assay, please consider the following:

1. The kit was validated only for the template nucleic acid volume which is 25% of the total qPCR volume.
2. The kit cannot be used with real-time PCR instruments without periodic maintenance records.
3. The kit for Bio-Rad Real-Time PCR systems has been validated with white reaction tubes specific to these systems. Clear reaction tubes result in 5-10 times lower fluorescence signal in Bio-Rad instruments compared to white reaction tubes. In addition, device-specific reaction tubes should be used in the BMS device. The kit's stated analytical performance can only be achieved using validated tubes.
4. To test for contamination, a negative control reaction containing NTC (Nuclease-free Water) must be set up in each run.

Program the qPCR device as follows and add the reagents into the qPCR tubes, close the tubes, place them into the qPCR instrument and start the run (Table 6)

Table 6. Reaction Setup and Real-Time PCR Program

Reaction Setup		RT-qPCR Program				QR Code for Thermal Protocol and Plate Setup
		CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) and Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)				
Reagent	**Volume/Rxn**	**Step**	**Cycle No.**	**Temperature**	**Duration**	
2X Prime Script Mix	10 µL	**Reverse Transcription**	1 Cycle	52 °C	3 min	
		Pre-Incubation	1 Cycle	95 °C	10 sec	
Oligo Mix	5 µL	**Denaturation**	12 Touchdown Cycles: 1 °C decrement in annealing temperature per cycle	95 °C	1 sec	
		Annealing and Extension		67 °C to 56 °C	15 sec	
Template Nucleic Acid/NTC/PC	5 µL	**Denaturation**	35 Cycles	95 °C	1 sec	
		Annealing and Extension		55 °C	15 sec	
Total Reaction Volume	**20 µL**	**Detection (Reading)**		(FAM-Green)/(HEX-Yellow)/(ROX-Orange)/(CY5-Red)		https://www.bioeksen.com.tr/files/BS_TD_3RT153555

WARNING: The RT-qPCR thermal programs (Bio-Rad and BMS-Mic) and the plate setup (Bio-Rad) file should be downloaded from the QR code or link above.

2. Interpretation of the Assay Results with The "Sigmoida" Software

Result files must be opened with the "**Sigmoida**" software provided by the manufacturer, and the analysis must be performed automatically by the software. Below are examples of results that can be achieved with the Sigmoida software. Below are examples of results that can be achieved with the Sigmoida software;

Negative: The sample tested is negative for the tested agent.
Positive: The sample tested is positive for the tested agent.
Contamination: Repeat the analysis paying attention to the "Warnings and Limitations" section.
Invalid: Sampling isn't successfully done or there is a problem during the sample transportation. A new sample from the same patient should be collected and tested again.
Reagent Problem: Test the PCs provided with the kit setting up the PC reactions as shown in Table 6. If the test result is positive, the run is valid. In case the software generates a "Reagent Problem" again, contact the manufacturer.

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3. Warnings and Limitations

1. False-negative results may occur if inadequate numbers (lower than the LoD) of organisms are present in the specimen.
2. Mutations within the target regions could affect primer and/or probe binding resulting in failure to detect the presence of agents.
3. Cotton or calcium alginate swabs or swabs with wooden sticks should not be used since they may contain substances that inactivate some pathogens and inhibit PCR.
4. A false-negative result may occur if a specimen is improperly collected, transported, or handled.
5. The clinical specimens shall be collected by a healthcare provider in accordance with the specimen collection guidelines.
6. Test procedures should be performed by personnel trained in the use of the kit.
7. Except for liquid transfers, sample tubes should always be kept closed.
8. Filtered and nuclease-free pipette tips should be used for sample transfer.
9. The components in the kit should not be used together with different lot numbers or chemicals of the same name but from different manufacturers.
10. ***The caps of the reaction tubes must not be opened after the PCR run.*** The PCR tubes should be placed in a bag and thrown away after the bag is tightly closed.
11. The surfaces of the workbenches should be wiped with freshly diluted 10% bleach (0.5% NaClO) at the beginning and end of each day.
12. Disposal of waste must be carried out in accordance with local, state, and federal regulations.

4. Explanation of Symbol

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
CE	European Conformity CE Mark	LOT	Batch code		Keep away from sunlight
IVD	*In vitro* diagnostic *medical device*	REF	Catalogue number		Protect from heat and radioactive sources
	Manufacturer	NON STERILE	Non-*sterile*		Do not use if package is damaged and consult *instructions for use*
	Use-by date		Consult *instructions for use* or consult electronic *instructions for use*		Keep dry
CONTROL -	Negative control		Caution		Keep upright
CONTROL +	Positive control		Temperature limit	Σ	Contains sufficient for *<n>* tests
CONTROL	Control				

5. Manufacturer and Technical Support

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Technical Support: support@bioeksen.com.tr

Notice to User: Please inform us about product-related incidents at "**vigilance@bioeksen.com.tr**" within 24 hours.

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Cat No: BS-SY-SI-100/BS-SY-SI-250/BS-SY-SI-500/BS-SY-SI-1000

COVID-19/Flu RT-qPCR

Package Insert

Table 1. Kit Content

Component	Intended Use	100 Reactions	250 Reactions	500 Reactions	1000 Reactions
2X Prime Script Mix	Optimized ready-to-use mix for RT-qPCR assay	1 x 1000 µL	2 x 1250 µL	4 x 1250 µL	8 x 1250 µL
CVD19/FLU Oligo Mix	**FAM**: SARS-CoV-2 **HEX:** Human (IC-Internal Control) **ROX:** Influenza A **CY5:** Influenza B	1 x 500 µL	1 x 1250 µL	2 x 1250 µ	4 x 1250 µL
NTC	Negative Control	1 x 1000 µL	1 x 1000 µL	1 x 1000 µL	1 x 1000 µL
PC-CVD19/FLU	Positive Control (PC)	1 x 250 µL	1 x 250 µL	1 x 500 µL	2 x 500 µL

Table 2. Transport Condition, Storage Condition, and Shelf Life of the Components

Component	Transport Condition	Storage Condition*	Shelf Life
2X Prime Script Mix	(-22) – (+8) °C	(-22) – (-18) °C	12 Months
CVD19/FLU Oligo Mix		(-22) – (-18) °C	
NTC		(+2) – (+8) °C	
PC-CVD19/FLU		(+2) – (+8) °C	

*Each reagent stored at storage temperature can be used until the expiration date indicated on the tube following the first opening. The kit's expiration date is determined by the expiration date of the reagents.

Table 3. Components Required but Not Included with The Test

Components Required but Not Included with The Test
1. Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS) or/and CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) Real-Time PCR systems
2. Micropipettes and compatible filtered pipette tips (nuclease-free) suitable for transferring 1-10, 10-100, and 100-1000 µL of liquid
3. A centrifuge or Mini-spin
4. Vortex
5. Reaction tubes and caps/films specific to qPCR instruments and compatible with reaction volume

Table 4. Intended Use, Test Principle, and Analytical Specifications

Function	Aid to diagnosis	**Sample Type(s)**	Table 5
Analyte(s)	Table 1	**Nucleic Acid Preparation Method(s)**	Table 5
Qualitative/Quantitative	Qualitative	**Validated PCR Instrument(s)**	Table 3
Test Principle	Reverse Transcription and Real-Time PCR (RT-qPCR)	**Inclusivity and Exclusivity**	Validated on the reference strains and the field isolates
Automated/Manual	Manual		
Intended Users	Professional use	**Limit of Detection (LoD)**	Table 5
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	%100.00 ve %100.00

Table 5. Collection, Storage, and Transfer of Clinical Specimens / Nucleic Acid Preparation Methods and the Respected LoD Values

Sample Type**	Sample Transfer	Sample Storage	Nucleic Acid Preparation Method	LoD (cp/mL)
Combined nasopharyngeal, and oropharyngeal swabs	***vNAT® Transfer Tube*** (Cat. No: BS-NA-513m)	3 months at (+2) – (+8) °C 1 year at -20 °C	Nucleic acid preparation is not required. The sample can be used directly in qPCR.	250
	Viral Transport Medium (VTM) (CDC SOP#: DSR-052-05)	3 days at (+2) – (+8) °C 1 year at -70 °C	***RINA™ M14 Nucleic Acid Extraction Device*** (Robot Catalog No: RINA-M14-01, Kit Cat. No: RN-NA-101) ***Zybio EXM3000 Nucleic Acid Isolation System*** (Robot Model No: EXM3000, Kit Cat. No: ZFNAE01)	125
Bronchoalveolar lavage (BAL) and nasopharyngeal aspirate	Preservative-free sterile containers/tubes	(+2) – (+8) °C'de 3 gün -70 °C'de 1 yıl		500

**Clinical specimens should be collected by a healthcare provider in accordance with national/international clinical specimen collection regulations.

Revision Date: 2023-07-31/Rev.01
Published Date: 2022-08-15

1. qPCR Application Protocol

Before starting the assay, please consider the following:

1. The kit was validated only for the template nucleic acid volume which is 25% of the total qPCR volume.
2. The kit cannot be used with real-time PCR instruments without periodic maintenance records.
3. The kit for Bio-Rad Real-Time PCR systems has been validated with white reaction tubes specific to these systems. Clear reaction tubes result in 5-10 times lower fluorescence signal in Bio-Rad instruments compared to white reaction tubes. In addition, device-specific reaction tubes should be used in the BMS device. The kit's stated analytical performance can only be achieved using validated tubes.
4. To test for contamination, a negative control reaction containing NTC (Nuclease-free Water) must be set up in each run.

Program the qPCR device as follows and add the reagents into the qPCR tubes, close the tubes, place them into the qPCR instrument and start the run. (Table 6)

Table 6. RT-qPCR Program Details

Reaction Setup		RT-qPCR Program				QR Code for Thermal Protocol and Plate Setup
		CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) and Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)				
Reagent	**Volume/Rxn**	**Step**	**Cycle No.**	**Temperature**	**Duration**	
2X qPCR Mix	5 µL	**Enzyme Activation**	1 Cycle	52 °C	3 min	
		Pre-Incubation	1 Cycle	95 °C	10 sec	
Oligo Mix	2.5 µL	**Denaturation**	12 Touchdown Cycles: 1 °C decrement in annealing temperature per cycle	95 °C	1 sec	
		Annealing and Extension		67 °C to 56 °C	15 sec	
Template Nucleic Acid/NTC/PC	2.5 µL	**Denaturation**	30 Cycles	95 °C	1 sec	
		Annealing and Extension		55 °C	15 sec	
Total Reaction Volume	**10 µL**	**Detection (Reading)**		(FAM-Green)/(HEX-Yellow) (ROX-Orange)/(CY5-Red)		https://www.bioeksen.com.tr/files/L_TD_43P/

WARNING: The qPCR thermal programs (Bio-Rad and BMS-Mic) and the plate setup (Bio-Rad) file should be downloaded from the QR code or link above.

2. Interpretation of the Assay Results

All default analysis options (e.g., auto-calculated threshold) in the Mic software should not be changed to calculate Cq values.

The shape of the amplification curves should be examined for all reaction wells returning with Cq values. All the sigmoidal curves above the threshold should be recorded as "positive" and their Cq values should be recorded. Non-sigmoidal curves should be recorded as "negative".

Table 7. Expected Performance of Kit Controls

Control Type	Control Name	Purpose	Expected Results and Cq Values	
			IC (HEX)	Target
Negative Control	NTC	Contamination control during RT-qPCR	**Not detected** (No Cq)	**Not detected** (No Cq)
Positive Control	PC	Reagent integrity	**Detected** (Cq≤26)	**Detected** (Cq≤26)
Internal/Extraction Control	IC	To monitor the integrity of nucleic acid extraction and RT-qPCR from each sample	**Detected** (Cq≤26) If the IC Cq>26, check the target Cq.	If the target has a valid Cq value according to the result interpretation criteria, IC is valid.

If any control does not work as described above, the run is reported as follows:

1. **Contamination:** If Cq≤26 in any NTC test channel.
   Recommended action: Repeat the analysis paying attention to the "Warnings and Limitations" section.
2. **Reagent Problem**: In case a sigmoidal curve with a Cq≤26 cannot be obtained for any of all the samples tested in the run, including the controls.
   Recommended action: Test the "**PC-CVD19/FLU"** provided with the kit setting up the PC reaction as shown in Table 6. If the test result is positive, the run is valid. In case the software generates a "Reagent Problem" again, contact the manufacturer.
3. **Invalid:** If the sample has a Cq>26 in the HEX channel of the test tube and no Cq in the other channels.
   Recommended action: Sampling isn't successfully done, or there is a problem during the sample transportation. A new sample from the same patient should be collected and tested again.

If all the controls are valid, the results are interpreted as follows:

Table 8. Interpretation of Patient Results

Target	Internal Control (IC)	Result Interpretation
Positive (+)	**Positive (+)** or **Negative (-)**	Results are valid Target is detected
Negative (-)	**Positive (+)**	Results are valid Target is not detected

The results generated by the qPCR instruments can be reported manually, as explained earlier, or automatically using the "**Sigmoida**" software. To obtain the "Sigmoida" software installer, please send an email to support@bioeksen.com.tr.

3. Warnings and Limitations

1. False-negative results may occur if inadequate numbers (lower than the LoD) of organisms are present in the specimen.
2. Mutations within the target regions could affect primer and/or probe binding, resulting in failure to detect the presence of agents.
3. The use of cotton or calcium alginate swabs or swabs with wooden sticks can lead to false negative results since they may contain substances that inactivate some pathogens and inhibit PCR.
4. A false-negative result may occur if a specimen is improperly collected, transported, or handled.
5. The clinical specimens shall be collected by a healthcare provider in accordance with the specimen collection guidelines.
6. Test procedures should be performed by personnel trained in the use of the kit.
7. Except for liquid transfers, sample tubes should always be kept closed.
8. Filtered and nuclease-free pipette tips should be used for sample transfer.
9. The components in the kit should not be used together with different lot numbers or chemicals of the same name but from different manufacturers.
10. ***The caps of the reaction tubes must not be opened after the PCR run.*** The PCR tubes should be placed in a bag and thrown away after the bag is tightly closed.
11. The surfaces of the workbenches should be wiped with freshly diluted 10% bleach (0.5% NaClO) at the beginning and end of each day.
12. Disposal of waste must be carried out in accordance with local, state, and federal regulations.

4. Explanation of Symbol

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
CE	European Conformity CE Mark	LOT	Batch code		Keep away from sunlight
IVD	*In vitro* diagnostic *medical device*	REF	Catalogue number		Protect from heat and radioactive sources
	Manufacturer	NON STERILE	Non-*sterile*		Do not use if package is damaged and consult *instructions for use*
	Use-by date		Consult *instructions for use* or consult electronic *instructions for use*		Keep dry
CONTROL -	Negative control		Caution		Keep upright
CONTROL +	Positive control		Temperature limit	Σ	Contains sufficient for *<n>* tests
CONTROL	Control				

5. Manufacturer and Technical Support

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Technical Support: support@bioeksen.com.tr

Notice to User: Please inform us about product-related incidents at "**vigilance@bioeksen.com.tr**" within 24 hours.

For in vitro diagnostic use only.
For professional use only.

Cat No: CCHFVD0125/CCHFVD01100

CCHFV RT-qPCR Detection Kit

Package Insert

Table 1. Kit Content

Component	Intended Use	50 Reactions	100 Reactions
2X Prime Script Mix	Optimized ready-to-use mix for RT-qPCR assay	1 x 125 µL	1 x 500 µL
CCHF Oligo Mix	Specific nucleic acid amplification and detection: **FAM:** Crimean–Congo hemorrhagic fever virus (CCHFV) **HEX:** Human (IC-Internal Control)	1 x 62,5 µL	1 x 250 µL
NTC	Negative Control	1 x 1000 µL	
PC-CCHF	Positive Control (PC)	1 x 100 µL	1 x 250 µL

Table 2. Transport Condition, Storage Condition, and Shelf Life of the Components

Component	Transport Condition	Storage Condition*	Shelf Life
2X Prime Script Mix	(-22) – (+8) °C	(-22) – (-18) °C	12 Months
CCHF Oligo Mix		(-22) – (-18) °C	
NTC		(+2) – (+8) °C	
PC-CCHF		(+2) – (+8) °C	

*Each reagent stored at storage temperature can be used until the expiration date indicated on the tube following the first opening. The kit's expiration date is determined by the expiration date of the reagents.

Table 3. Components Required but Not Included with The Test

Components Required but Not Included with The Test
1. Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS) or/and CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) Real-Time PCR systems
2. Micropipettes and compatible filtered pipette tips (nuclease-free) suitable for transferring 1-10, 10-100, and 100-1000 µL of liquid.
3. A centrifuge or Mini-spin
4. Vortex
5. Reaction tubes and caps/films specific to qPCR instruments and compatible with reaction volume

Table 4. Intended Use, Test Principle, and Analytical Specifications

Function	Aid to diagnosis	**Sample Type(s)**	Table 5
Analyte(s)	Table 1	**Nucleic Acid Preparation Method(s)**	Table 5
Qualitative/Quantitative	Qualitative	**Validated PCR Instrument(s)**	Table 3
Test Principle	Reverse transcription and Real-Time PCR (RT-qPCR)	**Results Interpretation and Reporting**	Automated (Sigmoida software)
Automated/Manual	Manual	**Inclusivity and Exclusivity**	Validated on the reference strains and the field isolates
Intended Users	Professional use	**Limit of Detection (LoD)**	Table 5
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	99.67% and 100.00%

Table 5. Collection, Storage, and Transfer of Clinical Specimens / Nucleic Acid Preparation Methods and the Respected LoD Values

Sample Type**	Sample Transfer	Sample Storage	Nucleic Acid Preparation Method	LoD (cp/mL)
Whole blood, serum, and plasma	Anti-coagulent treated tube	3 days at (+2) – (+8) °C 1 year at -70 °C	***Zybio EXM3000 Nucleic Acid Isolation System*** (Robot Model No: EXM3000, Kit Cat. No: ZFNAE01) ***RINA™ M14 Nucleic Acid Extraction Device*** (Robot Model No: RINA-M14-01, Kit Cat. No: RN-NA-101)	1000

**Clinical specimens should be collected by a healthcare provider in accordance with national/international clinical specimen collection regulations.

1. qPCR Application Protocol

Before starting the assay, please consider the following:

1. The kit was validated only for the template nucleic acid volume which is 25% of the total qPCR volume.
2. The kit cannot be used with real-time PCR instruments without periodic maintenance records.
3. The kit for Bio-Rad Real-Time PCR systems has been validated with white reaction tubes specific to these systems. Clear reaction tubes result in 5-10 times lower fluorescence signal in Bio-Rad instruments compared to white reaction tubes. In addition, device-specific reaction tubes should be used in the BMS device. The kit's stated analytical performance can only be achieved using validated tubes.
4. To test for contamination, a negative control reaction containing NTC (Nuclease-free Water) must be set up in each run.

Program the qPCR device as follows and add the reagents into the qPCR tubes, close the tubes, place them into the qPCR instrument and start the run. (Table 6)

Table 6. RT-qPCR Program Details

Reaction Setup		RT-qPCR Program				QR Code for Thermal Protocol and Plate Setup
		CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad)* and *Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)				
Reagent	**Volume/Rxn**	**Step**	**Cycle No.**	**Temperature**	**Duration**	
2X Prime Script Mix	5 µL	**Enzyme Activation**	1 Cycle	52 °C	3 min	
		Pre-Incubation	1 Cycle	95 °C	10 sec	
CCHF Oligo Mix	2,5 µL	**Denaturation**	12 Touchdown Cycles: 1 °C decrement in annealing temperature per cycle	95 °C	1 sec	
		Annealing and Extension		67 °C to 56 °C	15 sec	
Template Nucleic Acid/NTC/PC	2,5 µL	**Denaturation**	35 Cycles	95 °C	1 sec	https://www.bioeksen.com.tr/files/BS_TD_3RT153555
		Annealing and Extension		55 °C	15 sec	
Total Reaction Volume	**10 µL**	**Detection (Reading)**		(FAM-Green)/(HEX-Yellow)		

WARNING: The qPCR thermal programs (Bio-Rad and BMS-Mic) and the plate setup (Bio-Rad) file should be downloaded from the QR code or link above.

2. Interpretation of the Assay Results Using The "Sigmoida" Software

The data produced by the instruments must be evaluated and reported using the Sigmoida software. The result files opened with the "Sigmoida" software will be analyzed automatically. Below are examples of results that can be achieved with the Sigmoida software:

Negative: The sample tested is negative for the tested agent.
Positive: The sample tested is positive for the tested agent.
Contamination: Repeat the analysis paying attention to the "Warnings and Limitations" section.
Invalid: Sampling isn't successfully done, or there is a problem during the sample transportation. A new sample from the same patient should be collected and tested again.
Reagent Problem: Test the "PC-CCHF" provided with the kit setting up the PC reactions as shown in Table 6. If the test result is positive, the run is valid. In case the software generates a "Reagent Problem" again, contact the manufacturer.

3. Warnings and Limitations

1. False-negative results may occur if inadequate numbers (lower than the LoD) of organisms are present in the specimen.
2. Mutations within the target regions could affect primer and/or probe binding, resulting in failure to detect the presence of agents.
3. A false-negative result may occur if a specimen is improperly collected, transported, or handled.
4. The clinical specimens shall be collected by a healthcare provider in accordance with the specimen collection guidelines.
5. Test procedures should be performed by personnel trained in the use of the kit.
6. Except for liquid transfers, sample tubes should always be kept closed.
7. Filtered and nuclease-free pipette tips should be used for sample transfer.
8. The components in the kit should not be used together with different lot numbers or chemicals of the same name but from different manufacturers.
9. ***The caps of the reaction tubes must not be opened after the PCR run.*** The PCR tubes should be placed in a bag and thrown away after the bag is tightly closed.
10. The surfaces of the workbenches should be wiped with freshly diluted 10% bleach (0.5% NaClO) at the beginning and end of each day.
11. Disposal of waste must be carried out in accordance with local, state, and federal regulations.

4. Explanation of Symbol

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
CE	European Conformity CE Mark	LOT	Batch code		Keep away from sunlight
IVD	*In vitro* diagnostic *medical device*	REF	Catalogue number		Protect from heat and radioactive sources
	Manufacturer	NON STERILE	Non-*sterile*		Do not use if package is damaged and consult *instructions for use*
	Use-by date		Consult *instructions for use* or consult electronic *instructions for use*		Keep dry
CONTROL -	Negative control		Caution		Keep upright
CONTROL +	Positive control		Temperature limit	Σ	Contains sufficient for *<n>* tests
CONTROL	Control				

5. Manufacturer and Technical Support

Bioeksen AR GE Teknolojileri A.Ş
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Technical Support: support@bioeksen.com.tr

Notice to User: Please inform us about product-related incidents at "**vigilance@bioeksen.com.tr**" within 24 hours.

For in vitro diagnostic use only.
For professional use only.

Cat No: BS-NA-513m-100

*v*NAT® Transfer Tube

Instructions for Use (IFU)

1. PRODUCT DESCRIPTION

Table 1. Product overview

Product Name	*v*NAT® Transfer Tube
Catalog No	BS-NA-513m-100
Basic UDI	868187745NAEXT0672
Intended Use	The *v*NAT® Transfer Tube contains 2 ml of *v*NAT® reagent, which lyses cells, releases nucleic acids, and preserves them. The *v*NAT® reagent also inactivates viral and bacterial pathogens within 1 minute of contact with the clinical specimen. When clinical specimens suspected of respiratory tract infection are transferred into the *v*NAT® Transfer Tube, the liquid inside the tube can be directly used in Real-Time PCR (qPCR) reactions without the need for nucleic acid extraction.
Intended Users	Professional use with training in the sampling process.
Intended environment of use	Near-patient testing in non-laboratory conditions.
Special Conditions for Use Statements	For in vitro diagnostic use only.
Test Principle	The *v*NAT® reagent contains a combination of quaternary ammonium compound (QAC) and tween-20, which work together to effectively lyse cells and release the genomic material present in the sample. The QAC and NaN_3 in the reagent also play a crucial role in preserving the integrity of the released genomes.
Analyte	Respiratory tract pathogens.
Specimen Type (s)	Nasopharyngeal, oropharyngeal, and nasal, and oral/saliva swab samples from the respiratory tract.

Table 2. Product content

Component	Description	Amount
*v*NAT® *Transfer Tube*	Cell lysis and nucleic acid storage	100 tubes each containing 2 mL of *v*NAT® reagent

Table 3. Storage requirements and shelf life

Component	Transport Conditions	Storage Conditions	Shelf Life
*v*NAT® *Transfer Tube*	+2 °C to +50 °C	+2 °C to +30 °C	60 months

Table 4. Materials required but not included with the product.

Component	Intended use	Specifications
Vortex mixer	Sample homogenization	Speed up to 3000 rpm
Micropipettes	Liquid transfer	Adjustable volume; 10-100 µL or 0.1-10 µL
Micropipettes tips	Liquid transfer	Compatible with the micropipettes, filtered, nuclease-free

2 APPLICATION PROTOCOL

The collection of nasopharyngeal, oropharyngeal, nasal, and oral/saliva swab samples should be performed by a healthcare provider following the guidelines outlined in national and international clinical specimen collection regulations. These regulations include adherence to protocols such as the updated version of the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19, which can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html.

Once the swab samples are collected, it is important to immediately place them into the *v*NAT® Transfer Tube.

One minute after the sampling, the sample in the *v*NAT® ***Transfer Tube*** can be used directly in RT-qPCR. Vortex the tube at the highest speed for 3 seconds before adding the sample into the RT-qPCR.

Store the specimens at +2 °C to +8 °C and ship them to the laboratory on the ice pack. Specimens in the *v*NAT® ***Transfer Tube*** can be stored at +2 °C to +30 °C for up to 72 hours and +2 °C to +8 °C for up to 3 months after the collection.

3 PERFORMANCE CHARACTERISTICS

The *v*NAT® ***Transfer Tube*** has been validated specifically for use with RT-qPCR-based test kits manufactured by Bioeksen AR GE Teknolojileri A.Ş. The performance characteristics of the *v*NAT® ***Transfer Tube***, when used in conjunction with these specific kits for the in vitro diagnosis of targeted pathogens, are provided in the Instructions for Use (IFUs) of the respective RT-qPCR kits.

3.1 Shelf-life and shipping stability

Since the swab samples are placed into the *v*NAT® Transfer Tube immediately after its initial opening, stability studies were carried out only for the unopened *v*NAT® Transfer Tubes. Separate shelf-life stability studies for the components prepared in bulk and stored before use in different lots were not conducted since the components of the *v*NAT® Transfer Tube are always freshly prepared.

The shelf-life and shipping stability test involved three different lots all manufactured under routine production conditions. The stability study was initiated within one week after production. The *v*NAT® Transfer Tubes were stored for 113 weeks (26 months) in a stability chamber set at 2 °C, 30 °C and 50 °C to mimic all possible storage and shipping conditions. The stability chamber was set at 85% relative humidity for a worst-case scenario.

The Bio-Speedy® Respiratory ID-3 Panel (Cat No: BS-RIDP-3) was used to evaluate the stability of the stored *v*NAT® Transfer Tubes. Negative clinical samples were collected using freshly produced *v*NAT® Transfer Tubes. Subsequently, the samples were pooled together and subjected to 24 tests using the Bio-Speedy® Respiratory ID-3 Panel to confirm the absence of any positive results in the negative sample matrix. All tests yielded negative results for the analyte and positive results for the internal control (IC), with an average Cq value of 18.31 ± 0.74. Subsequently, reference materials of Group A *Streptococcus* (Zeptometrix, #0801512), *Streptococcus pneumoniae* (Zeptometrix, 0801439), *Mycoplasma pneumoniae* (Zeptometrix, 0801579), *Chlamydophila pneumoniae* (ATCC, VR-2282), *Haemophilus influenzae* (Zeptometrix, 0801679), *SARS-CoV-2* (Zeptometrix, 0810589CFHI), Influenza A (Zeptometrix, 0810036CF), RSV A (Zeptometrix, 0810040ACF), Adenovirus (Zeptometrix, 0810050CF), Rhinovirus (Zeptometrix, 0810012CFN), and Parainfluenza virus 3 (Zeptometrix, 0810016CF) were diluted in the negative clinical sample matrix to reach an analyte concentration that is 11x higher than the Limit of Detection (LoD) of the Bio-Speedy® Respiratory ID-3 Panel, which is 250 copies/mL.

Weekly testing was conducted on five *v*NAT® Transfer Tubes from each lot involved in the stability study, resulting in a total of 15 tubes (3 lots x 5 tubes) tested for each condition every week. The *v*NAT® Transfer Tubes were spiked with 0.2 mL of the sample matrix containing the analytes, leading to a final concentration of 250 copies/mL for each analyte. These spiked tubes were then subjected to testing using the Bio-Speedy® Respiratory ID-3 Panel.

For the study, a baseline was established by defining a 5% deterioration from the initial Cq value. The stability of the tube was determined by selecting the time point prior to the last time point at which it met the acceptance criteria. The results of the stability tests are presented in Table 5-7.

The results of the stability study indicated that the *v*NAT® Transfer Tubes remained stable at 2°C, 30 °C, and 50 °C even after 26 months of testing. To calculate the theoretical shelf-life at 30 °C, the data obtained from the tubes stored at 50 °C was analyzed using the Arrhenius equation, which establishes a relationship between the rate of product degradation and the storage temperature. The calculated theoretical shelf-life for the *v*NAT® Transfer Tubes was determined to be 105 months at 30 °C.

Table 5. Stability study results at 50 °C.

Analyte	t = 0					t = Week 113				
	Analyte		IC		Detection Rate	Analyte		IC		Detection Rate
	Cq	± SD	Cq	± SD		Cq	± SD	Cq	± SD	
Group A *Streptococcus*	25.33	0.66	18.58	0.47	15/15	25.17	0.82	18.14	0.49	15/15
Streptococcus pneumoniae	25.47	0.62	18.48	0.87	15/15	25.72	0.65	18.34	0.71	15/15
Mycoplasma pneumoniae	24.25	0.54	18.42	0.8	15/15	24.12	0.64	18.8	0.46	15/15
Chlamydophila pneumoniae	25.97	0.54	18.89	0.81	15/15	25.82	0.75	18.71	0.61	15/15
Haemophilus influenzae	24.86	0.75	18.78	0.49	15/15	24.57	0.6	18.49	0.79	15/15
SARS-CoV-2	24.20	0.79	18.6	0.56	15/15	25.63	0.47	18.14	0.73	15/15
Influenza A	25.19	0.47	18.67	0.53	15/15	24.76	0.47	18.94	0.43	15/15
RSV A	25.71	0.52	18.19	0.6	15/15	25.95	0.49	18.53	0.61	15/15
Adenovirus	24.77	0.62	18.37	0.65	15/15	25.38	0.81	18.24	0.64	15/15
Rhinovirus	24.42	0.45	18.38	0.53	15/15	24.76	0.66	18.15	0.59	15/15
Parainfluenza virus 3	25.55	0.76	18.18	0.45	15/15	25.24	0.66	18.44	0.72	15/15

Table 6. Stability study results at 30 °C.

Analyte	t = 0					t = Week 113				
	Analyte		IC		Detection Rate	Analyte		IC		Detection Rate
	Cq	± SD	Cq	± SD		Cq	± SD	Cq	± SD	
Group A *Streptococcus*	25.33	0.66	18.58	0.47	15/15	25.58	0.81	18.54	0.72	15/15
Streptococcus pneumoniae	25.47	0.62	18.48	0.87	15/15	25.72	0.56	18.69	0.68	15/15
Mycoplasma pneumoniae	24.25	0.54	18.42	0.8	15/15	24.68	0.69	18.96	0.69	15/15
Chlamydophila pneumoniae	25.97	0.54	18.89	0.81	15/15	24.81	0.78	18.86	0.51	15/15
Haemophilus influenzae	24.86	0.75	18.78	0.49	15/15	24.88	0.47	18.7	0.45	15/15
SARS-CoV-2	24.20	0.79	18.6	0.56	15/15	25.66	0.81	18.4	0.56	15/15
Influenza A	25.19	0.47	18.67	0.53	15/15	25.94	0.89	18.28	0.77	15/15
RSV A	25.71	0.52	18.19	0.6	15/15	24.28	0.45	18.59	0.5	15/15
Adenovirus	24.77	0.62	18.37	0.65	15/15	24.63	0.5	18.86	0.52	15/15

Rhinovirus	24.42	0.45	18.38	0.53	15/15	25.64	0.76	18.75	0.66	15/15
Parainfluenza virus 3	25.55	0.76	18.18	0.45	15/15	25.73	0.44	18.32	0.69	15/15

Table 7. Stability study results at 2 °C.

Analyte	t = 0					t = Week 113				
	Analyte		IC		Detection Rate	Analyte		IC		Detection Rate
	Cq	± SD	Cq	± SD		Cq	± SD	Cq	± SD	
Group A *Streptococcus*	25.33	0.66	18.58	0.47	15/15	25.65	0.62	18.49	0.6	15/15
Streptococcus pneumoniae	25.47	0.62	18.48	0.87	15/15	25.38	0.53	18.79	0.63	15/15
Mycoplasma pneumoniae	24.25	0.54	18.42	0.8	15/15	24.71	0.48	18.46	0.67	15/15
Chlamydophila pneumoniae	25.97	0.54	18.89	0.81	15/15	24.86	0.82	18.18	0.86	15/15
Haemophilus influenzae	24.86	0.75	18.78	0.49	15/15	25.27	0.65	18.68	0.45	15/15
SARS-CoV-2	24.20	0.79	18.6	0.56	15/15	25.57	0.49	18.15	0.62	15/15
Influenza A	25.19	0.47	18.67	0.53	15/15	24.44	0.66	18.18	0.86	15/15
RSV A	25.71	0.52	18.19	0.6	15/15	25.81	0.45	18.38	0.44	15/15
Adenovirus	24.77	0.62	18.37	0.65	15/15	25.35	0.52	18.65	0.6	15/15
Rhinovirus	24.42	0.45	18.38	0.53	15/15	25.73	0.55	18.34	0.69	15/15
Parainfluenza virus 3	25.55	0.76	18.18	0.45	15/15	24.72	0.75	18.53	0.56	15/15

3.2 Stability of specimens in the *v*NAT® Transfer Tube

The Bio-Speedy® Respiratory ID-3 Panel (Cat No: BS-RIDP-3) was used to evaluate the stability of the nasopharyngeal, oropharyngeal, nasal, and oral swab samples stored in the *v*NAT® Transfer Tubes. Negative clinical samples were collected using the *v*NAT® Transfer Tubes. Subsequently, each sample was subjected to 5 tests using the Bio-Speedy® Respiratory ID-3 Panel to confirm the absence of any positive results. All tests yielded negative results for the analyte and positive results for the internal control (IC). Then, reference materials of Group A *Streptococcus* (Zeptometrix, #0801512), *Streptococcus pneumoniae* (Zeptometrix, 0801439), *Mycoplasma pneumoniae* (Zeptometrix, 0801579), *Chlamydophila pneumoniae* (ATCC, VR-2282), *Haemophilus influenzae* (Zeptometrix, 0801679), SARS-CoV-2 (Zeptometrix, 0810589CFHI), Influenza A (Zeptometrix, 0810036CF), RSV A (Zeptometrix, 0810040ACF), Adenovirus (Zeptometrix, 0810050CF), Rhinovirus (Zeptometrix, 0810012CFN), and Parainfluenza virus 3 (Zeptometrix, 0810016CF) were diluted in the negative samples to reach an analyte concentration at the LoD of the Bio-Speedy® Respiratory ID-3 Panel, which is 250 copies/mL.

The spiked tubes were stored at 4 °C and 30 °C for four months at 85% relative humidity in the stability chamber. Daily testing was conducted on the five contrived samples for each condition using the Bio-Speedy® Respiratory ID-3 Panel. A baseline was established by defining a 5% deterioration from the initial Cq value. The stability of the sample was determined by selecting the time point prior to the last time point at which it met the acceptance criteria.

Table 8-15 displays the results of the specimen stability tests. The analysis reveals that the nasopharyngeal, oropharyngeal, nasal, and oral swab samples stored in the *v*NAT® Transfer Tubes remained stable for a period of 4 days at 30 °C. Therefore, it is recommended to store these samples at 30 °C for a maximum duration of 3 days.

Furthermore, all sample types in the *v*NAT® Transfer Tubes demonstrated stability even after 4 months of storage at 4 °C. As a result, it is advised to store these samples at 4 °C for up to 3 months.

Table 8. Stability results of nasopharyngeal swab samples at 30 °C

Analyte	t = 0					t = Day 4					t = Day 5				
	Analyte		IC		Hit Rate	Analyte		IC		Hit Rate	Analyte		IC		Hit Rate
	Cq	± SD	Cq	± SD		Cq	± SD	Cq	± SD		Cq	± SD	Cq	± SD	
Group A *Streptococcus*	25.72	0.6	17.81	0.53	5/5	26.61	0.54	18.12	0.58	5/5	28.19	1.85	19.49	0.63	3/5
Streptococcus pneumoniae	25.63	0.45	14.72	0.74	5/5	26.28	0.46	15.02	0.64	5/5	27.54	1.37	16	0.81	4/5
Mycoplasma pneumoniae	25.38	0.47	19.76	0.54	5/5	26.01	0.85	20.18	0.46	5/5	26.85	1.78	20.81	0.63	5/5
Chlamydophila pneumoniae	25.33	0.73	15.81	0.78	5/5	26.21	0.49	16.02	0.47	5/5	27.39	1.31	17.28	0.82	4/5
Haemophilus influenzae	24.29	0.79	17.3	0.48	5/5	24.93	0.68	17.81	0.76	5/5	25.95	1.32	18.45	0.59	5/5
SARS-CoV-2	24.75	0.51	12.3	0.87	5/5	25.24	0.81	12.58	0.73	5/5	26.2	1.28	13.27	0.7	5/5
Influenza A	24.27	0.42	14.33	0.81	5/5	25.07	0.57	14.85	0.57	5/5	26.11	1.75	15.65	0.56	5/5
RSV A	24.81	0.73	14.12	0.42	5/5	25.66	0.49	14.57	0.44	5/5	26.56	1.83	15.42	0.66	5/5
Adenovirus	25.59	0.72	18.23	0.56	5/5	26.09	0.64	18.66	0.89	5/5	26.95	1.43	19.16	0.63	5/5
Rhinovirus	24.90	0.66	13.27	0.64	5/5	25.53	0.49	13.86	0.41	5/5	27.31	1.33	14.79	0.6	4/5
Parainfluenza virus 3	25.82	0.43	14.38	0.57	5/5	26.64	0.72	14.96	0.7	5/5	27.8	1.61	15.78	0.81	2/5

Table 9. Stability results of nasopharyngeal swab samples at 4 °C

Analyte	t = 0					t = Day 120				
	Analyte		IC		Hit Rate	Analyte		IC		Hit Rate
	Cq	± SD	Cq	± SD		Cq	± SD	Cq	± SD	
Group A *Streptococcus*	25.72	0.6	17.81	0.53	5/5	26.38	0.4	18.09	0.24	5/5
Streptococcus pneumoniae	25.63	0.45	14.72	0.74	5/5	26.24	0.38	15.12	0.23	5/5
Mycoplasma pneumoniae	25.38	0.47	19.76	0.54	5/5	26.19	0.29	20.14	0.3	5/5
Chlamydophila pneumoniae	25.33	0.73	15.81	0.78	5/5	26.06	0.34	16.13	0.25	5/5
Haemophilus influenzae	24.29	0.79	17.3	0.48	5/5	24.81	0.29	17.57	0.31	5/5
SARS-CoV-2	24.75	0.51	12.3	0.87	5/5	25.31	0.23	12.64	0.3	5/5
Influenza A	24.27	0.42	14.33	0.81	5/5	24.91	0.32	14.72	0.26	5/5
RSV A	24.81	0.73	14.12	0.42	5/5	25.40	0.28	14.44	0.27	5/5
Adenovirus	25.59	0.72	18.23	0.56	5/5	26.44	0.35	18.49	0.37	5/5
Rhinovirus	24.90	0.66	13.27	0.64	5/5	25.66	0.39	13.56	0.22	5/5
Parainfluenza virus 3	25.82	0.43	14.38	0.57	5/5	26.29	0.39	14.72	0.4	5/5

Table 10. Stability results of oropharyngeal swab samples at 30 °C

Analyte	t = 0					t = Day 4					t = Day 5				
	Analyte		IC		Hit Rate	Analyte		IC		Hit Rate	Analyte		IC		Hit Rate
	Cq	± SD	Cq	± SD		Cq	± SD	Cq	± SD		Cq	± SD	Cq	± SD	
Group A *Streptococcus*	25.95	0.28	19.48	0.21	5/5	26.17	0.42	19.92	0.43	5/5	27.49	0.31	22.12	0.28	3/5
Streptococcus pneumoniae	24.64	0.67	14.85	0.25	5/5	25.09	0.37	15.13	0.4	5/5	27.79	0.44	16.53	0.42	4/5
Mycoplasma pneumoniae	25.85	0.64	13.45	0.34	5/5	26.12	0.34	13.88	0.43	5/5	27.74	0.43	16.03	0.22	3/5
Chlamydophila pneumoniae	24.47	0.47	16.18	0.23	5/5	24.86	0.45	16.64	0.36	5/5	27.20	0.42	18.94	0.39	4/5
Haemophilus influenzae	25.25	0.32	13.39	0.32	5/5	25.72	0.45	13.62	0.36	5/5	28.54	0.46	14.77	0.43	2/5
SARS-CoV-2	25.94	0.55	18.31	0.4	5/5	26.27	0.43	18.74	0.37	5/5	28.25	0.38	20.89	0.36	2/5
Influenza A	24.26	0.5	19.94	0.39	5/5	24.60	0.46	20.3	0.47	5/5	26.64	0.29	22.1	0.26	5/5
RSV A	25.13	0.33	19.15	0.27	5/5	25.56	0.31	19.58	0.33	5/5	28.14	0.25	21.73	0.21	3/5
Adenovirus	24.64	0.21	19.63	0.28	5/5	25.05	0.32	19.88	0.21	5/5	27.51	0.25	21.13	0.37	4/5
Rhinovirus	25.43	0.57	19.61	0.3	5/5	25.69	0.32	20.07	0.21	5/5	27.25	0.44	22.37	0.36	4/5
Parainfluenza virus 3	25.47	0.36	16.26	0.31	5/5	25.77	0.35	16.59	0.34	5/5	27.57	0.35	18.24	0.29	4/5

Table 11. Stability results of oropharyngeal swab samples at 4 °C

Analyte	t = 0					t = Day 120				
	Analyte		IC		Hit Rate	Analyte		IC		Hit Rate
	Cq	± SD	Cq	± SD		Cq	± SD	Cq	± SD	
Group A *Streptococcus*	25.95	0.28	19.48	0.21	5/5	26.64	0.24	19.75	0.42	5/5
Streptococcus pneumoniae	24.64	0.67	14.85	0.25	5/5	25.05	0.45	15.45	0.4	5/5
Mycoplasma pneumoniae	25.85	0.64	13.45	0.34	5/5	26.53	0.35	14.11	0.45	5/5
Chlamydophila pneumoniae	24.47	0.47	16.18	0.23	5/5	24.81	0.45	16.46	0.37	5/5
Haemophilus influenzae	25.25	0.32	13.39	0.32	5/5	25.86	0.26	13.79	0.43	5/5
SARS-CoV-2	25.94	0.55	18.31	0.4	5/5	26.52	0.3	18.56	0.36	5/5
Influenza A	24.26	0.5	19.94	0.39	5/5	24.61	0.23	20.29	0.32	5/5
RSV A	25.13	0.33	19.15	0.27	5/5	25.41	0.46	19.57	0.28	5/5
Adenovirus	24.64	0.21	19.63	0.28	5/5	25.08	0.34	20.26	0.24	5/5
Rhinovirus	25.43	0.57	19.61	0.3	5/5	26.08	0.42	20.08	0.33	5/5
Parainfluenza virus 3	25.47	0.36	16.26	0.31	5/5	25.91	0.28	16.83	0.25	5/5

Table 12. Stability results of nasal swab samples at 30 °C

Analyte	t = 0					t = Day 4					t = Day 5				
	Analyte		IC		Hit Rate	Analyte		IC		Hit Rate	Analyte		IC		Hit Rate
	Cq	± SD	Cq	± SD		Cq	± SD	Cq	± SD		Cq	± SD	Cq	± SD	
Group A *Streptococcus*	24.21	0.4	14.93	0.27	5/5	24.42	0.34	15.17	0.36	5/5	25.68	0.3	16.37	0.35	5/5
Streptococcus pneumoniae	24.74	0.39	15.49	0.28	5/5	25.17	0.38	15.76	0.42	5/5	27.75	0.29	17.11	0.31	4/5
Mycoplasma pneumoniae	24.30	0.28	14.23	0.36	5/5	24.69	0.41	14.64	0.33	5/5	27.03	0.27	16.69	0.29	4/5
Chlamydophila pneumoniae	25.92	0.34	13.42	0.26	5/5	26.28	0.31	13.76	0.4	5/5	28.44	0.22	15.46	0.31	3/5
Haemophilus influenzae	25.84	0.31	15.71	0.37	5/5	26.28	0.25	15.99	0.45	5/5	28.92	0.38	17.39	0.34	2/5
SARS-CoV-2	25.78	0.42	12.25	0.47	5/5	26.13	0.26	12.71	0.44	5/5	28.23	0.26	15.01	0.25	3/5
Influenza A	25.39	0.23	13.27	0.35	5/5	25.80	0.43	13.66	0.45	5/5	28.26	0.25	15.61	0.33	3/5
RSV A	25.85	0.41	18.69	0.46	5/5	26.20	0.44	19.07	0.38	5/5	28.30	0.38	20.97	0.22	3/5
Adenovirus	24.68	0.3	12.56	0.39	5/5	25.00	0.42	12.88	0.38	5/5	26.92	0.29	14.48	0.31	4/5
Rhinovirus	24.55	0.38	14.78	0.36	5/5	24.85	0.26	15.1	0.41	5/5	26.65	0.26	16.7	0.29	5/5
Parainfluenza virus 3	25.26	0.4	12.97	0.45	5/5	25.48	0.35	13.33	0.4	5/5	26.80	0.23	15.13	0.22	5/5

Table 13. Stability results of nasal swab samples at 4 °C

Analyte	t = 0					t = Day 120				
	Analyte		IC		Hit Rate	Analyte		IC		Hit Rate
	Cq	± SD	Cq	± SD		Cq	± SD	Cq	± SD	
Group A *Streptococcus*	24.21	0.4	14.93	0.27	5/5	24.67	0.24	15.27	0.31	5/5
Streptococcus pneumoniae	24.74	0.39	15.49	0.28	5/5	25.14	0.36	15.95	0.23	5/5
Mycoplasma pneumoniae	24.30	0.28	14.23	0.36	5/5	24.58	0.36	14.6	0.28	5/5
Chlamydophila pneumoniae	25.92	0.34	13.42	0.26	5/5	26.24	0.31	13.65	0.28	5/5
Haemophilus influenzae	25.84	0.31	15.71	0.37	5/5	26.28	0.4	16.16	0.28	5/5
SARS-CoV-2	25.78	0.42	12.25	0.47	5/5	26.23	0.31	12.52	0.31	5/5
Influenza A	25.39	0.23	13.27	0.35	5/5	25.60	0.34	13.59	0.38	5/5
RSV A	25.85	0.41	18.69	0.46	5/5	26.29	0.27	19.14	0.36	5/5
Adenovirus	24.68	0.3	12.56	0.39	5/5	24.95	0.4	13.02	0.3	5/5
Rhinovirus	24.55	0.38	14.78	0.36	5/5	24.77	0.29	15.24	0.4	5/5
Parainfluenza virus 3	25.26	0.4	12.97	0.45	5/5	25.65	0.28	13.29	0.43	5/5

Table 14. Stability results of oral swab samples at 30 °C

Analyte	t = 0					t = Day 4					t = Day 5				
	Analyte		IC		Hit Rate	Analyte		IC		Hit Rate	Analyte		IC		Hit Rate
	Cq	± SD	Cq	± SD		Cq	± SD	Cq	± SD		Cq	± SD	Cq	± SD	
Group A *Streptococcus*	24.56	0.4	15.28	0.4	5/5	24.86	0.46	15.59	0.43	5/5	26.66	0.24	17.14	0.26	5/5
Streptococcus pneumoniae	24.72	0.21	18.33	0.37	5/5	24.99	0.36	18.78	0.32	5/5	26.61	0.3	21.03	0.21	5/5
Mycoplasma pneumoniae	25.36	0.46	14.94	0.29	5/5	25.68	0.43	15.15	0.47	5/5	27.60	0.37	16.2	0.21	4/5
Chlamydophila pneumoniae	24.22	0.33	19.88	0.31	5/5	24.69	0.44	20.18	0.27	5/5	27.51	0.27	21.68	0.24	4/5
Haemophilus influenzae	25.57	0.45	17.96	0.21	5/5	25.95	0.42	18.35	0.46	5/5	28.23	0.26	20.3	0.3	3/5
SARS-CoV-2	25.88	0.33	12.76	0.4	5/5	26.26	0.4	13.13	0.35	5/5	28.54	0.38	14.98	0.44	2/5
Influenza A	24.13	0.33	16.41	0.45	5/5	24.55	0.21	16.66	0.42	5/5	27.07	0.22	17.91	0.47	4/5
RSV A	24.94	0.21	14.16	0.3	5/5	25.17	0.45	14.43	0.43	5/5	26.55	0.4	15.78	0.36	5/5
Adenovirus	24.63	0.28	18.82	0.35	5/5	24.85	0.4	19.22	0.44	5/5	26.17	0.43	21.22	0.24	5/5
Rhinovirus	25.35	0.43	13.9	0.29	5/5	25.72	0.33	14.13	0.34	5/5	27.94	0.34	15.28	0.26	4/5
Parainfluenza virus 3	24.73	0.26	16.71	0.34	5/5	24.97	0.38	16.93	0.27	5/5	26.41	0.21	18.03	0.45	5/5

Table 15. Stability results of oral swab samples at 4 °C

Analyte	t = 0					t = Day 120				
	Analyte		IC		Hit Rate	Analyte		IC		Hit Rate
	Cq	± SD	Cq	± SD		Cq	± SD	Cq	± SD	
Group A *Streptococcus*	24.56	0.4	15.28	0.4	5/5	24.78	0.43	15.72	0.37	5/5
Streptococcus pneumoniae	24.72	0.21	18.33	0.37	5/5	25.17	0.41	18.61	0.34	5/5
Mycoplasma pneumoniae	25.36	0.46	14.94	0.29	5/5	25.63	0.4	15.37	0.22	5/5
Chlamydophila pneumoniae	24.22	0.33	19.88	0.31	5/5	24.61	0.29	20.34	0.36	5/5
Haemophilus influenzae	25.57	0.45	17.96	0.21	5/5	26.04	0.24	18.19	0.27	5/5
SARS-CoV-2	25.88	0.33	12.76	0.4	5/5	26.21	0.44	13.19	0.21	5/5
Influenza A	24.13	0.33	16.41	0.45	5/5	24.47	0.24	16.77	0.21	5/5
RSV A	24.94	0.21	14.16	0.3	5/5	25.37	0.38	14.59	0.38	5/5
Adenovirus	24.63	0.28	18.82	0.35	5/5	25.04	0.27	19.07	0.35	5/5
Rhinovirus	25.35	0.43	13.9	0.29	5/5	25.61	0.38	14.36	0.3	5/5
Parainfluenza virus 3	24.73	0.26	16.71	0.34	5/5	25.03	0.3	17.04	0.34	5/5

3.3 Inactivation performance

Archived clinical respiratory tract samples that were collected in Copan Universal Transport Medium (UTM) were used in the inactivation performance studies. The samples were tested using the Bio-Speedy® Respiratory Tract RT-qPCR MX-24L Panel (Cat No: BS-SY-MX24L) or Bio-Speedy® Lower Respiratory Bacteria qPCR Panel (Cat No: BS-LRB-L), which detected the following pathogens: Group A *Streptococcus, Streptococcus pneumoniae, Mycoplasma pneumoniae, Chlamydophila pneumoniae, Haemophilus influenzae*, SARS-CoV-2, Influenza A, RSV A/B, Adenovirus, Rhinovirus, and Parainfluenza virus 3. For the subsequent viability studies, three levels of positivity were chosen. These levels include:

1. High positive samples: These samples exhibit a Cq value ranging from 6 to 10.
2. Positive samples: These samples have a Cq value ranging from 15 to 19.
3. Low positive samples: These samples possess a Cq value ranging from 23 to 26.

Pathogen viability in the samples was assessed using specific growth media. Group A *Streptococcus* and *Streptococcus pneumoniae* were cultured on Blood Agar. *Chlamydophila pneumoniae*, RSV A/B, and Parainfluenza virus 3 were assessed using HEp-2 cell culture media. *Mycoplasma pneumoniae* was cultured on SP4 agar. *Haemophilus influenzae* was cultured on Chocolate Agar. SARS-CoV-2 was propagated in Vero E6 cell culture media. Influenza A was cultured in Madin-Darby Canine Kidney (MDCK) cell culture media. Adenovirus was cultured in HEK293 cell culture media. Rhinovirus was cultured in nasal epithelial cell culture media.

The positive samples were added to both the *v*NAT® Transfer Tube and the Copan Universal Transport Medium (UTM) in a manner that resulted in a five-fold dilution of the sample within the media. After a one-minute incubation at room temperature, the tubes were immediately subjected to cultivation. The unused UTM and *v*NAT® tubes were also included in the cultivation as negative controls. Plaque-forming units (PFU)/mL, tissue culture infectious dose 50 (TCID50), or colony-forming units (CFU)/mL were subsequently calculated for each condition.

The results were presented in Table 16. The concentrations were between 10^2-10^6 units/mL when cultivated from the samples in the UTM. All the concentrations resulted in negative results for the samples in the *v*NAT® Transfer Tubes indicating successful inactivation by the *v*NAT® reagent.

Table 16-18 displays the results of the viability study. The concentrations of the cultivated samples from the Universal Transport Medium (UTM) ranged between 10^2-10^6 units/mL. However, all the concentrations derived from the samples in the *v*NAT® Transfer Tubes showed negative results, indicating successful inactivation of the analytes by the *v*NAT® reagent.

Table 16. Results of the viable pathogen count in the high positive samples

Analyte	Unit	Spiked Media		Clean Media	
		UTM	*v*NAT®	UTM	*v*NAT®
Group A *Streptococcus*	cfu/mL	$2.1x10^5$	Not detected	Not detected	Not detected
Streptococcus pneumoniae	cfu/mL	$8.6x10^5$	Not detected	Not detected	Not detected
Mycoplasma pneumoniae	cfu/mL	$8x10^4$	Not detected	Not detected	Not detected
Chlamydophila pneumoniae	cfu/mL	$1.2x10^5$	Not detected	Not detected	Not detected
Haemophilus influenzae	cfu/mL	$2.4x10^5$	Not detected	Not detected	Not detected
SARS-CoV-2	TCID50/mL	$3.2x10^4$	Not detected	Not detected	Not detected
Influenza A	PFU/mL	$8.9x10^5$	Not detected	Not detected	Not detected
RSV A	TCID50/mL	$8.6x10^4$	Not detected	Not detected	Not detected
Adenovirus	PFU/mL	$9.5x10^5$	Not detected	Not detected	Not detected
Rhinovirus	TCID50/mL	$9.1x10^4$	Not detected	Not detected	Not detected
Parainfluenza virus 3	PFU/mL	$8.3x10^5$	Not detected	Not detected	Not detected

Table 17. Results of the viable pathogen count in the positive samples

Analyte	Unit	Spiked Media		Clean Media	
		UTM	vNAT®	UTM	vNAT®
Group A *Streptococcus*	cfu/mL	$8.1x10^3$	Not detected	Not detected	Not detected
Streptococcus pneumoniae	cfu/mL	$9.2x10^3$	Not detected	Not detected	Not detected
Mycoplasma pneumoniae	cfu/mL	$9.7x10^2$	Not detected	Not detected	Not detected
Chlamydophila pneumoniae	cfu/mL	$3.3x10^3$	Not detected	Not detected	Not detected
Haemophilus influenzae	cfu/mL	$1.7x10^3$	Not detected	Not detected	Not detected
SARS-CoV-2	TCID50/mL	$8.6x10^2$	Not detected	Not detected	Not detected
Influenza A	PFU/mL	$9.1x10^3$	Not detected	Not detected	Not detected
RSV A	TCID50/mL	$8.6x10^2$	Not detected	Not detected	Not detected
Adenovirus	PFU/mL	$9.7x10^3$	Not detected	Not detected	Not detected
Rhinovirus	TCID50/mL	$3.8x10^2$	Not detected	Not detected	Not detected
Parainfluenza virus 3	PFU/mL	$7.5x10^3$	Not detected	Not detected	Not detected

Table 18. Results of the viable pathogen count in the low positive samples

Analyte	Unit	Spiked Media		Clean Media	
		UTM	vNAT®	UTM	vNAT®
Group A *Streptococcus*	cfu/mL	136	Not detected	Not detected	Not detected
Streptococcus pneumoniae	cfu/mL	255	Not detected	Not detected	Not detected
Mycoplasma pneumoniae	cfu/mL	331	Not detected	Not detected	Not detected
Chlamydophila pneumoniae	cfu/mL	214	Not detected	Not detected	Not detected
Haemophilus influenzae	cfu/mL	451	Not detected	Not detected	Not detected
SARS-CoV-2	TCID50/mL	102	Not detected	Not detected	Not detected
Influenza A	PFU/mL	394	Not detected	Not detected	Not detected
RSV A	TCID50/mL	155	Not detected	Not detected	Not detected
Adenovirus	PFU/mL	619	Not detected	Not detected	Not detected
Rhinovirus	TCID50/mL	113	Not detected	Not detected	Not detected
Parainfluenza virus 3	PFU/mL	652	Not detected	Not detected	Not detected

4 WARNINGS AND PRECAUTIONS

4.1 Use Statements

For In Vitro Diagnostic (IVD) Use Only.

For Professional Use Only.

4.2 Safety and Hazards

4.2.1 General Safety

Using this product in a manner not specified in the user documentation may result in personal injury or damage to the instrument or device. Ensure that anyone using this product has received instructions in general safety practices for laboratories and the safety information provided in this document.

4.2.2 Chemical Safety

To minimize hazards, ensure laboratory personnel read and practice the general safety guidelines for chemical usage, storage, and waste provided below, and consult the relevant SDS for specific precautions and instructions.

4.2.2.1 Biohazard

Follow all applicable local, state/provincial, and/or national regulations and standard precautions. All patient specimens should be considered potentially infectious and handled accordingly.

4.3 Waste Management

4.3.1 Medical Waste

Appropriate waste management and decontamination procedures should be used. Biological samples such as tissues, body fluids, infectious agents, and blood of humans and other animals have the potential to transmit infectious diseases. All medical wastes including the IVD, and its consumables used with it should be collected

in transportable and sealed biohazard bags/containers that are resistant to tear, puncture, breakage in accordance with the regulations on medical wastes. The contents of medical waste bags/containers should be never compressed, removed from the bag/container, emptied, and transferred to another container. Dispose of waste in a designated matter in accordance with local, regional, and federal regulations.

4.3.2. Molecular Waste

Nucleic acid contamination from molecular waste can be caused by dust and spreading aerosols. PCR products can be destroyed using a 3 % (mass fraction) hypochlorite solution (refer to ISO 22174:2005).

4.3.3. Chemical Waste

Characterize (by analysis if necessary) the waste generated by the applications, reagents, and substrates used in your laboratory.

Ensure use of primary and secondary waste containers (a primary waste container holds the immediate waste. A secondary container contains spills or leaks from the primary container. Both containers must be compatible with the waste material and meet federal, state, and local requirements for container storage).

After emptying a waste container, seal it with the cap provided.

Ensure that the waste is stored, transferred, transported, and disposed of according to all local, state/provincial, and/or national regulations.

IMPORTANT! Radioactive or biohazardous materials may require special handling, and disposal limitations may apply.

5 EXPLANATION OF SYMBOL

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
	European Conformity CE Mark		*In vitro* diagnostic *medical device*		Keep away from sunlight
	Manufacturer		Batch code		Protect from heat and radioactive sources
	Use-by date		Catalogue number		Do not use if package is damaged and consult *instructions for use*
	Temperature limit		Non-*sterile*		Keep dry
	Caution		Consult *instructions for use* or consult electronic *instructions for use*		
	Keep it upright		Do not re-use		

6 MANUFACTURER AND TECHNICAL SUPPORT

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Notice to User: Please inform us about product-related incidents at "**vigilance@bioeksen.com.tr**" within 24 hours.

For in vitro diagnostic use only.
For professional use only.
Cat No: BS-TF-T-25/BS-TF-T-100

Tropical Fever RT-qPCR Panel

Package Insert

Table 1. Kit Content

Component	Intended Use	25 Reactions	100 Reactions
2X Prime Script Mix	Optimized ready-to-use mix for RT-qPCR assay	2 x 1000 µL	7 x 1250 µL
TF Oligo Mix 1	Specific nucleic acid amplification and detection: **FAM:** Crimean-Congo Hemorrhagic Fever virus (CCHFV) **HEX:** Human (IC-Internal Control)	1 x 125 µL	1 x 500 µL
TF Oligo Mix 2	**FAM:** Dengue virus (DENV)	1 x 125 µL	1 x 500 µL
TF Oligo Mix 3	**FAM:** Ebola virus **ROX:** Hantavirus **CY5:** Mayaro Virus	1 x 125 µL	1 x 500 µL
TF Oligo Mix 4	**FAM:** Rift Valley virus **ROX:** *Trypanosoma cruzi* **CY5:** *Plasmodium* spp.	1 x 125 µL	1 x 500 µL
TF Oligo Mix 5	**FAM:** *Brucella* spp. **ROX:** *Coxiella burnetii* **CY5:** *Burkholderia pseudomallei*	1 x 125 µL	1 x 500 µL
TF Oligo Mix 6	**FAM:** *Salmonella* spp. **HEX:** *Rickettsia* spp. **ROX:** *Leptospira* spp. **CY5:** *Leishmania* spp.	1 x 125 µL	1 x 500 µL
TF Oligo Mix 7	**FAM:** West Nile Virus (WNV) **HEX:** Zika virus (ZIKV) **CY5:** *Streptococcus pneumoniae*	1 x 125 µL	1 x 500 µL
TF Oligo Mix 8	**FAM:** Yellow fever virus **ROX:** Chikungunya virus (CHIKV) **CY5:** Japanese Encephalitis (JE) virus	1 x 125 µL	1 x 500 µL
PC-TF 1 / PC-TF 2 / PC-TF 3 / PC-TF 4 PC-TF 5 / PC-TF 6 / PC-TF 7 / PC-TF 8	Positive Control (PC)	1 x 100 µL	1 x 250 µL
NTC	Negative Control	1 x 1000 µL	1 x 1000 µL

Table 2. Transport Condition, Storage Condition, and Shelf Life of the Components

Component	Transport Condition	Storage Condition*	Shelf Life
2X Prime Script Mix	(-22) – (+8) °C	(-22) – (-18) °C	12 Months
Oligo Mix		(-22) – (-18) °C	
PC		(+2) – (+8) °C	
NTC		(+2) – (+8) °C	

*Each reagent stored at storage temperature can be used until the expiration date indicated on the tube following the first opening. The kit's expiration date is determined by the expiration date of the reagents.

Table 3. Components Required but Not Included with The Test

Components Required but Not Included with The Test
1. Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS) or/and CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) Real-Time PCR systems
2. Micropipettes and compatible filtered pipette tips (nuclease-free) suitable for transferring 1-10, 10-100, and 100-1000 µL of liquid
3. A centrifuge or Mini-spin
4. Vortex
5. Reaction tubes and caps/films specific to RT-qPCR instruments and compatible with reaction volume

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Table 4. Intended Use, Test Principle, and Analytical Specifications

Function	Aid to diagnosis	**Sample Type(s)**	Table 5
Analyte(s)	Table 1	**Nucleic Acid Preparation Method(s)**	Table 5
Qualitative/Quantitative	Qualitative	**Validated PCR Instrument(s)**	Table 3
Test Principle	Reverse Transcription and Real-Time PCR (RT-qPCR)	**Inclusivity and Exclusivity**	Validated on the reference strains and the field isolates
Automated/Manual	Manual		
Intended Users	Professional use	**Limit of Detection (LoD)**	Table 5
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	98.55% and 99.21%

Table 5. Collection, Storage, and Transfer of Clinical Specimens / Nucleic Acid Preparation Methods and the Respected LoD Values

Sample Type**	Sample Transfer	Sample Storage	Nucleic Acid Preparation Method	LoD (cp/mL)
Whole blood, serum and plasma	EDTA-treated blood tube	3 days at (+2) – (+8) °C 1 year at -70 °C	***RINA™ M14 Nucleic Acid Extraction Device*** (Robot Catalog No: RINA-M14-01, Kit Cat. No: RN-NA-101) ***Zybio EXM3000 Nucleic Acid Isolation System*** (Robot Model No: EXM3000, Kit Cat. No: ZFNAE01)	500-1000
Urine	Preservative-free sterile tubes/containers			1000-2000

**Clinical specimens should be collected by a healthcare provider in accordance with national/international clinical specimen collection regulations.

1. RT-qPCR Application Protocol

Before starting the assay, please consider the following:

1. The kit was validated only for the template nucleic acid volume which is 25% of the total RT-qPCR volume.
2. The kit cannot be used with real-time PCR instruments without periodic maintenance records.
3. The kit for Bio-Rad Real-Time PCR systems has been validated with white reaction tubes specific to these systems. Clear reaction tubes result in 5-10 times lower fluorescence signal in Bio-Rad instruments compared to white reaction tubes. In addition, device-specific reaction tubes should be used in the BMS device. The kit's stated analytical performance can only be achieved using validated tubes.
4. To test for contamination, a negative control reaction containing NTC (Nuclease-free Water) must be set up in each run.

Program the qPCR device as follows and add the reagents into the qPCR tubes, close the tubes, place them into the qPCR instrument and start the run. (Table 6)

Table 6. RT-qPCR Program Details

Reaction Setup		**RT-qPCR Program** *CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) and Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)*				**QR Code for Thermal Protocol and Plate Setup**
Reagent	**Volume/Rxn**	**Step**	**Cycle No.**	**Temperature**	**Duration**	
2X Prime Script Mix	10 µL	**Reverse Trasncription**	1 Cycle	52 °C	3 min	
		Pre-Incubation	1 Cycle	95 °C	10 sec	
Oligo Mix	5 µL	**Denaturation**	12 Touchdown Cycles: 1 °C decrement in annealing temperature per cycle	95 °C	1 sec	
		Annealing and Extension		67 °C to 56 °C	15 sec	
Template Nucleic Acid/NTC/PC	5 µL	**Denaturation**	30 Cycles	95 °C	1 sec	
		Annealing and Extension		55 °C	15 sec	
Total Reaction Volume	**20 µL**	**Detection (Reading)**		(FAM-Green)/(HEX-Yellow) (ROX-Orange)/(CY5-Red)		https://www.bioeksen.com.tr/files/L_TD_43P

WARNING: The RT-qPCR thermal programs (Bio-Rad and BMS-Mic) and the plate setup (Bio-Rad) file should be downloaded from the QR code or link above.

2. Interpretation of the Assay Results

All default analysis options (e.g., auto-calculated threshold) in the PCR instrument software should not be changed to calculate Cq values.

The shape of the amplification curves should be examined for all reaction wells returning with Cq values. All the sigmoidal curves above the threshold should be recorded as "positive" and their Cq values should be recorded. Non-sigmoidal curves should be recorded as "negative".

Table 7. Expected Performance of Kit Controls

Control Type	**Purpose**	**Expected Results and Cq Values**	
		IC (HEX)	**Target**
Negative Control	Contamination control during RT-qPCR	**Not detected** (No Cq)	**Not detected** (No Cq)
Positive Control	Reagent integrity	**Detected** (Cq≤30)	**Detected** (Cq≤30)
Internal/Extraction Control	To monitor the integrity of nucleic acid extraction and RT-qPCR from each sample	**Detected** (Cq≤30) If the IC is "**Not detected**", check the target Cq.	If the target is "**Detected**" according to the result interpretation criteria, IC is valid.

If any control does not work as described above, the run is reported as follows:

1. **Contamination:** If Cq≤30 in any NTC test channel.
   Recommended action: Repeat the analysis paying attention to the "Warnings and Limitations" section.
2. **Reagent Problem**: In case a sigmoidal curve with a Cq≤30 cannot be obtained for any of all the samples tested in the run, including the controls.
   Recommended action: If all the tested samples show negative results for the target pathogens and controls, the run is considered invalid. In this scenario, it is essential to conduct testing on the "Positive Control(s)" included in the kit. A negative Positive Control test result suggests a potential "Reagent Problem." If encountered, please reach out to the manufacturer for further assistance.
3. **Invalid:** If the IC (Internal Control) and all other targets are "**Not detected**".
   Recommended action: Sampling isn't successfully done, or there is a problem during the sample transportation. A new sample from the same patient should be collected and tested again.

If all the controls are valid, the results are interpreted as follows:

Table 8. Interpretation of Patient Results

Target	Internal Control (IC)	Result Interpretation	
Positive (+)	**Positive (+)** or **Negative (-)**	Results are valid Target is detected	If 26<Cq ≤30 "Low Positive" If 16<Cq≤26 "Positive" If Cq≤16 "High Positive"
Negative (-)	**Positive (+)**	Results are valid Target is not detected	

The results generated by the qPCR instruments can be reported manually, as explained earlier, or automatically using the "**Sigmoida**" software. To obtain the "Sigmoida" software installer, please send an email to support@bioeksen.com.tr.

3. Warnings and Limitations

1. False-negative results may occur if inadequate numbers (lower than the LoD) of organisms are present in the specimen.
2. Mutations within the target regions could affect primer and/or probe binding, resulting in failure to detect the presence of agents.
3. A false-negative result may occur if a specimen is improperly collected, transported, or handled.
4. The clinical specimens shall be collected by a healthcare provider in accordance with the specimen collection guidelines.
5. Test procedures should be performed by personnel trained in the use of the kit.
6. Except for liquid transfers, sample tubes should always be kept closed.
7. Filtered and nuclease-free pipette tips should be used for sample transfer.
8. The components in the kit should not be used together with different lot numbers or chemicals of the same name but from different manufacturers.
9. ***The caps of the reaction tubes must not be opened after the PCR run.*** The PCR tubes should be placed in a bag and thrown away after the bag is tightly closed.
10. The surfaces of the workbenches should be wiped with freshly diluted 10% bleach (0.5% NaClO) at the beginning and end of each day.
11. Disposal of waste must be carried out in accordance with local, state, and federal regulations.

4. Explanation of Symbol

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
CE	European Conformity CE Mark	LOT	Batch code		Keep away from sunlight
IVD	*In vitro* diagnostic *medical device*	REF	Catalogue number		Protect from heat and radioactive sources
	Manufacturer	NON STERILE	Non-*sterile*		Do not use if package is damaged and consult *instructions for use*
	Use-by date		Consult *instructions for use* or consult electronic *instructions for use*		Keep dry
CONTROL -	Negative control		Caution		Keep upright
CONTROL +	Positive control		Temperature limit	Σ	Contains sufficient for <*n*> tests
CONTROL	Control				

5. Manufacturer and Technical Support

Bioeksen AR GE Teknolojileri A.Ş
Address: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul-TÜRKİYE
Phone: +90 (212) 285 10 17, **Fax:** +90 (212) 285 10 18
Web: www.bioeksen.com.tr, **e-mail:** info@bioeksen.com.tr,
Technical Support: support@bioeksen.com.tr

Notice to User: Please inform us about product-related incidents at "**vigilance@bioeksen.com.tr**" within 24 hours.

For in vitro diagnostic use only.
For professional use only.

Cat No: BS-NA-510-100/BS-NA-510-250/BS-NA-510-500/BS-NA-510-1000

vNAT® Viral Nucleic Acid Buffer

Package Insert

1. Product Content

Table 1: Product Content, Storage Requirements, and Shelf Life

Component	Amount				Transport Conditions	Storage Conditions	Shelf Life
vNAT® Viral Nucleic Acid Buffer	100 Test (1 X 10mL)	250 Test (1 X 25mL)	500 Test (1 X 50mL)	1000 Test (1 X 100mL)	2-50°C	15-30 °C	18 Months

2. Intended Use and Test Principle

The ***vNAT® Viral Nucleic Acid Buffer*** is a ***10x concentrated*** viral nucleic acid extractive and preservative liquid for nasopharyngeal swab, oropharyngeal swab, oral/saliva swab samples. The nucleic acid extractive and preservative liquid inactivates all viral, bacterial, or eukaryotic pathogens in the sample within 1 minutes after contact with the clinical specimen. The ***vNAT® Viral Nucleic Acid Buffer*** allows from sample to qPCR in a minute**.**

3. Analytical Specifications

vNAT® Viral Nucleic Acid Buffer is validated for detection kits produced by Bioeksen R&D Technologies Inc.

4. Sampling Protocol

Clinical samples are collected from individuals by a healthcare provider in accordance with the CDC Specimen Collection Guidelines: https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html.

5. Sample Transportation, Storage, and Application Protocol

The specimens in the ***vNAT® Viral Nucleic Acid Buffer*** can be stored at 2-8°C and ship to the laboratory on ice pack. If a specimen is frozen at -70°C or lower, ship overnight to the laboratory on dry ice. It is important that specimens are not exposed to continuous freeze-thaw exposure.

⚠ **WARNING:**

a) The VTM validated with the vNAT buffer is in accordance with the CDC directive and do not contain phenol-red (Preparation of viral transport medium, Centers for Disease Control and Prevention, SOP#: DSR-052-06).
b) The Amies medium should not contain charcoal.

Standard Protocol (Samples in VTM/Saline/Amies)

1. Vortex the sample tube at the highest speed for 3 seconds.
2. Transfer 100 µl of the ***vNAT® Viral Nucleic Acid Buffer*** into a clean tube.
3. Add 900 µL of the sample to the tube containing 100 µL ***vNAT® Viral Nucleic Acid Buffer***.
4. Mix the sample and the ***vNAT® Viral Nucleic Acid Buffer*** well by vortexing/shaking/pipetting.
5. Incubate the tube for 1 minute at room temperature.
6. 1000 µl mixture is ready to use in PCR reaction.

Protocol for Dry Swab Samples

1. Transfer the swab sample into a tube containing 100 µl ***vNAT® Viral Nucleic Acid Buffer*** + 900 µl nuclease-free water.
2. Apply the steps 1-6 of the "**Standard Protocol**".

6. Explanation of Symbol

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
CE	European Conformity CE Mark	LOT	Batch code		Keep away from sunlight
IVD	*In vitro* diagnostic *medical device*	REF	Catalogue number		Protect from heat and radioactive sources
	Manufacturer	NON STERILE	Non-*sterile*		Keep dry
	Use-by date		Consult *instructions for use* or consult electronic *instructions for use*		Keep it upright
	Temperature limit	Σ	Contains sufficient for <*n*> tests		Caution

7. Manufacturer and Technical Support

Bioeksen R&D Technologies Incorporated Company
Address: Resitpasa Mh. Katar Cd., 4/B-105. 34467, Sariyer, Istanbul, TURKEY.
Phone: +90 (212) 285 10 17, **Fax:** +90 (212) 285 10 18
Web: www.bioeksen.com.tr, **e-mail:** info@bioeksen.com.tr,
Technical Support: support@bioeksen.com.tr

Notice to User: Please inform us about product-related incidents at "**vigilance@bioeksen.com.tr**" within 24 hours.

www.dialab.at

STATEMENT

We, **DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.**, having a registered office at **IZ-NOE Sued Hondastrasse, Objekt M55, A-2351 Wr. Neudorf, AUSTRIA** assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 98/79/EEC. We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova. This declaration will stay in force for 2 years or if one of the parties is deciding to cancel it with a one-month notice.

Date :05.04.2023
Signature:

DIALAB
Produktion und Vertrieb von chemisch - technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
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E-Mail: office@dialab.at Website: www.dialab.at

Christina Ernst
Export Manager

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 026709 0009 Rev. 01

Holder of Certificate:

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued
Hondastrasse, Objekt M55
2351 Wr. Neudorf
AUSTRIA

Certification Mark:

Scope of Certificate:

Design, development, production and distribution of in-vitro diagnostic reagents and testkits in the areas of immunological detection of infectious diseases, immunochemistry/immunology/clinical chemistry biomarkers (analytes: enzymes, substrates, electrolytes reagents; controls/standards/calibrators), urinalysis, haematology, haemostasis and immunohaematology (blood grouping).
Distribution of in-vitro diagnostic instruments including accessories for immunology, clinical chemistry, haematology, haemostasis and urinalysis.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 026709 0009 Rev. 01

Report No.: 713237224

Valid from: 2022-03-29
Valid until: 2025-03-28

Date, 2022-03-17

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 026709 0009 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55, 2351 Wr. Neudorf, AUSTRIA

See Scope of Certificate

Parameters: ./.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

EC DECLARATION OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG

www.dialab.at

Dialab Produktion und Vertrieb von
chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55, A-2351 Wiener Neudorf

REF	Product Name / Produktname	Content / Inhalt
Z04380	HIV 1&2 Ag/Ab	*96 wells*
Z13382	HIV 1&2 Ag/Ab	*5x 96 wells*

Lot Numbers / Lotnummern: *HS20220401, HS20221001*

Notified Body / Benannte Stelle:
bqs. s.r.o., NB no. 2854, Študentská 1641/12, 911 01 Trenčín, Slovakia

No. CE Certificate / Nr. CE-Zertifikat: IVDD 22 003 0135, IVDD 22 003 0136

We declare, on our own responsibility, that our above-mentioned product classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC: **Devices of List A, Annex II**

meets the applicable provisions of the EU Directive 98/79/EC for in-vitro-diagnostic medical devices and the Austrian Medical Product Law.

The following (harmonized) standards have been applied: EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1: 2016, EN 13612: 2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2019, EN ISO 13485:2016 and CTS.

The product is in compliance with common technical specifications as they are defined within Commission Decision (2009/886/EC) of 27 November 2009 amending Decision 002/364/EC on common technical specifications for in vitro diagnostic medical devices.

This Declaration is based on approval according to Annex IV of the aforesaid Directive in cooperation with above mentioned notified body

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available.

This Declaration is valid until 2025-03-28.

Hiermit erklären wir, auf eigene Verantwortung, dass unser oben genanntes Produkt, gemäß der Richtlinie 98/79/EG über In-vitro-Diagnostika klassifiziert als: **Produkte der Liste A, Anhang II**

die anwendbaren Vorschriften der EU-Richtlinie 98/79/EG über in-Vitro-Diagnostika und des Österreichischen Medizinproduktegesetzes erfüllt.

Die folgenden (harmonisierten) Standards wurden angewandt: EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1: 2016, EN 13612: 2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 14971:2019, EN ISO 13485:2016 und CTS.

Das Produkt entspricht den Gemeinsamen Technischen Spezifikationen wie diese in der Entscheidung der Kommission vom 27. November 2009 (2009/886/EG) zur Änderung der Entscheidung 2002/364/EG über Gemeinsame Technische Spezifikationen für In-vitro-Diagnostika definiert sind.

Diese Erklärung basiert auf Freigabe gemäß Anhang IV der oben angeführten Richtlinie in Zusammenarbeit mit oben genannter Benannter Stelle.

Die Technische Dokumentation zum Nachweis der Konformität wird vom Hersteller aufbewahrt und kann zur Verfügung gestellt werden.

Diese Erklärung ist bis zum 2025-03-28 gültig.

DIALAB
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...odukten und Laborinstrumenten Gesellschaft m.b.H.
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Wiener Neudorf, 2023-01-30

Heidi Kroiß
Qualitätsmanagementbeauftragte
Quality Management Representative

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
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HIV 1&2 Ag/Ab

(en) English

REF

Content

Z04380

-1 Microwell plate: 96 wells (12 x 8-well antigen and antibody coated strips, individual breakaway)
-1x 1 mL Antibody Positive Control I (HIV 1)
-1x 1 mL Antibody Positive Control II (HIV 2)
-1x 1 mL Antigen Positive Control
-1x 1 mL Negative Control
-1x 12 mL Enzyme Conjugate
-1x 3 mL Biotin Conjugate
-1x 6 mL Substrate Solution A
-1x 6 mL Substrate Solution B
-1x 6 mL Stop Solution
-1x 50 mL Wash Buffer
-3 Cardboard Plate Covers
-1 Plastic Bag
-1 Package Insert
-1 Certificate of Analysis

96

Z13382

-5 Microwell plates: 96 wells (12 x 8-well antigen and antibody coated strips, individual breakaway)
-3x 1 mL Antibody Positive Control I (HIV 1)
-3x 1 mL Antibody Positive Control II (HIV 2)
-3x 1 mL Antigen Positive Control
-3x 1 mL Negative Control
-5x 12 mL Enzyme Conjugate
-5x 3 mL Biotin Conjugate
-1x 60 mL Substrate Solution A
-1x 60 mL Substrate Solution B
-1x 60 mL Stop Solution
-2x 125 mL Wash Buffer
-15 Cardboard Plate Covers
-5 Plastic Bags
-1 Package Insert
-1 Certificate of Analysis

480

For professional in vitro diagnostic use only.

INTENDED USE

HIV 1&2 Ag/Ab is an enzyme-linked immunosorbent assay (ELISA) intended for the qualitative detection of antigens and/or antibodies to Human Immunodeficiency Viruses (HIV) type 1 (group M - O) and/or type 2 in human serum or plasma samples. The method is also known as 4th generation ELISA for HIV detection. The kit is intended for screening of blood donors and as an aid in the diagnosis of clinical conditions related to infection with HIV-1 and/or HIV-2 – the etiological agents of the acquired immunodeficiency syndrome (AIDS).

DIAGNOSTIC SIGNIFICANCE

The human immunodeficiency viruses type 1 and type 2 are the etiological agents of the acquired immunodeficiency syndrome (AIDS). HIV has been isolated from patients with AIDS, AIDS related complex (ARC) and from healthy individuals at high risk for AIDS. Infection with HIV is followed by an acute flu-like illness. This phase may remain unnoticed and the relationship to HIV infection may not be clear in many cases. The acute phase is typically followed by an asymptomatic carrier state, which progresses to clinical AIDS in about 50% of infected individuals within 10 years after seroconversion. Serological evidence of infection with HIV may be obtained by testing for presence of HIV antigens or antibodies in serum of individuals suspected for HIV infection. Antigens can generally be detected during both acute phase and the symptomatic phase of AIDS only. The Antibodies to HIV-1 and/or HIV-2 can be detected throughout virtually the whole infection period, starting at, or shortly after the acute phase and lasting till the end stage of AIDS. Apart from sexual transmission, the principal route of infection with HIV is blood transfusion. HIV can present both in cellular and cell-free fractions of human blood. Therefore, all donations of blood or plasma should be tested due to the risk of HIV transmission through contaminated blood.
The ELISA tests for detection of HIV infection are characterized with high sensitivity, specificity and simple operation procedure. There are most appropriate for testing of large numbers of specimens and currently, internationally available are hundreds of HIV tests used in routine blood screening or clinical diagnosis. Since the first HIV ELISA

tests were commercially introduced in 1985, four generations have been developed. The 1st generation tests were based on viral lysate antigens derived from viruses that are grown in human T-lymphocyte lines. The presence of traces of host cell components in which the virions have been propagated could lead to cross-contamination and thus to very high rates of false-positive results. With the cloning of the HIV genome, improved assays based on recombinant proteins and/or synthetic peptides (known as 2nd generation), became rapidly available. The utilization of biotechnology methods allow predominantly expression of the important immunoreactive regions of the proteins and also enabled the production of combined HIV-1/HIV-2 assays. The recombinant antigen could also be produced with considerably more purity and in large amounts, and they can be bond to solid-phase surface with much tighter control over protein ratios and concentrations. The first and second generations HIV kits were based on indirect ELISA method and could detect IgG antibodies only by enzyme-labeled anti-human IgG antibody. The 3rd generation ELISA utilized double antigen "sandwich" method: again with antigens coated on solid phase polystyrene plates, but with antibodies detection achieved with the help of another enzyme-labeled antigen. The 3rd generation assays could detect all antibodies in specimen (IgG, IgM, etc.) which significantly increases the assay's sensitivity comparing to the previous generations. In addition, the detection of IgM antibodies that are present only during the early stages of infection, much shortens the antibody detection "window" period (the period of time in which there is no detectable antibody production), and compare to the second generation, "sandwich" tests could detect antibodies 11 days earlier. To reduce even further the antibody detection "window" period, 4th generation HIV ELISAs that could simultaneously detect HIV antigens (p24) and antibodies have been developed and are commercially available since 1998. With detection of p24, the 4th generation tests shorten the "window" period to 16 days, or compare to the 3rd generation, HIV infection could be detected 8 days earlier.

TEST PRINCIPLE

DIALAB HIV 1&2 Ag/Ab ELSIA test is a two-step incubation, "sandwich" enzyme immunoassay kit, which uses polystyrene microwell strips pre-coated with recombinant HIV antigens (recombinant HIV-1 gp41, gp120, and recombinant HIV-2 gp36) and anti-HIV (p24) antibodies. As a first step, biotinylated anti-HIV (p24) antibodies together with the patient's serum or plasma specimen are added into the wells. During incubation, the specific HIV-1/2 antibodies if present in specimen, will be captured inside the wells. Simultaneously, if HIV p24 antigen is present in specimen, it will also be captured as a double antibody "sandwich" complex comprising of the coated antibodies-p24-biotinylated antibodies. The microwells are then washed to remove unbound serum proteins. The detection of the captured HIV p24 antigen-biotinylated antibody complex or HIV-1/2 antibodies is achieved during the second incubation step by adding of the enzyme Horseradish Peroxidase (HRP) which has been conjugated to second HIV 1+2 recombinant antigens and to avidin.

p24 detection: When p24 has been captured inside the wells, avidin will react with the biotin and attach HRP to the Ab-p24-Ab complex.

HIV 1&2 antibody detection: When HIV-1/2 antibodies have been captured inside the wells, the HRP-conjugated antigens will bind to the captured antibodies forming Ag-Ab-Ag (HRP) "sandwich" immunocomplex. The microwells are washed to remove unbound conjugate, and Chromogen solutions are added to the wells. In wells containing the Ag-Ab-Ag (HRP) and/or Ab-p24-Ab (HRP) "sandwich" immunocomplexes, the colorless Chromogens are hydrolyzed by the bound HRP to a blue colored product. The blue color turns yellow after stopping the reaction with sulfuric acid. The amount of color intensity can be measured and is proportional to the amount of antibodies or p24 captured in the wells, and to the specimen respectively. Wells containing specimens negative for anti-HIV-1/2 or p24 remain colorless.

REAGENT COMPOSITION

Component	Description
Microwell plate	Blank microwell strips fixed on white strip holder. The plate is sealed in aluminum pouch with desiccant. Each well contains recombinant HIV 1/2 antigens and anti-p24 antibodies. The microwell strips can be broken to be used separately. Place unused strips in the provided plastic storage bag together with the desiccant and return to 2-8°C. Once opened, the plate strips are stable for 4 weeks when stored at 2-8°C together with the desiccant. The microwell strips are for SINGLE USE only. Do not use if the vacuum sealing has been damaged when first time taken of out the box.
Antibody Positive Control I (HIV 1)	Red-colored liquid filled in a vial with red screw cap. Preservative: 0.1 % ProClin™ 300. Protein-stabilized buffer solution tested positive for antibodies to HIV-1. Ready to use as supplied. Once opened, stable for 4 weeks at 2-8°C.
Antibody Positive Control II (HIV 2)	Red-colored liquid filled in a vial with yellow screw cap. Preservative: 0.1 % ProClin™ 300. Protein-stabilized buffer solution tested positive for antibodies to HIV-2. Ready to use as supplied. Once opened, stable for 4 weeks at 2-8°C.
Antigen Positive Control	Red-colored liquid filled in a vial with blue screw cap. Preservative: 0.1 % ProClin™ 300. Protein-stabilized buffer solution tested positive for HIV p24 recombinant antigen. Ready to use as supplied. Once opened, stable for 4 weeks at 2-8°C.

Negative Control	Yellow-colored liquid filled in a vial with green screw cap. Preservative: 0.1 % ProClin™ 300.Protein-stabilized buffer tested non-reactive for HBsAg and antibodies to HIV 1/2, HCV, TP. Ready to use as supplied. Once opened, stable for 4 weeks at 2-8°C.
Enzyme Conjugate	Red-colored liquid in a white vial with red screw cap. Preservative: 0.1 % ProClin™ 300. Horseradish peroxidase-conjugated recombinant HIV 1+2 antigens. Horseradish peroxidase conjugated avidin. Ready to use as supplied. Once opened, stable for 4 weeks at 2-8°C.
Biotin Conjugate	Blue-colored liquid in a white vial with blue screw cap. Preservative: 0.1 % ProClin™ 300. Biotinylated anti-HIV p24 antibodies diluted in protein-stabilized buffer. Ready to use as supplied. Once opened, stable for 4 weeks at 2-8°C.
Substrate Solution A	Colorless liquid filled in a white vial with green screw cap. Urea peroxide solution. Ready to use as supplied. Once opened, stable for 4 weeks at 2-8°C.
Substrate Solution B	Colorless liquid filled in a black vial with black screw cap. TMB (Tetramethyl benzidine), N,N-dimethylformamide. Ready to use as supplied. Once opened, stable for 4 weeks at 2-8°C.
Stop Solution	Colorless liquid in a white vial with yellow screw cap. Diluted sulfuric acid solution (0.5M H_2SO_4). Ready to use as supplied. Once opened, stable for 4 weeks at 2-8°C.
Wash Buffer	Colorless liquid filled in a clear bottle with white screw cap. Detergent: Tween-20. Buffer solution containing surfactant. The concentrate must be diluted 1 to 20 with distilled/ deionized water before use. Once diluted, stable for 1 week at room temperature, or for 2 weeks when stored at 2-8°C.

MATERIAL REQUIRED BUT NOT PROVIDED

- Freshly distilled or deionized water
- Disposable gloves and timer
- Appropriate waste containers for potentially contaminated materials
- Dispensing system and/or pipette (single or multichannel), disposable pipette tips
- Absorbent tissue or clean towel
- Dry incubator or water bath, 37±1°C
- Plate reader, single wavelength 450 nm or dual wavelength 450 nm and 600-650 nm
- Microwell aspiration/wash system

--- Microplate reader and microplate washers are available from Dialab. ---

REAGENT PREPARATION

Allow the reagents and samples to reach room temperature **(18-30°C)**. Check the Wash buffer concentrate for the presence of salt crystals. If crystals have formed, resolubilize by warming at 37°C until crystals dissolve. Dilute the Wash Buffer 1:20 with distilled or deionized water. Use only clean vessels to dilute the buffer. All other reagents are **ready to use as supplied**.

STORAGE AND STABILITY

The components of the kit will remain stable through the expiration date indicated on the label and package when stored between 2-8°C, do not freeze. To assure maximum performance of HIV 1&2 Ag/Ab ELISA during storage, protect the reagents from contamination with microorganisms or chemicals.

WARNINGS AND PRECAUTIONS

Warning

ProClin™ 300

H317: May cause an allergic skin reaction.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
P363: Wash contaminated clothing before reuse.

Danger

N,N-dimethylformamide:

H360D:	May damage the unborn child.
P201:	Obtain special instructions before use.
P280:	Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313:	IF exposed or concerned: Get medical advice/attention.

This kit is intended **FOR PROFESSIONAL IN VITRO USE ONLY**

The ELISA assay is time and temperature sensitive. To avoid incorrect result, strictly follow the test procedure steps and do not modify them.

- Do not exchange reagents from different lots or use reagents from other commercially available kits. The components of the kit are precisely matched for optimal performance of the tests.
- Make sure all the reagents are within the validity indicated on the kit box and of the same lot. Never use reagents beyond their expiry date stated on labels or boxes.
- **CAUTION - CRITICAL STEP:** Allow the reagents and samples to stabilize at room temperature (18-30°C) before use. Shake reagent gently before, and return to 2-8°C immediately after use.
- Use only sufficient volume of sample as indicated in the procedure steps. Failure to do so may cause in low sensitivity of the assay.
- Do not touch the bottom exterior of the wells; fingerprints or scratches may interfere with microwell reading. When reading the results, ensure that the plate bottom is dry and there are no air-bubbles inside the wells.
- Never allow the microplate wells to dry after the washing step. Immediately proceed to the next step. Avoid the formation of air-bubbles when adding the reagents.
- Avoid assay steps long time interruptions. Assure same working conditions for all wells.
- Calibrate the pipette frequently to assure the accuracy of samples/reagents dispensing. Use different disposal pipette tips for each specimen and reagents as to avoid cross-contaminations.
- Assure that the incubation temperature is 37°C inside the incubator.
- When adding samples, avoid touching the well's bottom with the pipette tip.
- When measuring with a plate reader, it is required to determine the absorbance at 450 nm or at 450/600-650 nm.
- The enzymatic activity of the HRP-conjugate might be affected from dust and reactive chemical and substances like sodium hypochlorite, acids, alkalis etc. Do not perform the assay in the presence of these substances.
- If using fully automated equipment, during incubation, do not cover the plates with the plate cover. The tapping out of the remainders inside the plate after washing can also be omitted.
- All specimens from human origin should be considered as potentially infectious. Strict adherence to GLP (Good Laboratory Practices) can ensure the personal safety.
- **WARNING:** Materials from human origin may have been used in the preparation of the Negative Control of the kit. These materials have been tested with test kits with accepted performance and found negative for antibodies to HIV 1&2, HCV, TP and HBsAg. However, there is no analytical method that can assure that infectious agents in the specimens or reagents are completely absent. Therefore, handle reagents and specimens with extreme caution as if capable of transmitting infectious diseases. Bovine derived sera have been used for stabilizing of the positive and negative controls. Bovine serum albumin (BSA) and fetal calf sera (FCS) are derived from animals from BSE/TSE-free geographical areas.
- Never eat, drink, smoke or apply cosmetics in the assay laboratory. Never pipette solutions by mouth.
- Chemicals should be handled and disposed of only in accordance with the current GLP (Good Laboratory Practices) and the local or national regulations.
- The pipette tips, vials, strips and sample containers should be collected and autoclaved for not less than two hours at 121°C or treated with 10% sodium hypochlorite for 30 minutes to decontaminate before any further steps for disposal. Solutions containing sodium hypochlorite should NEVER be autoclaved. Material Safety Data Sheet (MSDS) available upon request.
- Some reagents may cause toxicity, irritation, burns or have carcinogenic effect as raw materials. Contact with the skin and the mucosa should be avoided but not limited to the following reagents: Stop Solution, Substrate Solutions and the Wash Buffer.
- The Stop solution (0.5M H_2SO_4) is an acid. Use it with appropriate care. Wipe up spills immediately or wash with water if come into contact with the skin or eyes.
- ProClin™ 300 0.1% used as a preservative can cause sensation of the skin. Wipe up spills immediately or wash with water if come into contact with the skin or eyes.

Indication of instability and deterioration of the reagent:
Before use, please check the vials for presence of turbidity and/or particles. If present, this is indication of possible microbial contamination and the reagents should not be used. Values of the Positive or Negative Controls, which are out of the indicated quality control range, are indicators of possible deterioration of the reagents and/or operator or equipment errors. In such case, the results should be considered as invalid and the specimens must be retested. In case of constant erroneous results and proven deterioration or instability of the reagents, immediately substitute the reagents with new one or contact Dialab's technical support for further assistance.

SPECIMEN COLLECTION AND STORAGE

- **Sample Collection**: No special patient's preparation required. Collect the specimen in accordance with the normal laboratory practice. Either fresh serum or plasma specimens can be used with this assay. Blood collected by venipuncture should be allowed to clot naturally and completely – the serum/plasma must be separated from the clot as early as possible as to avoid haemolysis of the RBC. Care should be taken to ensure that the serum specimens are clear and not contaminated by microorganisms. Any visible particulate matters in the specimen should be removed by centrifugation at 3000 RPM (round per minutes) for 20 minutes at room temperature or by filtration.
- Plasma specimens collected into EDTA, sodium citrate or heparin can be tested, but **highly lipaemic, icteric or hemolytic specimens** should not be used as they can give false results in the assay. Do not heat inactivate specimens. This can cause deterioration of the target analyte. Specimens with visible microbial contamination should never be used.
- Dialab HIV 1&2 Ag/Ab ELISA test is intended **ONLY** for testing of individual serum or plasma specimens. Do not use the assay for testing of cadaver specimens, saliva, urine or other body fluids or pooled (mixed) blood.
- **Transportation and Storage:** Store samples at 2-8°C. Samples not required for assaying within 1 week should be stored frozen (-20°C or lower). Multiple freeze-thaw cycles should be avoided. For shipment, samples should be packaged and labeled in accordance with the existing local and international regulations for transport of clinical samples and ethological agents.

TEST PROCEDURE

Step 1 **Preparation:** Mark three wells as Negative control (e.g. B1, C1, D1), three wells as Positive control (e.g. E1 for HIV-1, F1 for HIV-2 and G1 for HIV-Ag) and one Blank (e.g. A1, neither specimens nor Conjugate should be added into the Blank well). If the results will be determined by using dual wavelength plate reader, the requirement for use of Blank well could be omitted. Use only number of strips required for the test.

Step 2 **Adding Biotin Conjugate:** Add **20 µL** of Biotin Conjugate into each well except in the Blank.

Step 3 **Adding Samples:** Add **100 µL** of Positive Controls, Negative Control and Samples into their respective wells, mix gently. **Note: Use a separate disposal pipette tip for each specimen, Negative Control, Positive Control to avoid cross-contamination.**

Step 4 **Incubating:** Cover the plate with the plate cover and incubate for **60 minutes at 37°C**

Step 5 **Washing:** At the end of the incubation, remove and discard the plate cover. Wash each well **5 times** with diluted Wash buffer. Each time, allow the microwells to soak for 30-60 seconds. After the final washing cycle, turn the plate down onto blotting paper or clean towel, and tap it as to remove any remaining liquids.

Step 6 **Adding Enzyme Conjugate:** Add **100 µL** Enzyme Conjugate into each well except in the Blank.

Step 7 **Incubating:** Cover the plate with the plate cover and incubate for **30 minutes** at **37°C**.

Step 8 **Washing:** At the end of the incubation, remove and discard the plate cover. Wash each well 5 times with diluted Wash buffer. Each time, allow the microwells to soak for 30-60 seconds. After the final washing cycle, turn the plate down onto blotting paper or clean towel, and tap it as to remove any remaining liquids.

Step 9 **Coloring:** Add **50 µL** of Substrate Solution A and then **50 µL** of Substrate Solution B into each well including the Blank, mix gently. Incubate the plate at **37°C for 30 minutes avoiding light**. The enzymatic reaction between the Substrate Solutions and the Enzyme Conjugate produces blue color in Positive Controls and HIV 1/2 positive for antigens/antibodies sample wells.

Step 10 **Stopping Reaction:** Using a multichannel pipette or manually, add **50 µL** of Stop Solution into each well and mix gently. Intensive yellow color develops in Positive control and HIV 1/2 positive for antigens / antibodies specimen wells.

Step 11 **Measuring the Absorbance:** Calibrate the plate reader with the Blank well and read the absorbance at **450 nm**. If a dual filter instrument is used, set the reference wavelength at **600-650 nm**. Calculate the Cut-off value and evaluate the results.

Note: read the absorbance within 10 minutes after stopping the reaction.

Instructions for Washing:

- A good washing procedure is essential in order to obtain correct and precise analytical data.

- It is therefore, recommended to use a good quality ELISA microplate washer, maintained at the best level of washing performances. In general, no less than **5 automatic washing cycles** of **350-400 µl/well** are sufficient to avoid false positive reactions and high background.
- To avoid cross-contaminations of the plate with specimen or HRP-conjugate, after incubation do not discard the content of the wells but allow the plate washer to aspirate it automatically.
- Assure that the microplate washer liquid dispensing channels are not blocked or contaminated and sufficient volume of Wash buffer is dispensed each time into the wells.
- In case of manual washing, we suggest to carry out **5 washing cycles**, dispensing **350-400 µl/well** and aspirating the liquid for **5 times.** If poor results (high background) are observed, increase the washing cycles or soaking time per well.
- In any case, the liquid aspirated out the strips should be treated with a sodium hypochlorite solution (final concentration of 2.5%) for 24 hours, before liquids are disposed in an appropriate way.
- The concentrated Wash buffer should be diluted **1:20** before use. If less than a whole plate is used, prepare the proportional volume of solution.

INTERPRETATION OF RESULTS

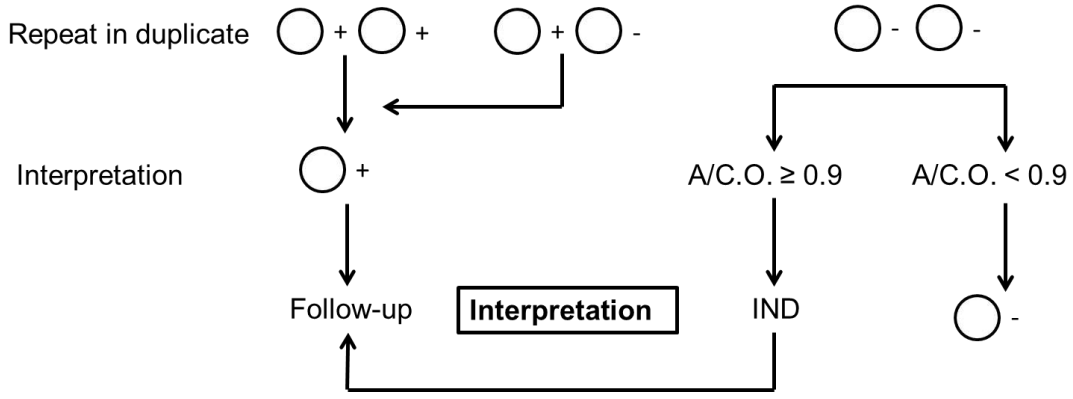
Negative Results (OD/C.O.<1): Samples giving absorbance less than the Cut-off value are negative for this assay, which indicates that no HIV 1&2 antibodies or p24 antigen have been detected with the Dialab HIV 1&2 Ag/Ab ELISA kit, therefore the patient is probably not infected or the blood unit do not contain antibodies to HIV 1&2 or p24 antigen and could be transfused in case that other infectious diseases markers are also absent.

Positive Results (OD/C.O.≥1): Samples giving an absorbance equal to or greater than the Cut-off value are considered initially reactive, which indicates that HIV 1&2 antibodies and/or p24 antigen have probably been detected using Dialab HIV 1&2 Ag/Ab ELISA kit. All initially reactive specimens should be retested in duplicate using Dialab HIV 1&2 Ag/Ab ELISA kit before the final assay results interpretation. Repeatedly reactive specimens can be considered positive for antibodies to HIV 1/2 and/or p24 antigen with Dialab HIV 1&2 Ag/Ab ELISA kit.

Borderline (OD/C.O.=0.9-1.1): Samples with absorbance to Cut-off ratio between 0.9 and 1.1 are considered borderline and retesting of these samples in duplicates is recommended to confirm the results.

Follow-up, confirmation and supplementary testing of any positive specimen with other analytical system (e.g. WB, PCR) is required. Clinical diagnosis should not be established based on a single test result. It should integrate clinical and other laboratory data and findings.

Initial result interpretation and follow up:



IND = non interpretable

- If, after retesting of the initially reactive samples, both wells are negative results (OD/CO<0.9), these samples should be considered as non-repeatable positive (or, false positive) and recorded as negative. As with many very sensitive ELISA assays, false positive results can occur due to the several reasons, most of which are connected with, but not limited to, inadequate washing step.
- If, after retesting in duplicates, one or both wells are positive results, the final result from this ELISA test should be recorded as repeatedly reactive. Repeatedly reactive specimens can be considered positive for antibodies to HIV 1&2 and/or p24 antigen and therefore the patient is probably infected with HIV 1&2 and the blood unit must be discarded.
- After retesting in duplicates, samples with values close to the Cut-off value should be interpreted with caution and considered as "borderline" zone sample or uninterpretable for the time of testing.

QUALITY CONTROL AND CALIBRATION

Each microplate must be considered separately when calculating and interpreting results of the assay, regardless of the number of plates concurrently processed. The results are calculated by relating each sample optical density (OD) value to the Cut-off value (C.O.) of the plate. If the Cut-off reading is based on single filter plate reader, the results

must be calculated by subtracting the Blank well OD value from the print report values of samples and controls. In case the reading is based on dual filter plate reader, do not subtract the Blank well OD value from the print report values of specimens and controls

Calculation of Cut-off value: (C.O.) = *Nc + 0.12

***Nc =** the mean absorbance value for three negative controls

Quality control (assay validation): The test results are valid if the Quality Control criteria are verified. It is recommended that each laboratory must establish appropriate quality control system with quality control material similar to, or identical with the patient sample being analyzed.

Quality control criteria:

1. The OD value of the Blank well, which contains only Substrate and Stop Solution, must be < 0.080 at 450 nm.

2. The OD value of the Positive Controls must be ≥ 0.800 at 450/600-650 nm or at 450 nm after blanking.

3. The OD value of the Negative Control must be ≤ 0.100 at 450/600-650 nm or at 450nm after blanking.

If one of the Negative Control OD values does not meet the Quality Control criteria, it should be discarded and the mean value calculated again using the remaining two values. If more than one Negative Control OD values do not meet the Quality Control Range specifications, the test is invalid and must be repeated.

Example:

1. Quality Control
Blank well A value: A1= 0.025 at 450nm (Note: blanking is required only when reading with single filter at 450nm)

Well No.:	**B1**	**C1**	**D1**
Negative Control OD values after blanking:	0.020	0.012	0.016
Well No.:	**E1**	**F1**	**G1**
Positive Control OD values after blanking:	2.421	2.369	2.893

All control values are within the stated quality control range
2. Calculation of Nc: = (0.020 + 0.012 + 0.016)/3 = 0.016
3. Calculation of the Cut-off: (C.O.) = 0.016 + 0.12 = 0.136

PERFORMANCE CHARACTERISTICS

The analytical and clinical performance characteristics of Dialab HIV 1&2 Ag/Ab ELISA kit were evaluated by two external evaluation centres.

Diagnostic sensitivity:

100% (500/500 positive samples) tested on 310 anti-HIV-1, 100 anti-HIV-2 and 40 anti-HIV-1 non B subtypes (A, C, D, F, G, H, J, K, O, CRF01_AE and other circulating recombinant forms) serum/plasma samples and 50 anti-HIV-Ab / HIV-1 Ag positive samples.

The kit represents state of the art on 20 seroconversion panels:

- On the 38 (of a total of 68) early seroconversion samples that were positive on one or more HIV Ag/Ab tests, the Dialab HIV 1&2 Ag/Ab ELISA kit detected 34 samples
- All seroconversion HIV samples were positive on the Dialab HIV 1&2 Ag/Ab ELISA kit

Same day samples: no complement interference was observed on 25 same day fresh samples spiked with a small amount of an HIV Ag/Ab positive sample.

Diagnostic specificity: 99.96% tested on 5004 negative plasma samples of blood donors – based on the results after repeat testing of initially reactive samples.

Analytical specificity: 200/200 hospitalized patients were negative on the Dialab HIV 1&2 Ag/Ab ELISA kit. 95/101 samples containing potentially cross reactive substances, including samples from pregnant women, were negative on the Dialab HIV 1&2 Ag/Ab ELISA kit. Serum to plasma equivalence is demonstrated on 25 positive and 25 negative serum / EDTA plasma / heparin plasma / sodium citrate plasma couples.

p24 antigen analytical sensitivity: 1.25 U/mL

TRACEABILITY

HIV p24 antigen international reference standard (WHO 90/636) was used as a reference for the Dialab HIV 1&2 Ag/Ab ELISA.

EXPECTED VALUES

Dialab HIV 1&2 Ag/Ab is a qualitative assay and cannot be used to measure the antigen concentration, therefore the concept of expected values is not applicable. Example values for absorbance can be found in the chapter QUALITY CONTROL AND CALIBRATION.

LIMITATIONS

- Positive results must be confirmed with another available method and interpreted in conjunction with the patient clinical information.
- Antibodies or p24 antigen may be undetectable during the early stage of the disease and in some immunosuppressed individuals. Therefore, negative results obtained Dialab HIV 1&2 Ag/Ab ELISA kit are only indication that the specimen does not contain detectable level of HIV1/2 antibodies or p24 antigen and any negative result should not be considered as conclusive evidence that the individual is not infected with HIV 1/2 or the blood unit is not infected with HIV 1/2.
- If, after retesting of the initially reactive specimens, the assay results are negative, these specimens should be considered as non-repeatable (false positive) and interpreted as negative. As with many very sensitive ELISA assays, false positive results can occur due to the several reasons, most of which are related but not limited to inadequate washing step.
- The most common assay mistakes are: using kits beyond the expiry date, bad washing procedures, contaminated reagents, incorrect assay procedure steps, insufficient aspiration during washing, failure to add specimens or reagents, improper operation with the laboratory equipment, timing errors, the use of highly hemolyzed specimens or specimens containing fibrin, incompletely clotted serum specimens.
- The prevalence of the marker will affect the assay's predictive values.
- This assay cannot be utilized to test pooled (mixed) serum or plasma. Dialab HIV 1&2 Ag/Ab ELISA kit has been evaluated only with individual serum or plasma specimens.
- Dialab HIV 1&2 Ag/Ab ELISA kit is a qualitative assay and the results cannot be used to measure antibody or antigen concentration. This assay cannot distinguish infections with HIV-1 and HIV-2. This assay cannot distinguish antibody and p24 antigen positive results.

WASTE MANAGEMENT

Reagents must be disposed of in accordance with local regulations.

LITERATURE

1. Barbe, F. et al., (1994) Early detection of anti bodies to HIV-1 by a third generation enzyme immunoassay. Ann. Biol. Clin. (Paris), 52: 341-345.
2. Barre-Sinoussi, F. et al., (1984) Isolation of a T-lymphotropic retrovirus from a patient at risk for acquired immunodeficiency syndrome (AIDS), Science, 220: 868-871.
3. Clave, F. et al. (1991) Solution conformation preferences of immunogenic peptides derived from the principal neutralization determination of the HIV-1 envelope glycoprotein gp120. Biochemistry. 30: 9187-9194.
4. Constantine, N., T. et al., (1993) Serologic test for the retroviruses: approaching a decade of evolution. AIDS, 7: 1-13Gnann JW et al. (1987) Science; 237: 1346-1349.
5. Barbe, F. et al.,(1994) Early detection of antibodies to HIV-1 by a third generation enzyme immunoassay. Ann.Biol.Clin.(Paris),52, 341-345.
6. Barr P.J. et al.,(1987) Antigenicity of domains of the HIV envelope polypeptide expressed in the yeast Saccharomyces cerevisiae.Vaccine,5:90-101.

USED SYMBOLS

Symbol	Description
Cont.	Content
CE 2854	
IVD	
2°C 8°C	

EKVITESTLAB LLC

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03150 Kyiv, Ukraine
Tel. 0-800-31-89-87
e-mail: info@equitest.com.ua
www.equitest.com.ua

STATEMENT

We, EKVITESTLAB LLC, having a registered office at Velyka Vasylkivska street 114, Kyiv, 03150, Ukraine assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Date: 03 January 2024

Signature: _____

Director, Anna Yurchuk

CERTIFICATE

MANAGEMENT SYSTEM CERTIFICATION BODY
«CONFORMITY ASSESSMENT BODY «PROMSTANDART», LLC
certifies that the enterprise

EKVITESTLAB
Limited Liability Company

registration code 38745936

legal address:
Ukraine, 03150, Kyiv, 114 Velyka Vasylkivska street,

manufacturer's address:
Ukraine, 04212, Kyiv, 60/2 Peremohy Avenue

has established and applies quality management system for
development, production, storage and sale of ELISA kits for in vitro diagnostic

Audit, № report 2020/015-20.2.1
confirmed that the requirements

ISO 13485:2016
«Medical devices — Quality management systems — Requirements for regulatory purposes»

are performed.

The control of conformity of the certified quality management system to the requirements of the specified standard is carried out by means of supervisory audit, the periodicity and procedures of which are regulated by the program.

Certificate registration number	**№ UA.QMS.00014-21**
Registered	**06 April 2021**
Valid until	**05 April 2024**

8O156
DSTU EN ISO/IEC 17021-1

Director of Certification Body
«CAB «PROMSTANDART», LLC

stamp (signature)

Sergiy Dubrovskyi

210107

The validity of certificate can be verified by telephone: (056) 742-82-39
or on website of «CAB «PROMSTANDART», LLC: prom-standart.com.ua

ПРОМСТАНДАРТ ■ PROMSTANDART ■ ПРОМСТАНДАРТ ■ PROMSTANDART ■ ПРОМСТАНДАРТ

ПРОМСТАНДАРТ ПРОМСТАНДАРТ PROMSTANDART ПРОМСТАНДАРТ

СЕРТИФІКАТ

ОРГАН З СЕРТИФІКАЦІЇ СИСТЕМ МЕНЕДЖМЕНТУ
ТОВ «Орган з оцінки відповідності «ПРОМСТАНДАРТ»

засвідчує, що підприємство

ТОВАРИСТВО З ОБМЕЖЕНОЮ ВІДПОВІДАЛЬНІСТЮ «ЕКВІТЕСТЛАБ»

місцезнаходження юридичної особи:
Україна, 03150, м. Київ, вул. Велика Васильківська, 114
фактичне місцезнаходження:
Україна, 03057, м. Київ, проспект Перемоги, 60/2

код ЄДРПОУ 38745936

впровадило та використовує систему управління якістю
стосовно сфери діяльності:

Розробка, виробництво, зберігання та реалізація ІФА-наборів для діагностики in vitro

Аудит, № звіту 2020/015-20.2.1
підтвердив, що вимоги

ДСТУ EN ISO 13485:2018 (EN ISO 13485:2016, IDT; ISO 13485:2016, IDT)

виконуються.

Контроль відповідності сертифікованої системи управління якістю вимогам зазначеного стандарту здійснюється шляхом періодичних наглядових аудитів.

Реєстраційний номер сертифікату	**№ UA.QMS.00014-21**
Чинний з	**06 квітня 2021 р.**
Чинний до	**05 квітня 2024 р.**

8О156
ДСТУ EN ISO/IEC 17021-1

210020

Керівник ОС СМ
ТОВ «ООВ «ПРОМСТАНДАРТ» МП _____ *(підпис)* ***С. В. Дубровський***

Чинність сертифіката можна перевірити за тел. (056) 742-82-39 та
на сайті ТОВ «Орган з оцінки відповідності «ПРОМСТАНДАРТ» prom-standart.com.ua

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

EKVITESTLAB LLC

Velyka Vasylkivska St. 114, Kyiv, Ukraine, 03150, tel. 0(800)31-89-87; +38 (044)334-89-87

e-mail: info@equitest.com.ua, web-site: www.equitest.com.ua

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

EQUI anti-Lamblia - ELISA kit for the qualitative detection of antibodies to *Giardia lamblia (intestinalis)*, REF EI-606

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

- **ISO 13485:2016 «Medical devices — Quality management systems — Requirements for regulatory purposes»**

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e-mail: info@equitest.com.ua
RESPONSIBLE PERSON'S name: Anna Yurchuk
Position: Director

SIGNATURE : 

Date : October 25, 2021
Stamp

European Authorized Representative:
Registered Address:
Obelis s.a.
Bd. Général Wahis 53
B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
Fax: 32.2.732.60.03
E-mail: mail@obelis.net
Representative: Mr. Gideon ELKAYAM (CEO)

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

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e-mail: info@equitest.com.ua, web-site: www.equitest.com.ua

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

EQUI Ascaris lumbricoides IgG - ELISA kit for the qualitative detection of IgG antibodies to *Ascaris lumbricoides*, REF EI-601

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

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Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

EQUI Toxocara canis IgG - ELISA kit for the qualitative detection of IgG antibodies to *Toxocara canis*, REF EI-603

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

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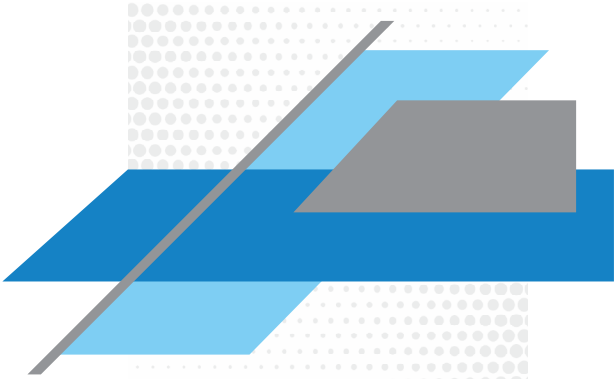
Fax: 32.2.732.60.03
E-mail: mail@obelis.net
Representative: Mr. Gideon ELKAYAM (CEO)

Toxocara canis IgG

ELISA kit for the qualitative detection of IgG antibodies to *Toxocara canis*

Instructions for use



IVD

REF EI-603

Σ 96 tests

CE

EQUI Toxocara canis IgG

ELISA kit for the qualitative detection of
IgG antibodies to *Toxocara canis*

1. INTENDED USE

The «EQUI Toxocara canis IgG» is ELISA kit intended to qualitatively detect anti-*Toxocara canis* IgG in human serum or plasma by enzyme-linked immunosorbent assay (ELISA) in order to diagnose toxocariasis. The testing procedure is designed for both manual arrangement with automatic pipettes and standard equipment, and for automated «open» immunoassay analysers.

Target group: children, pet owners, rural people, summer visitors, forest guards, veterinarians.

Usage: ELISA kit is used in clinical diagnostic laboratories and other institutions engaged in *in vitro* diagnostics.

2. CLINICAL SIGNIFICANCE

Toxocariasis is a common disease induced by *Toxocara* helminth which is transmitted from animals to human. Toxocariasis is spread throughout the world, however, it is more common in depressed areas with poor hygienic conditions. In some regions, up to 90 % of puppies and up to 10 % of adult domesticated dogs are infested with toxocara. The risk of infestation is higher for owners of cats and dogs and for children due to playing in the sandpits and on the playgrounds contaminated with animal faeces.

Toxocara are threadworms belonging to *Nematoda*. Human conditions are mostly caused by *Toxocara canis*, which infested canids, rare - *Toxocara cati*, which is more common in felids. Adult toxocara in the body of infested animals reaches 5–15 cm in length; their propagation takes place here. Female helminths lay about 200 thous eggs daily, which are excreted in the environment with faeces. If conditions are favourable, following several weeks of maturation in the soil they become invasive — a larva is developed in the eggs. In the paratenic host (mice, poultry, cows, pigs, etc.). larva develops without propagation. If the conditions are unfavourable, larvae are encapsulated and may maintain viability for a long time (up to 10 years). They may also be the source of invasion.

People are infested through faecal-oral route when ingesting *Toxocara canis* mature eggs with soil-contaminated vegetables, fruits, berries, via dirty hands or when consuming meat of paratenic hosts. In the small intestine, larvae leave their cover and penetrates blood circulation through the intestinal walls. The larvae migrate to other organs and tissues with blood, namely: liver, lungs, muscles, eyes, CNS, etc. In the most of the infested, toxocariasis is asymptomatic. Clinical manifestations of this disease are associated with the site of larvae migration and depend on the intensity of invasion and age of the host. Visceral syndrome larva migrans is typical after infestation of the internal organs with *Toxocara canis* and ocular

toxocariasis, when eye and optic nerve are involved. Symptoms of visceral toxocariasis: fever, fatigue, abdominal pain, anorexia, hepatomegaly, cough and others. Heart and respiratory failure may develop in severe cases. Due to a strong immune response to larvae antigens, immediate and delayed hypersensitivity reactions develop. Granulomatosis in occular toxocariasis may result in retinal detachment and loss of vision.

Diagnosis of toxocariasis is complicated due to the lack of specific manifestations of the disease, even upon intense invasion. Furthermore, a man is an intermediate host of *Toxocara canis* and does not excrete parasites in the environment, whereas it is difficult to localise larvae in certain organs via non-invasive methods. Eosinophilia may appear in blood tests, however, serological tests are more common to detect toxocariasis (immunofluorescence reaction, ELISA and immunoblotting). Detection of specific anti-*Toxocara canis* IgG to larvae antigens may suggest current or previous invasion. High titter of IgE antibodies is also typical for active invasion. However, the combination of clinical manifestations and laboratory findings are necessary for diagnosis.

3. ANALYSIS PRINCIPLE

The procedure of testing for anti-*Toxocara canis* IgG in «EQUI Toxocara canis IgG» ELISA kit is based on «indirect» solid-phase ELISA with a two-stage incubation. Antigens of *Toxocara canis* larvae are entrapped in the wells. During the first step of incubation of ELISA plate wells with test samples, specific anti-*Toxocara canis* antibodies (if present in the samples) bind to the solid-phase antigens. The wells are washed to remove unbound antibodies and have only specific antigen-antibody complexes left. Then, a conjugate of anti-species IgG monoclonal antibodies with horseradish peroxidase is added, which binds to solid-phase immune complexes. Unbound components are removed by washing. Antigen-antibody complexes are detected by adding a solution of chromogen 3,3',5,5'-tetramethylbenzidine (TMB) with hydrogen peroxide. After 30-minute incubation, the reaction is stopped by adding the stop solution. The optical density (OD) in the wells is determined using a spectrophotometer at 450/620-695 nm. The intensity of the yellow colour is proportional to the level of antibodies in the sample.

4. MATERIALS AND EQUIPMENT

4.1. Contents of the ELISA kit

STRIPS	1 x 96 wells	**Microplate** Each plate well is coated with *Toxocara canis* larval antigens. The wells are detachable. After the first opening, store unused strips in the package at 2-8 °C for a maximum of 6 months

CONTROL +	1 x 0,25 ml	**Positive control** Conjugated specific monoclonal antibody solution with preservative (pink). Store at 2-8 °C
CONTROL -	1 x 0,6 ml	**Negative control** Negative human serum with a preservative (yellow). Store at 2-8 °C
DIL SAMPLE	1 x 13 ml	**Serum dilution solution** Buffer solution with a milk extract, a detergent and a preservative (brown). Store at 2-8 °C
SOLN CONJ	1 x 13 ml	**Conjugate solution (ready to use)** Buffer solution of monoclonal antibodies to human IgG, conjugated with horseradish peroxidase, with stabilizers and preservative (green). Store at 2-8 °C
SOLN TMB	1 x 13 ml	**TMB solution (ready to use)** TMB solution, H_2O_2, a stabilizer, a preservative (colourless). Store at 2-8 °C
TWEEN WASH 20x	1 x 50 ml	**Washing solution TWEEN (20x concentrated)** 20-fold phosphate buffer concentrate with Tween-20 (colourless). Dilute TWEEN detergent (20x) at 1:20 with distilled or deionized water (e. g., 5 mL of concentrate + 95 mL of water for 8 wells) before use. Store the diluted solution at 2-8 °C for a maximum of 7 days
SOLN STOP	1 x 13 ml	**Stop Solution (ready to use)** 0.5 mol H_2SO_4 solution (colourless). Store at 2-8 °C

The ELISA kit also includes adhesive films (2 items), sample application plan (1 item), checklist, and instruction for use.

4.2. Optional reagents, materials and equipment

Automatic single and multichannel pipettes 10–1000 µL, tips, volumetric laboratory glassware (10–1,000 mL), deionized or distilled water, thermostat at 37 °C, automatic or semi-automatic plate washer, spectrophotometer (reader) for microplates at 450/620-695 nm, appropriate containers for potentially contaminated waste, timer, filter paper, disposable powder-free gloves, disinfectants.

5. PRECAUTIONS AND SAFETY

5.1. Precautions

Be sure to read the instructions for use carefully before the test. The validity of the test results depends on strict following of the test procedure.

– do not use the ELISA kit components after the expiry date;
– do not use for analysis or mix components of different batches, components of kits for different nosologies, or reagents from other manufacturers with the «EQUI Toxocara canis IgG» ELISA kit;

– do not freeze the ELISA kit or its contents;
– after using a reagent, close each vial with its cap;
– when washing, control filling and complete aspiration of solution from the wells;
– use a new pipette tip each time you add samples or reagents;
– prevent direct sunlight from reaching the reagents from the ELISA kit;
– SOLN|TMB solution must be colourless before use. Do not use the solution if its colour is blue or yellow. Avoid contact of SOLN|TMB with metals or metal ions. Use only clean glassware thoroughly rinsed with distilled water;
– do not use reagents with colour not in line with para. 4.1;
– under no circumstances should the same glassware be used for SOLN|CONJ and SOLN|TMB;
– do not evaluate the test results visually (without a reader);
– any optional equipment that is in direct contact with biological material or kit components should be considered contaminated and requires cleaning and decontamination;
– the ELISA kit includes materials for 96 tests. Dispose of the used components as well as any remaining unused components.

5.2. Safety requirements

– all reagents in the ELISA kit are for laboratory professional use for *in vitro* diagnosis only and may only be used by qualified personnel;
– conduct the tests in disposable powder-free gloves and goggles only;
– do not eat, drink, smoke, or apply make-up in the test room;
– do not mouth-pipette the solutions;
– controls from the «EQUI Toxocara canis IgG» ELISA kit have been tested and found to be for anti-HIV1/2, anti-HCV and anti-*Treponema pallidum* antibodies and HBsAg negative; however, controls and test samples should be handled as potentially hazardous infectious materials;
– some of the kit components contain low concentrations of harmful substances and can damage skin or mucoga. In case of contact of SOLN|TMB, SOLN|STOP and SOLN|CONJ with mucous membranes or skin, immediately wash the affected area with plenty of water;
– in case of spillage of acid-free solutions, e. g. sera, treat the surface with a disinfectant solution and then wipe dry with filter paper. Otherwise first neutralize acid with sodium bicarbonate solution and then wipe the surface dry as described above.

5.3. Waste inactivation and disposal

– the liquid waste must be inactivated, for example, with hydrogen peroxide solution at the final concentration of 6% for 3 hours at room temperature, or with sodium hypochlorite at the final concentration of 5% for 30 minutes, or with other approved disinfectants;

– the solid waste must be inactivated by autoclaving at a temperature not less than 132°C;
– do not autoclave the solutions that contain sodium azide or sodium hypochlorite;
– disposal of inactivated waste must be conducted due to national laws and regulations.

6. STORAGE AND STABILITY

ELISA kit is stable up to the expiry date stated on the label when stored at 2-8°C. The kit should be transported at 2-8°C. Single transportation at a temperature up to 23°C for two days is possible.

7. SAMPLE COLLECTION, TRANSPORTATION AND STORAGE GUIDELINES

Collect blood from the vein into the sterile test tube. Test tube must be marked with patient ID and date of sample collecting. Blood before serum separation can be stored at 2-8 ºC for 24 hours, avoiding freezing.

Serum or plasma can be stored at 2-8 °C for maximum 3 days. Frozen serum can be stored for longer periods of time at -20 °C or -70 °C. Thaw frozen samples and keep them at room temperature for 30 minutes before use. After thawing, the stir samples to achieve homogeneity. Avoid repeated freezing-thawing cycles for test samples. If serum (or plasma) is turbid, remove insoluble inclusions by centrifugation at 3000 rpm for 10-15 minutes. Do not use serum samples with hyperlipidemia, hemolysis, and bacterial growth.

Transport serum samples in insulated containers. To do that, put closed labelled tubes in a plastic bag, tightly seal it and place in the centre of an insulated container.Put the frozen cold packs on the bottom, along the side walls of the insulated container and on top of the serum samples.

8. REAGENT PREPARATION

NOTE! It is very important to keep all ELISA kit components for at least 30 min at room temperature 18-25 ºC before the assay!

8.1. Microplate preparation

To prevent water condensation in the wells, keep the STRIPS for 30 minutes at a room temperature before opening. Open the vacuum pack, detach the appropriate number of wells, and carefully pack the remaining wells with a desiccant and store tightly zip-locked at 2-8 °C. Storing the packed plate this way ensures its stability for 6 months.

8.2. Washing solution preparation

To prepare detergent, dilute TWEEN WASH 20x at 1:20 (1+19) with distilled or deionized water and stir. E. g., 5 mL of concentrate + 95 mL of water, which is enough for 8 wells. If there are crystals present in the detergent concentrate, heat the vial at 37 °C until the crystals dissolve completely (15–20 minutes). Store the diluted solution at 2-8 °C for a maximum of 7 days.

9. ASSAY PROCEDURE

9.1. Prepare the necessary number of wells (four wells for controls and a necessary number of wells for test samples) and insert them into the ELISA plate frame. Be sure to add control wells in every test run.

9.2. Fill in the sample application plan.

9.3. Prepare the detergent as per para. 8.2.

9.4. Add 90 µL of DIL SAMPLE into each plate well.

9.5. Add 10 µL of controls and test samples into the wells:
CONTROL + – into well A1,
CONTROL - – into wells B1, C1 and D1,
and test samples into the remaining wells.
At the time of adding, the solution changes its colour from brown to blue. Pipette the mix in the wells carefully to avoid foaming.

9.6. Cover the strips up with adhesive film and incubate for **30 minutes at 37 °C**.

9.7. Remove and discard the adhesive film and wash all wells 5 times with automatic washer or 8-channel pipette as follows:
– aspirate the content of all wells into a liquid waste container;
– add a minimum of 300 µl of diluted washing solution to each well, soak each well for 30 seconds;
– aspirate the content of all wells again. The residual volume after every aspiration should be less than 5 µl;
– repeat the washing step 4 more times;
– after the final aspiration, eliminate extra moisture by tapping the plate against a piece of filter paper.

9.8. Add 100 µL of SOLN CONJ into each well. Cover the strips with a new piece of adhesive film and incubate for **30 minutes at 37 °C**.

9.9. Following incubation, remove the film carefully and wash the wells five times as described in para. 9.7.

9.10. Add 100 µL of SOLN TMB into the wells; do not touch the bottom and the walls of the plate wells.

9.11. Incubate the strips for **30 minutes** in a dark place at a room temperature of 18-25 °C. Do not use adhesive film at this stage.

9.12. Add 100 µL of SOLN STOP into each strip well to stop the enzymatic reaction; adhere to the same sequence of actions as when adding SOLN TMB. At the time of adding, the solution colour changes from blue to yellow, and clear solution slightly changes its shade.

9.13. Measure the optical density (OD) of the wells at 450/620-695 nm wavelength using an ELISA microplate reader within 5 minutes after stopping the reaction. Pay attention to the cleanness of the plate bottom and the absence of bubbles in the wells before reading.

Measurement at the single wavelength of 450 nm is possible, in that case, it is needed to leave one well for blank (only SOLN TMB and SOLN STOP must be added

in blank well).

10. CALCULATION AND INTERPRETATION OF RESULTS

10.1. Calculation of results

Calculate the average OD for the negative control ($\overline{Nc}$), Cut off (CO) and a sample positivity index (IP_{sample}).

$$\overline{Nc} = (Nc1 + Nc2 + Nc3)/3; \quad CO = \overline{Nc} + 0,3$$

$IP_{sample} = OD_{sample}/CO$, where: OD_{sample} is the OD sample.

10.2. Quality control (assay validation)

The test results are considered valid if they meet the following requirements:

CONTROL + $OD \geq 1,0$

CONTROL - $OD \leq 0,150$

CONTROL - $\overline{Nc} \times 0,5 \leq Ncn \leq \overline{Nc} \times 2,0$ where Ncn is the OD for each Nc run

If any of the OD values for the negative control is beyond the above interval, it should be discarded, and $\overline{Nc}$ is calculated based on the remaining OD values for the negative control. If several OD values for the negative control fail to meet the above requirements, the test is considered invalid and requires a new run.

10.3. Interpretation of results

$IP_{sample} > 1,1$	POSITIVE
$0,9 \leq IP_{sample} \leq 1,1$	BORDERLINE*
$IP_{sample} < 0,9$	NEGATIVE

* Uncertain samples are recommended to be re-examined in two wells of the ELISA kit. If the results are again uncertain, a new sample should be selected and analyzed in 2-4 weeks. In case of repeated indeterminate results, such samples shall be considered negative.

11. PERFORMANCE CHARACTERISTICS

11.1. Analytical performance characteristics

Precision of measurement

Intra assay repeatability

The coefficient of variation (CV) for three sera with different levels of specific antibodies was evaluated in 24 replicates on one series of ELISA kits.

Sample No.	OD_{av}	IP_{av}	CV, %
669	0,927	2,81	4,8
544	1,503	4,56	1,4
666	1,694	5,14	4,5

Inter assay reproducibility

The coefficient of variation (CV) for three sera with different levels of specific antibodies was evaluated for 4 days in 4 sets of analysis, 8 replicates in each analysis.

Sample No.	OD_{av}	IP_{av}	CV, %
669	1,016	3,04	4,7
544	1,516	4,54	1,9
666	1,683	5,04	4,1

Analytical specificity

The test results are not affected by bilirubin at up to 0.21 mg/mL (361.8 μmol/L), haemoglobin at up to 10 mg/mL and triglycerides at up to 10 mg/mL (11.3 mmol/l) present in the sample.

11.2. Diagnostic characteristics

To evaluate diagnostic characteristics of «EQUI Toxocara canis IgG» ELISA kits, 78 serum samples from patients with clinical symptoms typical for toxocariasis and 60 serum samples from patients without clinical manifestations (seronegative in terms of *Toxocara canis*) were used. Clinical sensitivity of «EQUI Toxocara canis IgG» ELISA kits was 98.7 %, clinical specificity — 96.7 %.

Method characteristics in comparison with equal commercial ELISA kit was studied in target paediatric population (160 samples) and population of donors (298 samples). For paediatric population serum, relative specificity of «EQUI Toxocara canis IgG» ELISA kits was established at the level of 99.28 % and percent agreement was 97.45 %. For donor population serum, relative specificity of was 89.19 %, relative specificity — 93.55 % and percent agreement was 91.73 %.

12. LIMITATIONS OF ASSAY

Positive result in «EQUI Toxocara canis IgG» ELISA kit supports presence of anti-*Toxocara canis* specific IgG antibodies. Presence of this class antibodies in newborns is not an evidence of *Toxocara canis* invasion.

Inconclusive results may suggest a history of *Toxocara canis* invasion.

Negative result of «EQUI Toxocara canis IgG» ELISA kit supports the absence of anti-*Toxocara canis* specific IgG antibodies in the test sample or concentration of specific antibodies is below the sensitivity limit of the assay.

The results of serological test only are not the basis for final diagnosis. When establishing the diagnosis, the results of complex laboratory and instrumental tests, as well as clinical manifestations should be considered. Cross-reactions with antibodies to antigens of other helminths cannot be fully ruled out.

13. DIFFICULTIES THAT CAN OCCUR DURING THE ASSAY PROCEDURE

Possible reasons	Solution
High background in all wells	
Contaminated washer	Clean the washer head and rinse according to the instructions for use
Poor quality or contaminated water	Use purified water with specific resistance ≥ 10 MΩ · cm
Use of poorly washed glassware	Use chemically clean utensils
Use of chlorinated disinfectants	Do not use chlorine disinfectants
Use of contaminated tips	Use new tips
Increased incubation times or change in the temperature conditions	Adhere to the incubation regime according to the instructions for use
High background in a row of wells	
Repeat application of TMB solution	TMB solution should be applied once
Contamination of the automatic pipette nozzle with conjugate solution	Clean the pipette and dial carefully liquid
Contamination of one of the washer's channel	Clean the flush channel, rinse washer
Received OD of the positive control is below the border value	
One of the reagents (conjugate solution or TMB solution) was not prepared in a correct way or was not added	Re-conduct ELISA, pay attention to the correctness of the introduction of these reagents
Reduced incubation times at any stage	Incubate according to instructions for use
The colour density of the wells fails to meet the obtained optical density value	
This may suggest that the optical beam has been displaced	Check the correct operation of the reader

14. TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

In case of technical problems, you can obtain assistance by contacting the manufacturer.

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	Manufacturer
EC REP	Authorized Representative in the European Community
IVD	In vitro diagnostic medical device
REF	Catalogue number
	Date of manufacture
	Use by date
LOT	Batch code
	Temperature limit
Σ	Contains sufficient for <n> tests
	Caution
NON STERILE	Non-Sterile
	Consult instructions for use
	Keep away from sunlight
	Keep dry
CE	Compliance with EU safety requirements

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For questions and suggestions regarding the ELISA kit contact:

EC REP

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ASSAY PROCEDURE SCHEME

Keep all reagents for 30 min at temperature18-25°C before use
Dispense 90 µl DIL SAMPLE into the wells (brown)
Add to 10 µl of controls and samples into the wells: A1 – CONTROL +, B1, C1, D1 – CONTROL –, other wells – examined samples (change of colour from brown to blue)
Cover strips with an adhesive film, incubate for **30 min at 37°C**
Rinse the wells 5 times with prepared 1:20 (1+19) washing solution TWEEN (300 µl per well)
Add 100 µl of SOLN CONJ into all wells (green)
Cover strips with an adhesive film, incubate for **30 min at 37°C**
Rinse the wells 5 times with prepared 1:20 (1+19) washing solution TWEEN (300 µl per well)
Add 100 µl of SOLN TMB into all wells
Incubate for **30 min** in the dark at **18-25°C**
Add 100 µl of SOLN STOP into all wells (change of colour from blue to yellow)
Measure the optical density (OD) with an ELISA microplate reader at 450/620-695 nm

CALCULATION OF RESULTS

$\overline{Nc} = (Nc1 + Nc2 + Nc3)/3;$

$CO = \overline{Nc} + 0,3;$

$IP_{sample} = OD_{sample}/CO$

$\overline{Nc}$ - the average value of OD 3-x CONTROL –

CO - Cut off

IP_{sample} - sample positivity index

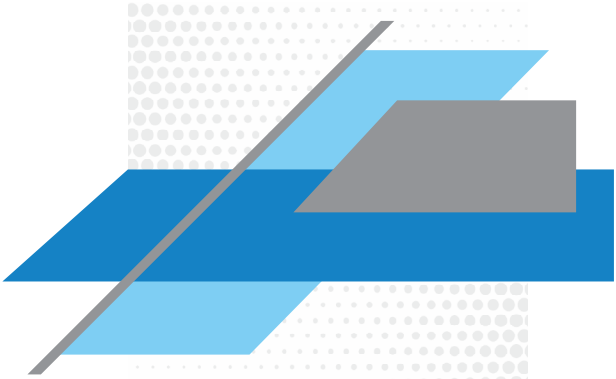
INTERPRETATION OF RESULTS

$IP_{sample} > 1,1$	POSITIVE
$0,9 \leq IP_{sample} \leq 1,1$	BORDERLINE
$IP_{sample} < 0,9$	NEGATIVE

anti-Lamblia

ELISA kit for the qualitative detection of antibodies to *Giardia lamblia (intestinalis)*

Instructions for use



IVD

REF EI-606

Σ 96 tests

CE

EQUI anti-Lamblia

ELISA kit for the qualitative detection of antibodies to
до *Giardia lamblia (intestinalis)*

1. INTENDED USE

The «EQUI anti-Lamblia» is ELISA kit intended to qualitatively detect antibodies to *Giardia lamblia (intestinalis)* in human serum or plasma by enzyme-linked immunosorbent assay (ELISA) to diagnose giardiasis. The testing procedure is designed for both manual arrangement with automatic pipettes and standard equipment, and for automated «open» immunoassay analysers.

Target group: children, pet owners, citizens of rural areas, summer house owners.

Usage: ELISA kit is used in clinical diagnostic laboratories and other institutions engaged in *in vitro* diagnostics.

2. CLINICAL SIGNIFICANCE

Giardiasis is considered one of the most common parasitic diseases of the small intestine in the world. This infection is a major cause of acute and chronic diarrhea, especially in children. The etiological agent of giardiasis is *Giardia lamblia*, which is also called *Giardia intestinalis* or *Giardia duodenalis*.

Giardia lamblia are unicellular flagellate protozoa that parasitize in the intestines of humans and some other mammals. During the life cycle of these parasites, two stages alternate: cysts, resistant to external conditions, and a vegetative form - trophozoites. Infection occurs when cysts enter the human gastrointestinal tract. After experiencing the effects of gastric acid, cysts in the duodenum turn into trophozoites, which parasitize in the upper parts of the small intestine. They absorb nutrients from the intestinal lumen, block parietal digestion and disrupt the motility of the intestine.

Humans get infected via fecal-oral routes through cyst-contaminated food, water, unwashed hands, and so on. Giardia can also be transmitted to humans from infected cats, dogs, and livestock. Giardiasis is especially common in regions with poor sanitation. In addition, human-to-human transmission is common in preschools.

In many cases, the invasion of Giardia occurs without clinical manifestations. In other cases, the first symptoms of giardiasis appear in 1-3 weeks after infection. They are most often manifested by spasms, bloating, nausea and diarrhea, which leads to dehydration and weight loss. The acute form of the disease can last up to two weeks and end in recovery without additional treatment or become chronic. Chronic giardiasis develops when the duration of the invasion is longer than 2 month and the exacerbation of clinical manifestations (diarrhea) is cyclical. *Giardia lamblia* parasitism can lead to malabsorption syndrome, which disrupts the absorption of carbohydrates and fats, as well as the metabolism of vitamins B12, A and C.

Immune response to invasion and non-immune factors are important to control the development of the disease and the severity of clinical manifestations. Both

humoral and cellular immunity play the part in the eradication of the pathogen, the role of which is still subjected to scientific research. In addition, partial resistance to re-infection is formed due to protective mechanisms of the body.

Typically, to diagnose giardiasis, the duodenal contents and feces are examined for trophozoites and cysts of giardiasis. In case of the chronic course of the disease, cysts get excreted periodically, and, considering this, the additional tests should be performed regularly for several weeks. Another method of diagnosing giardiasis is to detect *Giardia lamblia* antigens in the feces. However, serodiagnosis with the detection of specific antibodies to Giardia antigens is an important step in assessing the immune response of patients. Detection of specific IgM antibodies suggests an acute stage of giardiasis. However, the detection of specific IgG and IgA antibodies should be interpreted with caution: in some regions they persist for a long time after infection, while in others their level decreases after eradication of the pathogen.

3. ANALYSIS PRINCIPLE

The procedure of testing for *Giardia lamblia* specific antibodies in «EQUI anti-Lamblia» ELISA kit is based on «indirect» solid-phase ELISA with a two-stage incubation. Recombinant *Giardia lamblia* antigens are entrapped in the wells. During the first step of incubation of the test samples in the wells of the ELISA plate, *Giardia lamblia*-specific antibodies, if present in the samples, bind to the solid phase antigens. The wells are washed to remove unbound antibodies and have only specific antigen-antibody complexes left. Then, a conjugate of anti-species (anti-IgG and anti-IgA) monoclonal antibodies with horseradish peroxidase is added, which binds to solid-phase immune complexes. Unbound components are removed by washing. Antigen-antibody complexes are detected by adding a solution of chromogen 3,3',5,5'-tetramethylbenzidine (TMB) with hydrogen peroxide. After 30-minute incubation, the reaction is stopped by adding the stop solution. The optical density (OD) in the wells is determined using a spectrophotometer at 450/620-695 nm. The intensity of the yellow colour is proportional to the level of antibodies in the sample.

4. MATERIALS AND EQUIPMENT

4.1. Contents of the ELISA kit

		Microplate
STRIPS	1 x 96 wells	Each plate well is coated with *Giardia lamblia* purified antigens. The wells are detachable. After the first opening, store unused strips in the package at 2-8 °C for a maximum of 6 months
		Positive control
CONTROL +	1 x 0,35 ml	Conjugated specific monoclonal antibody solution with preservative (pink). Store at 2-8 °C
		Negative control
CONTROL -	1 x 1,2 ml	Negative human serum with a preservative (yellow). Store at 2-8 °C

DIL SAMPLE	1 x 11 ml	**Serum dilution solution** Buffer solution with a milk extract, a detergent and a preservative (purple). Store at 2-8 °C
SOLN CONJ	1 x 13 ml	**Conjugate solution (ready to use)** Buffer solution of monoclonal antibodies to human IgG and IgA, conjugated with horseradish peroxidase, with stabilizers and preservative (green). Store at 2-8 °C
SOLN TMB	1 x 13 ml	**TMB solution (ready to use)** TMB solution, H_2O_2, a stabilizer, a preservative (colourless). Store at 2-8 °C
TWEEN WASH 20x	1 x 50 ml	**Washing solution TWEEN (20x concentrated)** 20-fold phosphate buffer concentrate with Tween-20 (colourless). Dilute TWEEN detergent (20x) at 1:20 with distilled or deionized water (e. g., 5 mL of concentrate + 95 mL of water for 8 wells) before use. Store the diluted solution at 2-8 °C for a maximum of 7 days
SOLN STOP	1 x 13 ml	**Stop Solution (ready to use)** 0.5 mol H_2SO_4 solution (colourless). Store at 2-8 °C

The ELISA kit also includes adhesive films (2 items), sample application plan (1 item), checklist, and instruction for use.

4.2. Optional reagents, materials and equipment

Automatic single and multichannel pipettes 10–1000 µL, tips, volumetric laboratory glassware (10–1,000 mL), deionized or distilled water, thermostat at 37 °C, automatic or semi-automatic plate washer, spectrophotometer (reader) for microplates at 450/620-695 nm, appropriate containers for potentially contaminated waste, timer, filter paper, disposable powder-free gloves, disinfectants.

5. PRECAUTIONS AND SAFETY

5.1. Precautions

Be sure to read the instructions for use carefully before the test. The validity of the test results depends on strict following of the test procedure.

- do not use the ELISA kit components after the expiry date;
- do not use for analysis or mix components of different batches, components of kits for different nosologies, or reagents from other manufacturers with the «EQUI anti-Lamblia» ELISA kit;
- do not freeze the ELISA kit or its contents;
- after using a reagent, close each vial with its cap;
- when washing, control filling and complete aspiration of solution from the wells;
- use a new pipette tip each time you add samples or reagents;
- prevent direct sunlight from reaching the reagents from the ELISA kit;
- SOLN TMB solution must be colourless before use. Do not use the solution if its colour is blue or yellow. Avoid contact of SOLN TMB with metals or metal ions. Use only clean glassware thoroughly rinsed with distilled water;

– do not use reagents with colour not in line with para. 4.1;
– under no circumstances should the same glassware be used for SOLN|CONJ and SOLN|TMB;
– do not evaluate the test results visually (without a reader);
– any optional equipment that is in direct contact with biological material or kit components should be considered contaminated and requires cleaning and decontamination;
– the ELISA kit includes materials for 96 tests. Dispose of the used components as well as any remaining unused components.

5.2. Safety requirements

– all reagents in the ELISA kit are for laboratory professional use for *in vitro* diagnosis only and may only be used by qualified personnel;
– conduct the tests in disposable powder-free gloves and goggles only;
– do not eat, drink, smoke, or apply make-up in the test room;
– do not mouth-pipette the solutions;
– controls from the «EQUI anti-Lamblia» ELISA kit have been tested and found to be for anti-HIV1/2, anti-HCV and anti-*Treponema pallidum* antibodies and HBsAg negative; however, controls and test samples should be handled as potentially hazardous infectious materials;
– some of the kit components contain low concentrations of harmful substances and can damage skin or mucoga. In case of contact of SOLN|TMB, SOLN|STOP and SOLN|CONJ with mucous membranes or skin, immediately wash the affected area with plenty of water;
– in case of spillage of acid-free solutions, e. g. sera, treat the surface with a disinfectant solution and then wipe dry with filter paper. Otherwise first neutralize acid with sodium bicarbonate solution and then wipe the surface dry as described above.

5.3. Waste inactivation and disposal

– the liquid waste must be inactivated, for example, with hydrogen peroxide solution at the final concentration of 6% for 3 hours at room temperature, or with sodium hypochlorite at the final concentration of 5% for 30 minutes, or with other approved disinfectants;
– the solid waste must be inactivated by autoclaving at a temperature not less than 132°C;
– do not autoclave the solutions that contain sodium azide or sodium hypochlorite;
– disposal of inactivated waste must be conducted due to national laws and regulations.

6. STORAGE AND STABILITY

ELISA kit is stable up to the expiry date stated on the label when stored at 2-8°C. The kit should be transported at 2-8°C. Single transportation at a

temperature up to 23°C for two days is possible.

7. SAMPLE COLLECTION, TRANSPORTATION AND STORAGE GUIDELINES

Collect blood from the vein into the sterile test tube. Test tube must be marked with patient ID and date of sample collecting. Blood before serum separation can be stored at 2-8 ºC for 24 hours, avoiding freezing.

Serum or plasma can be stored at 2-8 °C for maximum 3 days. Frozen serum can be stored for longer periods of time at -20 °C or -70 °C. Thaw frozen samples and keep them at room temperature for 30 minutes before use. After thawing, the stir samples to achieve homogeneity. Avoid repeated freezing-thawing cycles for test samples. If serum (or plasma) is turbid, remove insoluble inclusions by centrifugation at 3000 rpm for 10-15 minutes. Do not use serum samples with hyperlipidemia, hemolysis, and bacterial growth.

Transport serum samples in insulated containers. To do that, put closed labelled tubes in a plastic bag, tightly seal it and place in the centre of an insulated container.Put the frozen cold packs on the bottom, along the side walls of the insulated container and on top of the serum samples.

8. REAGENT PREPARATION

NOTE! It is very important to keep all ELISA kit components for at least 30 min at room temperature 18-25 ºC before the assay!

8.1. Microplate preparation

To prevent water condensation in the wells, keep the STRIPS for 30 minutes at a room temperature before opening. Open the vacuum pack, detach the appropriate number of wells, and carefully pack the remaining wells with a desiccant and store tightly zip-locked at 2-8 °C. Storing the packed plate this way ensures its stability for 6 months.

8.2. Washing solution preparation

To prepare detergent, dilute TWEEN WASH 20x at 1:20 (1+19) with distilled or deionized water and stir. E. g., 5 mL of concentrate + 95 mL of water, which is enough for 8 wells. If there are crystals present in the detergent concentrate, heat the vial at 37 °C until the crystals dissolve completely (15–20 minutes). Store the diluted solution at 2-8 °C for a maximum of 7 days.

9. ASSAY PROCEDURE

9.1. Prepare the necessary number of wells (four wells for controls and a necessary number of wells for test samples) and insert them into the ELISA plate frame. Be sure to add control wells in every test run.

9.2. Fill in the sample application plan.

9.3. Prepare the detergent as per para. 8.2.

9.4. Add 80 µL of DIL SAMPLE into each plate well.

9.5. Add 20 µL of controls and test samples into the wells:
CONTROL + – into well A1,
CONTROL - – into wells B1, C1 and D1,
and test samples into the remaining wells.

At the time of adding, the solution changes its colour from brown to blue. Pipette the mix in the wells carefully to avoid foaming.

9.6. Cover the strips up with adhesive film and incubate for **30 minutes at 37 °C**.

9.7. Remove and discard the adhesive film and wash all wells 5 times with automatic washer or 8-channel pipette as follows:
– aspirate the content of all wells into a liquid waste container;
– add a minimum of 300 µl of diluted washing solution to each well, soak each well for 30 seconds;
– aspirate the content of all wells again. The residual volume after every aspiration should be less than 5 µl;
– repeat the washing step 4 more times;
– after the final aspiration, eliminate extra moisture by tapping the plate against a piece of filter paper.

9.8. Add 100 µL of SOLN CONJ into each well. Cover the strips with a new piece of adhesive film and incubate for **30 minutes at 37 °C**.

9.9. Following incubation, remove the film carefully and wash the wells five times as described in para. 9.7.

9.10. Add 100 µL of SOLN TMB into the wells; do not touch the bottom and the walls of the plate wells.

9.11. Incubate the strips for **30 minutes** in a dark place at a room temperature of 18-25 °C. Do not use adhesive film at this stage.

9.12. Add 100 µL of SOLN STOP into each strip well to stop the enzymatic reaction; adhere to the same sequence of actions as when adding SOLN TMB. At the time of adding, the solution colour changes from blue to yellow, and clear solution slightly changes its shade.

9.13. Measure the optical density (OD) of the wells at 450/620-695 nm wavelength using an ELISA microplate reader within 5 minutes after stopping the reaction. Pay attention to the cleanness of the plate bottom and the absence of bubbles in the wells before reading.

Measurement at the single wavelength of 450 nm is possible, in that case, it is needed to leave one well for blank (only SOLN TMB and SOLN STOP must be added in blank well).

10. CALCULATION AND INTERPRETATION OF RESULTS

10.1. Calculation of results

Calculate the average OD for the negative control ($\overline{Nc}$), Cut off (CO) and a sample positivity index (IP_{sample}).

$$\overline{Nc} = (Nc1 + Nc2 + Nc3)/3; \quad CO = \overline{Nc} + 0{,}25$$

$$IP_{sample} = OD_{sample}/CO, \text{ where } OD_{sample} \text{ is the OD sample.}$$

10.2. Quality control (assay validation)

The test results are considered valid if they meet the following requirements:

CONTROL + OD ≥ 1,0

CONTROL - OD ≤ 0,150

CONTROL - $\overline{Nc} \times 0,5 \leq Ncn \leq \overline{Nc} \times 2,0$ where Ncn is the OD for each Nc run

If any of the OD values for the negative control is beyond the above interval, it should be discarded, and $\overline{Nc}$ is calculated based on the remaining OD values for the negative control. If several OD values for the negative control fail to meet the above requirements, the test is considered invalid and requires a new run.

10.3. Interpretation of results

$IP_{sample} > 1,1$	POSITIVE
$0,9 \leq IP_{sample} \leq 1,1$	BORDERLINE*
$IP_{sample} < 0,9$	NEGATIVE

* Uncertain samples are recommended to be re-examined in two wells of the ELISA kit. If the results are again uncertain, a new sample should be selected and analyzed in 2-4 weeks. In case of repeated indeterminate results, such samples shall be considered negative.

11. PERFORMANCE CHARACTERISTICS

11.1. Analytical performance characteristic

Precision of measurement

Intra assay repeatability

The coefficient of variation (CV) for two sera with different levels of specific antibodies was evaluated in 32 replicates on one series of ELISA kits.

Sample No.	OD_{av}	IP_{av}	CV, %
14L	0,679	2,47	6,5
16L	0,490	1,79	6,6

Inter assay reproducibility

The coefficient of variation (CV) for three sera with different levels of specific antibodies was evaluated for 3 days in 3 sets of analysis, 8 replicates in each analysis.

Sample No.	OD_{av}	IP_{av}	CV, %
14L	0,670	2,39	5,55
16L	0,463	1,65	7,06

Analytical specificity

The test results are not affected by bilirubin at up to 0.21 mg/mL (361.8 µmol/L), haemoglobin at up to 10 mg/mL and triglycerides at up to 10 mg/mL (11.3 mmol/l) present in the sample.

11.2. Diagnostic characteristics

Studies of the characteristics of the method in comparison with a similar commercial ELISA kit were performed on a sample of characterized sera, the target group of children and a group of donors. The relative sensitivity of «EQUI anti-Lamblia» ELISA kits was determined from a group of 23 serum samples that were tested for antibodies to *Giardia lamblia* and characterized as positive in a commercial ELISA kit. All sera were also determined to be positive in «EQUI anti-Lamblia» kits, so the relative sensitivity equals 100%. For 148 serum samples of children that were tested and characterized in commercial analogues, the relative specificity of «EQUI anti-Lamblia» ELISA kits was 98.86%, the percentage of co-incidence - 93.24%. According to a similar principle, for 238 serum samples of donor blood, the relative specificity was 97,94% and the percentage of coincidence was 96.64%.

12. LIMITATIONS OF ASSAY

The final diagnosis cannot be made solely on the basis of serological test results, sunce clinical manifestations of the disease and laboratory data (such as the detection of cysts in faecal samples or trophozoites in duodenal contents; the results of detection of *Giardia lamblia* antigen in faeces) should be taken into account as well.

Addionally, cross-reactions with antibodies to antigens of other parasites cannot be completely ruled out.

Giardia lamblia-specific antibodies may not be detected in case of children with persistent and prolonged giardiasis.

It should be noted that IgG antibodies to *Giardia lamblia* can be detected via ELISA for a long time, even after successful treatment.

13. DIFFICULTIES THAT CAN OCCUR DURING THE ASSAY PROCEDURE

Possible reasons	Solution
High background in all wells	
Contaminated washer	Clean the washer head and rinse according to the instructions for use
Poor quality or contaminated water	Use purified water with specific resistance ≥ 10 MΩ · cm
Use of poorly washed glassware	Use chemically clean utensils
Use of chlorinated disinfectants	Do not use chlorine disinfectants
Use of contaminated tips	Use new tips
Increased incubation times or change in the temperature conditions	Adhere to the incubation regime according to the instructions for use
High background in a row of wells	

Repeat application of TMB solution	TMB solution should be applied once
Contamination of the automatic pipette nozzle with conjugate solution	Clean the pipette and dial carefully liquid
Contamination of one of the washer's channel	Clean the flush channel, rinse washer
Received OD of the positive control is below the border value	
One of the reagents (conjugate solution or TMB solution) was not prepared in a correct way or was not added	Re-conduct ELISA, pay attention to the correctness of the introduction of these reagents
Reduced incubation times at any stage	Incubate according to instructions for use
The colour density of the wells fails to meet the obtained optical density value	
This may suggest that the optical beam has been displaced	Check the correct operation of the reader

14. TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

In case of technical problems, you can obtain assistance by contacting the manufacturer.

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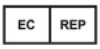
	Manufacturer
	Authorized Representative in the European Community
	In vitro diagnostic medical device
	Catalogue number
	Date of manufacture
	Use by date
	Batch code
	Temperature limit
	Contains sufficient for <n> tests
	Caution
	Non-Sterile
	Consult instructions for use
	Keep away from sunlight
	Keep dry
CE	Compliance with EU safety requirements

Edition 7, 18.02.2022

For questions and suggestions regarding the ELISA kit contact:



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ASSAY PROCEDURE SCHEME

Keep all reagents for 30 min at temperature18-25°C before use
Dispense 80 µl DIL SAMPLE into the wells (purple)
Add to 20 µl of controls and samples into the wells: A1 – CONTROL +, B1, C1, D1 – CONTROL –, other wells – examined samples (change of colour from purple to blue)
Cover strips with an adhesive film, incubate for **30 min at 37°C**
Rinse the wells 5 times with prepared 1:20 (1+19) washing solution TWEEN (300 µl per well)
Add 100 µl of SOLN CONJ into all wells (green)
Cover strips with an adhesive film, incubate for **30 min at 37°C**
Rinse the wells 5 times with prepared 1:20 (1+19) washing solution TWEEN (300 µl per well)
Add 100 µl of SOLN TMB into all wells
Incubate for **30 min** in the dark at **18-25°C**
Add 100 µl of SOLN STOP into all wells (change of colour from blue to yellow)
Measure the optical density (OD) with an ELISA microplate reader at 450/620-695 nm

CALCULATION OF RESULTS

$\overline{Nc} = (Nc1 + Nc2 + Nc3)/3;$

$CO = \overline{Nc} + 0,25;$

$IP_{sample} = OD_{sample}/CO$

$\overline{Nc}$ - the average value of OD 3-x CONTROL –

CO - Cut off

IP_{sample} - sample positivity index

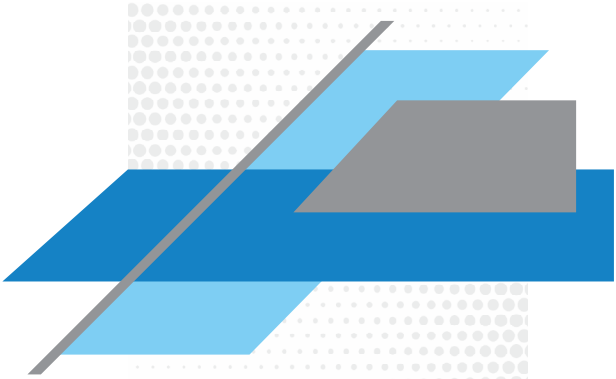
INTERPRETATION OF RESULTS

$IP_{sample} > 1,1$	POSITIVE
$0,9 \leq IP_{sample} \leq 1,1$	BORDERLINE
$IP_{sample} < 0,9$	NEGATIVE

Ascaris lumbricoides IgG

ELISA kit for the qualitative detection of IgG antibodies to *Ascaris lumbricoides*

Instructions for use



IVD

REF EI-601

Σ 96 tests

CE

EQUI Ascaris lumbricoides IgG

ELISA kit for the qualitative detection of
IgG antibodies to *Ascaris lumbricoides*

1. INTENDED USE

The «EQUI Ascaris lumbricoides IgG» is ELISA kit intended to qualitatively detect anti-*Ascaris lumbricoides* IgG in human serum or plasma by enzyme-linked immunosorbent assay (ELISA) in order to diagnose lumbricosis. The testing procedure is designed for both manual arrangement with automatic pipettes and standard equipment, and for automated «open» immunoassay analysers.

Target group: children, rural people, summer visitors.

Usage: ELISA kit is used in clinical diagnostic laboratories and other institutions engaged in *in vitro* diagnostics.

2. CLINICAL SIGNIFICANCE

Ascaris lumbricoides is a human parasite resulting in lumbricosis — one of the most common helminthiases in the world. By some estimates, over a milliard of people infested with acaricides are on earth.

Human ascaris belongs to *Nematoda* roundworms infesting the small intestine of a man who is its exclusive host. *Ascaris lumbricoides* eggs are excreted in the environment with faeces of the infested man. In a warm, wet soil, ascaris larvae develops in the eggs, therefore eggs become invasive only after a maturation period (2 to 3 weeks at 25–30 °C, lower temperatures require longer term). After infestation, larvae leave eggs in the human intestine, penetrates blood circulation and migrate to the liver and lungs with blood flow. The larvae move to the pharynx from the lungs, and here they are re-ingested and further enter the small intestine. In 2 to 3 months, adult ascaris able to propagate develops from larvae in the small intestine.

The helminths are transferred by faecal-oral route upon injection of mature eggs of *Ascaris lumbricoides* with soil-contaminated vegetables, fruits, water, as well as through dirty hands after contact with soil. Lumbricosis is conditionally divided into the early stage (migration of larvae) and late stage (parasitism of adults in the intestine). Invasion is asymptomatic in most cases. Primary feeling of being unwell occurs as early as several days after infestation and is accompanied by weakness, abdominal pain, nausea. Migration of larvae to the lungs may manifest as rales and cough. In some cases, intense invasion may result in pneumonia and liver damage. However, the most common symptom of early lumbricosis are allergic reactions due to hypersensitivity to metabolic products of larvae.

Late stage manifests as decreases appetite, abdominal pain, vomiting, diarrhoea, constipation. Massive ascaris invasion may result in the intestinal obstruction with a lump of helminths or rupture of the walls with peritonitis. When ascarides penetrate other organs, complications may develop such as

hepatitis, cholangitis, pancreatitis and even asphyxia. Cases of neurological disorders sometimes develop in lumbricosis, namely: headache, irritability, sleep impairment, inattention, etc. If no timely treatment is started for intense invasion, it may lead to death, especially in younger children.

Strong immune response to *Ascaris lumbricoides* invasion develops as early as at the early stage. It includes cellular and humoral immunity. Antigens of ascaris larvae stimulate secretion of all-class specific immunoglobulins, however, the level of specific and total IgE antibodies is the highest. The intensity of the immune response (including increased IgG titres) correlates with the massiveness of the invasion.

For diagnosis of lumbricosis, parasitologic stool test for presence of ascaris larvae and eggs is the most common. X-ray imaging of the lungs is additionally applied at the early stage of invasion. Complete blood count (eosinophilia develops in lumbricosis) and detection of serum anti-*Ascaris lumbricoides* antibodies also is included in the set of exams. The presence of specific anti-ascaris antibodies may suggest asymptomatic invasion, and allows initiation of treatment before complications develop in conjunction with other diagnostic instruments.

3. ANALYSIS PRINCIPLE

The procedure of testing for anti-*Ascaris lumbricoides* IgG in «EQUI Ascaris lumbricoides IgG» ELISA kit is based on «indirect» solid-phase ELISA with a two-stage incubation. Antigens of *Ascaris lumbricoides* larvae are entrapped in the wells. During the first step of incubation of ELISA plate wells with test samples, specific anti-*Ascaris lumbricoides* antibodies (if present in the samples) bind to the solid-phase antigens. The wells are washed to remove unbound antibodies and have only specific antigen-antibody complexes left. Then, a conjugate of anti-species IgG monoclonal antibodies with horseradish peroxidase is added, which binds to solid-phase immune complexes. Unbound components are removed by washing. Antigen-antibody complexes are detected by adding a solution of chromogen 3,3',5,5'-tetramethylbenzidine (TMB) with hydrogen peroxide. After 30-minute incubation, the reaction is stopped by adding the stop solution. The optical density (OD) in the wells is determined using a spectrophotometer at 450/620-695 nm. The intensity of the yellow colour is proportional to the level of antibodies in the sample.

4. MATERIALS AND EQUIPMENT

4.1. Contents of the ELISA kit

STRIPS	1 x 96 wells	**Microplate** Each plate well is coated with *Ascaris lumbricoides* antigen. The wells are detachable. After the first opening, store unused strips in the package at 2-8 °C for a maximum of 6 months

CONTROL +	1 x 0,25 ml	**Positive control** Conjugated specific monoclonal antibody solution with preservative (pink). Store at 2-8 °C
CONTROL -	1 x 0,6 ml	**Negative control** Negative human serum with a preservative (yellow). Store at 2-8 °C
DIL SAMPLE	1 x 13 ml	**Serum dilution solution** Buffer solution with a milk extract, a detergent and a preservative (brown). Store at 2-8 °C
SOLN CONJ	1 x 13 ml	**Conjugate solution (ready to use)** Buffer solution of monoclonal antibodies to human IgG, conjugated with horseradish peroxidase, with stabilizers and preservative (green). Store at 2-8 °C
SOLN TMB	1 x 13 ml	**TMB solution (ready to use)** TMB solution, H_2O_2, a stabilizer, a preservative (colourless). Store at 2-8 °C
TWEEN WASH 20x	1 x 50 ml	**Washing solution TWEEN (20x concentrated)** 20-fold phosphate buffer concentrate with Tween-20 (colourless). Dilute TWEEN detergent (20x) at 1:20 with distilled or deionized water (e. g., 5 mL of concentrate + 95 mL of water for 8 wells) before use. Store the diluted solution at 2-8 °C for a maximum of 7 days
SOLN STOP	1 x 13 ml	**Stop Solution (ready to use)** 0.5 mol H_2SO_4 solution (colourless). Store at 2-8 °C

The ELISA kit also includes adhesive films (2 items), sample application plan (1 item), checklist, and instruction for use.

4.2. Optional reagents, materials and equipment

Automatic single and multichannel pipettes 10–1000 µL, tips, volumetric laboratory glassware (10–1,000 mL), deionized or distilled water, thermostat at 37 °C, automatic or semi-automatic plate washer, spectrophotometer (reader) for microplates at 450/620-695 nm, appropriate containers for potentially contaminated waste, timer, filter paper, disposable powder-free gloves, disinfectants.

5. PRECAUTIONS AND SAFETY

5.1. Precautions

Be sure to read the instructions for use carefully before the test. The validity of the test results depends on strict following of the test procedure.

– do not use the ELISA kit components after the expiry date;
– do not use for analysis or mix components of different batches, components of kits for different nosologies, or reagents from other manufacturers with the «EQUI Ascaris lumbricoides IgG» ELISA kit;
– do not freeze the ELISA kit or its contents;
– after using a reagent, close each vial with its cap;

– when washing, control filling and complete aspiration of solution from the wells;
– use a new pipette tip each time you add samples or reagents;
– prevent direct sunlight from reaching the reagents from the ELISA kit;
– SOLN TMB solution must be colourless before use. Do not use the solution if its colour is blue or yellow. Avoid contact of SOLN TMB with metals or metal ions. Use only clean glassware thoroughly rinsed with distilled water;
– do not use reagents with colour not in line with para. 4.1;
– under no circumstances should the same glassware be used for SOLN CONJ and SOLN TMB;
– do not evaluate the test results visually (without a reader);
– any optional equipment that is in direct contact with biological material or kit components should be considered contaminated and requires cleaning and decontamination;
– the ELISA kit includes materials for 96 tests. Dispose of the used components as well as any remaining unused components.

5.2. Safety requirements

– all reagents in the ELISA kit are for laboratory professional use for *in vitro* diagnosis only and may only be used by qualified personnel;
– conduct the tests in disposable powder-free gloves and goggles only;
– do not eat, drink, smoke, or apply make-up in the test room;
– do not mouth-pipette the solutions;
– controls from the «EQUI Ascaris lumbricoides IgG» ELISA kit have been tested and found to be for anti-HIV1/2, anti-HCV and anti-*Treponema pallidum* antibodies and HBsAg negative; however, controls and test samples should be handled as potentially hazardous infectious materials;
– some of the kit components contain low concentrations of harmful substances and can damage skin or mucoga. In case of contact of SOLN TMB, SOLN STOP and SOLN CONJ with mucous membranes or skin, immediately wash the affected area with plenty of water;
– in case of spillage of acid-free solutions, e. g. sera, treat the surface with a disinfectant solution and then wipe dry with filter paper. Otherwise first neutralize acid with sodium bicarbonate solution and then wipe the surface dry as described above.

5.3. Waste inactivation and disposal

– the liquid waste must be inactivated, for example, with hydrogen peroxide solution at the final concentration of 6% for 3 hours at room temperature, or with sodium hypochlorite at the final concentration of 5% for 30 minutes, or with other approved disinfectants;
– the solid waste must be inactivated by autoclaving at a temperature not less than 132°C;

– do not autoclave the solutions that contain sodium azide or sodium hypochlorite;
– disposal of inactivated waste must be conducted due to national laws and regulations.

6. STORAGE AND STABILITY

ELISA kit is stable up to the expiry date stated on the label when stored at 2-8°C. The kit should be transported at 2-8°C. Single transportation at a temperature up to 23°C for two days is possible.

7. SAMPLE COLLECTION, TRANSPORTATION AND STORAGE GUIDELINES

Collect blood from the vein into the sterile test tube. Test tube must be marked with patient ID and date of sample collecting. Blood before serum separation can be stored at 2-8 ºC for 24 hours, avoiding freezing.

Serum or plasma can be stored at 2-8 °C for maximum 3 days. Frozen serum can be stored for longer periods of time at -20 °C or -70 °C. Thaw frozen samples and keep them at room temperature for 30 minutes before use. After thawing, the stir samples to achieve homogeneity. Avoid repeated freezing-thawing cycles for test samples. If serum (or plasma) is turbid, remove insoluble inclusions by centrifugation at 3000 rpm for 10-15 minutes. Do not use serum samples with hyperlipidemia, hemolysis, and bacterial growth.

Transport serum samples in insulated containers. To do that, put closed labelled tubes in a plastic bag, tightly seal it and place in the centre of an insulated container.Put the frozen cold packs on the bottom, along the side walls of the insulated container and on top of the serum samples.

8. REAGENT PREPARATION

NOTE! It is very important to keep all ELISA kit components for at least 30 min at room temperature 18-25 ºC before the assay!

8.1. Microplate preparation

To prevent water condensation in the wells, keep the STRIPS for 30 minutes at a room temperature before opening. Open the vacuum pack, detach the appropriate number of wells, and carefully pack the remaining wells with a desiccant and store tightly zip-locked at 2-8 °C. Storing the packed plate this way ensures its stability for 6 months.

8.2. Washing solution preparation

To prepare detergent, dilute TWEEN WASH 20x at 1:20 (1+19) with distilled or deionized water and stir. E. g., 5 mL of concentrate + 95 mL of water, which is enough for 8 wells. If there are crystals present in the detergent concentrate, heat the vial at 37 °C until the crystals dissolve completely (15–20 minutes). Store the diluted solution at 2-8 °C for a maximum of 7 days.

9. ASSAY PROCEDURE

9.1. Prepare the necessary number of wells (four wells for controls and a necessary number of wells for test samples) and insert them into the ELISA plate frame. Be sure to add control wells in every test run.

9.2. Fill in the sample application plan.

9.3. Prepare the detergent as per para. 8.2.

9.4. Add 90 µL of DIL SAMPLE into each plate well.

9.5. Add 10 µL of controls and test samples into the wells:
CONTROL + – into well A1,
CONTROL - – into wells B1, C1 and D1,
and test samples into the remaining wells.
At the time of adding, the solution changes its colour from brown to blue. Pipette the mix in the wells carefully to avoid foaming.

9.6. Cover the strips up with adhesive film and incubate for **30 minutes at 37 °C**.

9.7. Remove and discard the adhesive film and wash all wells 5 times with automatic washer or 8-channel pipette as follows:
– aspirate the content of all wells into a liquid waste container;
– add a minimum of 300 µl of diluted washing solution to each well, soak each well for 30 seconds;
– aspirate the content of all wells again. The residual volume after every aspiration should be less than 5 µl;
– repeat the washing step 4 more times;
– after the final aspiration, eliminate extra moisture by tapping the plate against a piece of filter paper.

9.8. Add 100 µL of SOLN CONJ into each well. Cover the strips with a new piece of adhesive film and incubate for **30 minutes at 37 °C**.

9.9. Following incubation, remove the film carefully and wash the wells five times as described in para. 9.7.

9.10. Add 100 µL of SOLN TMB into the wells; do not touch the bottom and the walls of the plate wells.

9.11. Incubate the strips for **30 minutes** in a dark place at a room temperature of 18-25 °C. Do not use adhesive film at this stage.

9.12. Add 100 µL of SOLN STOP into each strip well to stop the enzymatic reaction; adhere to the same sequence of actions as when adding SOLN TMB. At the time of adding, the solution colour changes from blue to yellow, and clear solution slightly changes its shade.

9.13. Measure the optical density (OD) of the wells at 450/620-695 nm wavelength using an ELISA microplate reader within 5 minutes after stopping the reaction. Pay attention to the cleanness of the plate bottom and the absence of bubbles in the wells before reading.

Measurement at the single wavelength of 450 nm is possible, in that case, it is needed to leave one well for blank (only SOLN TMB and SOLN STOP must be added

in blank well).

10. CALCULATION AND INTERPRETATION OF RESULTS

10.1. Calculation of results

Calculate the average OD for the negative control ($\overline{Nc}$), Cut off (CO) and a sample positivity index (IP_{sample}).

$$\overline{Nc} = (Nc1 + Nc2 + Nc3)/3; \quad CO = \overline{Nc} + 0,3$$

$$IP_{sample} = OD_{sample}/CO, \text{ where } OD_{sample} \text{ is the OD sample.}$$

10.2. Quality control (assay validation)

The test results are considered valid if they meet the following requirements:

CONTROL + OD ≥ 1,0

CONTROL - OD ≤ 0,150

CONTROL - $\overline{Nc} \times 0,5 \leq Ncn \leq \overline{Nc} \times 2,0$ where Ncn is the OD for each Nc run

If any of the OD values for the negative control is beyond the above interval, it should be discarded, and $\overline{Nc}$ is calculated based on the remaining OD values for the negative control. If several OD values for the negative control fail to meet the above requirements, the test is considered invalid and requires a new run.

10.3. Interpretation of results

$IP_{sample} > 1,1$	POSITIVE
$0,9 \leq IP_{sample} \leq 1,1$	BORDERLINE*
$IP_{sample} < 0,9$	NEGATIVE

* Uncertain samples are recommended to be re-examined in two wells of the ELISA kit. If the results are again uncertain, a new sample should be selected and analyzed in 2-4 weeks. In case of repeated indeterminate results, such samples shall be considered negative.

11. PERFORMANCE CHARACTERISTICS

11.1. Analytical performance characteristics

Precision of measurement

Intra assay repeatability

The coefficient of variation (CV) for three sera with different levels of specific antibodies was evaluated in 24 replicates on one series of ELISA kits.

Sample No.	OD_{av}	IP_{av}	CV, %
547	0,504	1,43	2,9
671	0,753	2,13	3,6
413	1,165	3,30	3,1

Inter assay reproducibility

The coefficient of variation (CV) for three sera with different levels of specific antibodies was evaluated for 4 days in 4 sets of analysis, 8 replicates in each analysis.

Sample No.	OD_{av}	IP_{av}	CV, %
547	0,534	1,55	5,0
671	0,750	2,17	4,6
413	1,159	3,36	3,6

Analytical specificity

The test results are not affected by bilirubin at up to 0.21 mg/mL (361.8 μmol/L), haemoglobin at up to 10 mg/mL and triglycerides at up to 10 mg/mL (11.3 mmol/l) present in the sample.

11.2. Diagnostic characteristics

To evaluate clinical sensitivity and specificity of «EQUI Ascaris lumbricoides IgG» ELISA kits, 55 serum samples from patients with clinical symptoms typical for lumbricosis and 60 serum samples from patients without clinical manifestations (seronegative in terms of *Ascaris lumbricoides*) were used. Clinical sensitivity of «EQUI Ascaris lumbricoides IgG» ELISA kits was 94.55 % and clinical specificity — 93.3 %.

Method characteristics in comparison with equal commercial ELISA kit was studied in target paediatric population (160 samples) and population of donors (346 samples). For paediatric population serum, relative specificity of «EQUI Ascaris lumbricoides IgG» ELISA kits was established at the level of 97.92 % and percent agreement was 95.51 %. For donor population serum, relative specificity of was 89.74 %, relative specificity — 96.30 % and percent agreement was 95.47 %.

12. LIMITATIONS OF ASSAY

Positive result in «EQUI Ascaris lumbricoides IgG» ELISA kit supports presence of anti-*Ascaris lumbricoides* specific IgG antibodies. Presence of this class antibodies in newborns is not an evidence of *Ascaris lumbricoides* invasion.

Inconclusive results may suggest a history of *Ascaris lumbricoides* invasion.

Negative result of «EQUI Ascaris lumbricoides IgG» ELISA kit supports the absence of anti- *Ascaris lumbricoides* IgG specific antibodies in the test sample or concentration of specific antibodies is below the sensitivity limit of the assay.

The results of serological test only are not the basis for final diagnosis. When establishing the diagnosis, the results of complex laboratory and instrumental tests, as well as clinical manifestations should be considered. Cross-reactions with antibodies to antigens of other helminths cannot be fully ruled out.

13. DIFFICULTIES THAT CAN OCCUR DURING THE ASSAY PROCEDURE

Possible reasons	Solution
High background in all wells	
Contaminated washer	Clean the washer head and rinse according to the instructions for use
Poor quality or contaminated water	Use purified water with specific resistance ≥ 10 MΩ · cm
Use of poorly washed glassware	Use chemically clean utensils
Use of chlorinated disinfectants	Do not use chlorine disinfectants
Use of contaminated tips	Use new tips
Increased incubation times or change in the temperature conditions	Adhere to the incubation regime according to the instructions for use
High background in a row of wells	
Repeat application of TMB solution	TMB solution should be applied once
Contamination of the automatic pipette nozzle with conjugate solution	Clean the pipette and dial carefully liquid
Contamination of one of the washer's channel	Clean the flush channel, rinse washer
Received OD of the positive control is below the border value	
One of the reagents (conjugate solution or TMB solution) was not prepared in a correct way or was not added	Re-conduct ELISA, pay attention to the correctness of the introduction of these reagents
Reduced incubation times at any stage	Incubate according to instructions for use
The colour density of the wells fails to meet the obtained optical density value	
This may suggest that the optical beam has been displaced	Check the correct operation of the reader

14. TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

In case of technical problems, you can obtain assistance by contacting the manufacturer.

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	Manufacturer
	Authorized Representative in the European Community
	In vitro diagnostic medical device
	Catalogue number
	Date of manufacture
	Use by date
	Batch code
	Temperature limit
	Contains sufficient for <n> tests
	Caution
	Non-Sterile
	Consult instructions for use
	Keep away from sunlight
	Keep dry
	Compliance with EU safety requirements

Edition 8, 10.02.2022

For questions and suggestions regarding the ELISA kit contact:

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ASSAY PROCEDURE SCHEME

Keep all reagents for 30 min at temperature18-25°C before use
Dispense 90 µl DIL SAMPLE into the wells (brown)
Add to 10 µl of controls and samples into the wells: A1 – CONTROL +, B1, C1, D1 – CONTROL –, other wells – examined samples (change of colour from brown to blue)
Cover strips with an adhesive film, incubate for **30 min at 37°C**
Rinse the wells 5 times with prepared 1:20 (1+19) washing solution TWEEN (300 µl per well)
Add 100 µl of SOLN CONJ into all wells (green)
Cover strips with an adhesive film, incubate for **30 min at 37°C**
Rinse the wells 5 times with prepared 1:20 (1+19) washing solution TWEEN (300 µl per well)
Add 100 µl of SOLN TMB into all wells
Incubate for **30 min** in the dark at **18-25°C**
Add 100 µl of SOLN STOP into all wells (change of colour from blue to yellow)
Measure the optical density (OD) with an ELISA microplate reader at 450/620-695 nm

CALCULATION OF RESULTS

$\overline{Nc} = (Nc1 + Nc2 + Nc3)/3;$

$CO = \overline{Nc} + 0,3;$

$IP_{sample} = OD_{sample}/CO$

$\overline{Nc}$ - the average value of OD 3-x CONTROL –

CO - Cut off

IP_{sample} - sample positivity index

INTERPRETATION OF RESULTS

$IP_{sample} > 1,1$	POSITIVE
$0,9 \leq IP_{sample} \leq 1,1$	BORDERLINE
$IP_{sample} < 0,9$	NEGATIVE

Certificate number: 2022-IVDD/CE382

Certificate of CE-Notification

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, **CEpartner4U BV** agrees to perform all duties and responsibilities as the Authorized Representative for

Monocent Inc.
9237 Eton Ave.,
Chatsworth, CA 91311
United States

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have accepted the manufacturer's medical device registrations by CEpartner4U as listed on the product list attached to the manufacturer's Declaration of Conformity:

IVD devices were registered with the Dutch Competent Authority with registration number:

IVD Devices groups:	Registration number:
CLIA Test Kits	NL-CA002-2020-50897
ELISA Test Kits	NL-CA002-2020-50898
IFA Test Kits	NL-CA002-2020-50899
Instruments	NL-CA002-2020-50900
PCR Test Kits	NL-CA002-2020-50901
Rapid Tests	NL-CA002-2020-50902
Serology Test Kits	NL-CA002-2020-50903

see appendix

The manufacturer has provided CEpartner4U with all necessary documentation, together with an appropriate Declaration of Conformity that the IVD medical devices fulfil the essential requirements of Directive 98/79/EC.

Issue date: 2022-10-31

This Certificate of CE-Notification is valid until May 26, 2025

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Appendix

List of devices.

CLIA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Allergy Assays					
IgE	CL3-5055	Low Risk	C	30275	2020-04-14
Thyroid Assays					
T3	CL3-5028	Low Risk	C	30312	2020-04-14
T4	CL3-5029	Low Risk	C	30314	2020-04-14
TSH	CL2-5030	Low Risk	C	30318	2020-04-14
T3 Uptake	CL3-5072	Low Risk	C	30313	2020-04-14
FT3	CL3-5026	Low Risk	C	30309	2020-04-14
FT4	CL3-5027	Low Risk	C	30308	2020-04-14
Tg (Thyroglobulin)	CL3-5073	Low Risk	C	30490	2020-04-14
TBG	CL3-5074	Low Risk	C	30316	2020-04-14
Anti-Tg	CL3-5075	Low Risk	C	30490	2020-04-14
Anti-TPO	CL3-5076	Low Risk	C	30317	2020-04-14
Ultra-Sensitive TSH	CL2-5077	Low Risk	C	30318	2020-04-14
Fertility Assays					
LH	CL3-5006	Low Risk	C	38965	2020-04-14
FSH	CL3-5004	Low Risk	C	30322	2020-04-14
Prolactin	CL3-5008	Low Risk	C	30325	2020-04-14
hCG	CL2-5005	Low Risk	B	30513	2020-04-14
AMH	CL3-5069	Low Risk	C	43148	2020-04-14
Beta hCG	CL2-5055	Low Risk	B	30332	2020-04-14
HGH	CL3-5007	Low Risk	C	30333	2020-04-14
PAPP-A	CL3-5068	Low Risk	C	31533	2020-04-14
Diabetes Assays					
Insulin	CL2-5003	Low Risk	C	30338	2020-04-14
C-peptide	CL2-5002	Low Risk	C	30336	2020-04-14
Tumor Markers Assays					
AFP	CL3-5031	Low Risk	C	30295	2020-04-14
CEA	CL3-5036	Low Risk	C	30288	2020-04-14
Free Beta hCG	CL2-5037	Low Risk	C	30333	2020-04-14
Beta 2 Microglobulin	CL2-5032	Low Risk	C	30296	2020-04-14
NSE	CL2-5039	Low Risk	C	30301	2020-04-14
CA-12-5	CL3-5034	Low Risk	C	30283	2020-04-14
CA-19-9	CL2-5035	Low Risk	C	30280	2020-04-14
CA-15-3	CL2-5033	Low Risk	C	30279	2020-04-14
Ferritin	CL3-5001	Low Risk	C	30377	2020-04-14
Cyfra21-1	CL2-5079	Low Risk	C	44431	2020-04-14
Pro-GRP	CL2-5080	Low Risk	C	44438	2020-04-14
PAP	CL2-5081	Low Risk	C	34226	2020-04-14
Steroid Assays					
Progesterone	CL3-5021	Low Risk	C	30294	2020-04-14
Estradiol	CL3-5016	Low Risk	C	30321	2020-04-14
Testosterone	CL3-5022	Low Risk	C	30327	2020-04-14

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CLIA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Free Testosterone	CL9-5023	Low Risk	C	30327	2020-04-14
Testosterone (Saliva)	CL9-5025	Low Risk	C	30327	2020-04-14
5a-Androstane-3a, 17b-diol Glucuronide (3a- Diol G)	CL9-5009	Low Risk	C	31533	2020-04-14
17 OH Progesterone	CL3-5010	Low Risk	C	30324	2020-04-14
Androstenedione	CL3-5070	Low Risk	C	30319	2020-04-14
Aldosterone	CL3-5011	Low Risk	C	31428	2020-04-14
Cortisol	CL3-5012	Low Risk	C	31394	2020-04-14
DHEA	CL3-5013	Low Risk	C	39894	2020-04-14
DHEA-S	CL3-5014	Low Risk	C	39894	2020-04-14
uE3	CL3-5041	Low Risk	C	30330	2020-04-14
Estriol (Saliva)	CL9-5018	Low Risk	C	30329	2020-04-14
Estrone (Saliva)	CL9-5019	Low Risk	C	33293	2020-04-14
Estrone	CL3-5020	Low Risk	C	33293	2020-04-14
Plasma Renin Activity (PRA)	CL9-5024	Low Risk	C	43444	2020-04-14
SHBG	CL3-5071	Low Risk	C	30326	2020-04-14
Procalcitonin	CL3-5067	Low Risk	C	12069016	2020-04-14
Infectious Disease Assays					
Digoxin	CL3-5059	Low Risk	C	30386	2020-04-14
hs-CRP	CL2-5060	Low Risk	C	30499	2020-04-14
CK-MB	CL3-5061	Low Risk	C	30499	2020-04-14
Myoglobin	CL3-5062	Low Risk	C	30264	2020-04-14
cTn I	CL2-5063	Low Risk	C	30266	2020-04-14
Bone Metabolism					
ACTH	CL3-5017	Low Risk	C	39005	2020-04-14
Calcitonin	CL3-5064	Low Risk	C	30342	2020-04-14
PTH	CL3-5065	Low Risk	C	30353	2020-04-14
Vitamin D	CL3-5066	Low Risk	C	30350	2020-04-14
Autoimmune Disease					
Cardiolipin IgA	CL2-5051	Low Risk	C	30475	2020-04-14
Cardiolipin IgG	CL2-5052	Low Risk	C	30475	2020-04-14
Cardiolipin IgM	CL2-5053	Low Risk	C	30475	2020-04-14
ds-DNA	CL2-5054	Low Risk	C	30458	2020-04-14
RF IgM	CL2-5114	Low Risk	C	30500	2020-04-14
B2GP1 IgA	CL2-5115	Low Risk	C	30478	2020-04-14
B2GP1 IgG	CL2-5116	Low Risk	C	30478	2020-04-14
B2GP1 IgM	CL2-5117	Low Risk	C	30478	2020-04-14
Thyroglobulin IgG	CL2-5118	Low Risk	C	30315	2020-04-14
Anti-CCP	CL2-5119	Low Risk	C	44202	2020-04-14
Anemia Assays					
Folate	CL3-5056	Low Risk	C	30378	2020-04-14
Vitamin B12	CL3-5057	Low Risk	C	30384	2020-04-14
Transferrin Soluble Receptor (sTfR)	CL3-5058	Low Risk	C	30253	2020-04-14
NeoNatal Assays					
Neonatal TSH	CL2-5078	Low Risk	C	30310	2020-04-14

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CLIA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Infectious Disease Assays					
H. pylori IgA	CL2-5048	Low Risk	B	30691	2020-04-14
H. pylori IgG	CL2-5049	Low Risk	B	30691	2020-04-14
H. pylori IgM	CL2-5050	Low Risk	B	30691	2020-04-14
H. pylori IgG (Quantitative)	CL2-5082	Low Risk	B	30691	2020-04-14
H. pylori Antigen	CL2-5083	Low Risk	B	30691	2020-04-14
EBV VCA IgA	CL2-5084	Low Risk	D	30809	2020-04-14
EBV VCA IgG	CL2-5085	Low Risk	D	30809	2020-04-14
EBV VCA IgM	CL2-5086	Low Risk	D	30809	2020-04-14
EBV EA-D IgA	CL2-5087	Low Risk	D	30809	2020-04-14
EBV EA-D IgG	CL2-5088	Low Risk	D	30809	2020-04-14
EBV EA-D IgM	CL2-5089	Low Risk	D	30809	2020-04-14
EBNA IgA	CL2-5090	Low Risk	D	30808	2020-04-14
EBNA IgG	CL2-5091	Low Risk	D	30808	2020-04-14
EBNA IgM	CL2-5092	Low Risk	D	30808	2020-04-14
Measles IgG	CL2-5093	Low Risk	C	44019	2020-04-14
Measles IgM	CL2-5094	Low Risk	C	44019	2020-04-14
VZV IgG	CL2-5095	Low Risk	C	44027	2020-04-14
VZV IgM	CL2-5096	Low Risk	C	44027	2020-04-14
Mumps IgG	CL2-5097	Low Risk	C	33908	2020-04-14
Mumps IgM	CL2-5098	Low Risk	C	33908	2020-04-14
Dengue IgG	CL2-5099	Low Risk	C	32481	2020-04-14
Dengue IgM	CL2-5100	Low Risk	C	32481	2020-04-14
HSV 1/2 IgG	CL2-5101	Low Risk	C	40176	2020-04-14
HSV 1/2 IgM	CL2-5102	Low Risk	C	40176	2020-04-14
HSV 1 IgA	CL2-5103	Low Risk	C	38870	2020-04-14
HSV 1 IgG	CL2-5104	Low Risk	C	38870	2020-04-14
HSV 1 IgM	CL2-5105	Low Risk	C	38870	2020-04-14
HSV 2 IgA	CL2-5106	Low Risk	C	38875	2020-04-14
HSV 2 IgG	CL2-5107	Low Risk	C	38875	2020-04-14
HSV 2 IgM	CL2-5108	Low Risk	C	38875	2020-04-14

ELISA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Allergy					
Total Human IgE	EL1-1000, EL2-1000	Low Risk	B	30275	2020-04-14
Human Specific IgG	EL15-1001	Low Risk	C	44211	2020-04-14
Human Specific IgG4	EL15-1002	Low Risk	C	44211	2020-04-14
Histamine	EL30-1003	Low Risk	C	30274	2020-04-14
Anemia					
Vitamin B12	EL1-1007	Low Risk	B	30384	2020-04-14
Folate	EL1-1005	Low Risk	B	30378	2020-04-14
sTfR-Transferrin Soluble Receptor	EL3-1006	Low Risk	B	30253	2020-04-14
Ferritin	EL1-1004	Low Risk	B	30377	2020-04-14

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Hepcidin	EL1-1008	Low Risk	B	12070190	2020-04-14
Autoimmune Disease					
Anti-CCP	EL2-1011	Low Risk	B	44202	2020-04-14
Anti-CP IgG	EL20-1288	Low Risk	B	44202	2020-04-14
Beta 2 Glycoprotein 1 IgA	EL2-1017	Low Risk	B	30478	2020-04-14
Beta 2 Glycoprotein 1 IgG	EL2-1018	Low Risk	B	30478	2020-04-14
Beta 2 Glycoprotein 1 IgM	EL2-1019	Low Risk	B	30478	2020-04-14
Anti-Tissue Transglutaminase IgG	EL20-1015	Low Risk	C	44385	2020-04-14
Anti-Tissue Transglutaminase IgA	EL20-1014	Low Risk	C	44385	2020-04-14
ANA Screen IgG	EL1-1009	Low Risk	B	30454	2020-04-14
ENA IgG Profile-6	EL10-1024	Low Risk	B	30455	2020-04-14
ENA Screen IgG	EL20-1025	Low Risk	B	30455	2020-04-14
Rheumatoid Factor (RF) IgA	EL15-1034	Low Risk	B	30500	2020-04-14
Rheumatoid Factor (RF) IgG	EL15-1035	Low Risk	B	30500	2020-04-14
Rheumatoid Factor (RF) IgM	EL2-1038	Low Risk	B	30500	2020-04-14
Sm/RNP IgG	EL1-1040	Low Risk	B	30464	2020-04-14
Sm IgG	EL1-1041	Low Risk	B	17276	2020-04-14
Jo-1 IgG	EL21-1029	Low Risk	C	30461	2020-04-14
Scl-70 IgG	EL1-1039	Low Risk	B	30463	2020-04-14
SS-A (Ro)	EL1-1042	Low Risk	B	44202	2020-04-14
SS-B (La)	EL1-1043	Low Risk	B	44202	2020-04-14
dsDNA	EL1-1023	Low Risk	B	30458	2020-04-14
Cardiolipin IgG	EL1-1021	Low Risk	C	30475	2020-04-14
Cardiolipin IgM	EL1-1022	Low Risk	C	30475	2020-04-14
Cardiolipin IgA	EL1-1020	Low Risk	C	30475	2020-04-14
Cardiolipin Total Ab	EL1-1044	Low Risk	C	30475	2020-04-14
Mitochondrial Antibody (MA)	EL1-1031	Low Risk	C	30476	2020-04-14
Thyroglobulin Antigen (Anti-Tg)	EL3-1016	Low Risk	C	30315	2020-04-14
PR3 (c-ANCA)	EL20-1033	Low Risk	B	30484	2020-04-14
ANCA screen IgG	EL10-1010	Low Risk	B	30483	2020-04-14
MPO, Myeloperoxidase (p-ANCA)	EL20-1032	Low Risk	B	30483	2020-04-14
Gliadin IgG	EL36-1026	Low Risk	C	30480	2020-04-14
Gliadin IgA	EL36-1027	Low Risk	C	30480	2020-04-14
TPO	EL1-1012	Low Risk	C	30317	2020-04-14
Anti-Phospholipids Screen	EL20-1013	Low Risk	B	30582	2020-04-14
ASMA	EL29-1302	Low Risk	B	30274	2020-04-14
Beta-2-Glycoprotein IgA	EL2-1017	Low Risk	B	30478	2020-04-14
Beta-2-Glycoprotein IgG	EL2-1018	Low Risk	B	30478	2020-04-14
Beta-2-Glycoprotein IgM	EL2-1019	Low Risk	B	30478	2020-04-14
Tumor markers					
Prostatic Acid Phosphatase (PAP)	EL2-1289	Low Risk	C	34226	2020-04-14
Beta-2-Microglobulin	EL2-1277	Low Risk	C	30296	2020-04-14
AFP (Alpha Fetoprotein)	EL1-1276	Low Risk	C	43480	2020-04-14
CEA	EL1-1283	Low Risk	C	30288	2020-04-14
CA-15-3	EL1-1279	Low Risk	C	30279	2020-04-14
CA-12-5	EL1-1278	Low Risk	C	30283	2020-04-14

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CA-19-9	EL1-1280	Low Risk	C	30280	2020-04-14
NSE	EL2-1286	Low Risk	C	30301	2020-04-14
Free Beta HCG	EL1-1284	Low Risk	C	30333	2020-04-14
Pro-GRP (Gastrin-Releasing Peptide)	EL2-1290	Low Risk	C	44438	2020-04-14
Chromogranin A	EL1-1281	Low Risk	C	30289	2020-04-14
HE4	EL1-1306	Low Risk	C	30289	2020-04-14
Cyfra21-1	EL2-1034	Low Risk	C	30289	2020-04-14
Bone Metabolism					
Intact PTH	EL3-1048	Low Risk	C	30353	2020-04-14
25-OH Vitamin D	EL1-1045	Low Risk	B	30350	2020-04-14
ACTH	EL3-1046	Low Risk	C	39005	2020-04-14
Cardiac					
Digoxin	EL3-1051	Low Risk	C	30386	2020-04-14
CK-MB	EL3-1050	Low Risk	C	30499	2020-04-14
Troponin I	EL1-1054	Low Risk	C	30266	2020-04-14
Myoglobin	EL6-1053	Low Risk	C	30264	2020-04-14
C-Reactive Protein (CRP)	EL1-1049	Low Risk	C	30499	2020-04-14
Diabetes					
Insulin	EL1-1058	Low Risk	C	30338	2020-04-14
C-peptide	EL1-1055	Low Risk	C	30336	2020-04-14
Leptin	EL9-1059	Low Risk	B	12069017	2020-04-14
Adiponectin	EL9-1056	Low Risk	B	12069017	2020-04-14
(IGFBP-1) Insulin-Like Growth Factor Binding Protein-1	EL9-1057	Low Risk	B	42852	2020-04-14
Anti-GAD	EL8-1060	Low Risk	B	30340	2020-04-14
IAA	EL8-1061	Low Risk	B	30339	2020-04-14
IGF-1	EL8-1062	Low Risk	B	30361	2020-04-14
Pro-Insulin	EL1-1063	Low Risk	C	42852	2020-04-14
Fertility					
Human Growth Hormone (HGH)	EL1-1083	Low Risk	B	30333	2020-04-14
hCG Visual	EL6-1082	Low Risk	B	30513	2020-04-14
Beta hCG (Total)	EL2-1078	Low Risk	B	30332	2020-04-14
FSH	EL1-1080	Low Risk	B	31533	2020-04-14
LH	EL1-1084	Low Risk	B	38246	2020-04-14
Prolactin	EL1-1086	Low Risk	B	30325	2020-04-14
PAPP-A	EL3-1085	Low Risk	B	31533	2020-04-14
SHBG	EL3-1261	Low Risk	B	30326	2020-04-14
AMH	EL3-1079	Low Risk	B	43148	2020-04-14
hCG	EL1-1081	Low Risk	B	30332	2020-04-14
Sperm Ab	EL8-1087	Low Risk	B	30486	2020-04-14
Infectious Diseases					
Adenovirus IgG	EL15-1102	Low Risk	C	39468	2020-04-14
Adenovirus IgA	EL15-1101	Low Risk	C	39468	2020-04-14
Adenovirus IgM	EL15-1103	Low Risk	C	39468	2020-04-14
Influenza A IgA	EL15-1365	Low Risk	B	39463	2020-04-14
Influenza A IgG	EL15-1366	Low Risk	B	39463	2020-04-14

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Influenza A IgM	EL15-1367	Low Risk	B	39463	2020-04-14
Influenza B IgA	EL15-1368	Low Risk	B	39463	2020-04-14
Influenza B IgG	EL15-1369	Low Risk	B	39463	2020-04-14
Influenza B IgM	EL15-1370	Low Risk	B	39463	2020-04-14
Chikungunya IgG	EL4-1114	Low Risk	D	32481	2020-04-14
Chikungunya IgM	EL4-1113	Low Risk	D	32481	2020-04-14
COVID-19 IgA	EL45-1373	Low Risk	D	42994	2020-04-14
COVID-19 IgG	EL1-1360	Low Risk	D	42994	2020-04-14
COVID-19 IgM	EL1-1361	Low Risk	D	42994	2020-04-14
COVID-19 IgG	EL36-1360R	Low Risk	D	42994	2020-04-14
COVID-19 IgM	EL36-1361R	Low Risk	D	42994	2020-04-14
COVID-19 IgG	EL45-1360	Low Risk	D	42994	2020-04-14
COVID-19 IgM	EL45-1361	Low Risk	D	42994	2020-04-14
COVID-19 Total Ab	EL45-1379	Low Risk	D	42994	2020-12-06
Mycobacterium Tuberculosis (TB) IgA	EL15-1317	Low Risk	C	30635	2020-04-14
Mycobacterium Tuberculosis (TB) IgG	EL15-1201	Low Risk	C	30635	2020-04-14
Mycobacterium Tuberculosis (TB) IgM	EL15-1202	Low Risk	C	30635	2020-04-14
Herpes Simplex 1 IgG (HSV1 IgA)	EL2-1162	Low Risk	C	38870	2020-04-14
Herpes Simplex 1 IgG (HSV1 IgG)	EL1-1163	Low Risk	C	38870	2020-04-14
Herpes Simplex 1 IgM (HSV1 IgM)	EL1-1164	Low Risk	C	38870	2020-04-14
Herpes Simplex 2 IgG (HSV2 IgG)	EL1-1165	Low Risk	C	38875	2020-04-14
Herpes Simplex 2 IgM (HSV2 IgM)	EL1-1166	Low Risk	C	38875	2020-04-14
Herpes Simplex 1,2 IgG (HSV1,2 IgG)	EL1-1167	Low Risk	C	40176	2020-04-14
Herpes Simplex 1,2 IgM (HSV1,2 IgM)	EL1-1168	Low Risk	C	40176	2020-04-14
Epstein Barr Virus VCA IgA (EBV, VCA IgA)	EL2-1135	Low Risk	D	30809	2020-04-14
Epstein Barr Virus VCA IgG (EBV, VCA IgG)	EL1-1136	Low Risk	D	30809	2020-04-14
Epstein Barr Virus VCA IgM (EBV, VCA IgM)	EL1-1137	Low Risk	D	30809	2020-04-14
Epstein Barr Virus Early Antigen (EA) IgM	EL2-1134	Low Risk	D	30809	2020-04-14
Epstein Barr Virus Early Antigen (EA) IgG	EL2-1133	Low Risk	D	30809	2020-04-14
Epstein Barr Virus Early Antigen (EA) IgA	EL2-1132	Low Risk	D	30809	2020-04-14
Epstein Barr Virus Nuclear Antigen (EBNA) IgG	EL2-1130	Low Risk	D	30808	2020-04-14
Epstein Barr Virus Nuclear Antigen (EBNA) IgM	EL2-1131	Low Risk	D	30808	2020-04-14
Epstein Barr Virus Nuclear Antigen (EBNA) IgA	EL2-1129	Low Risk	D	30808	2020-04-14
Measles IgG	EL1-1177	Low Risk	C	44019	2020-04-14
Measles IgM	EL1-1178	Low Risk	C	44019	2020-04-14
Mumps IgG	EL1-1179	Low Risk	C	33908	2020-04-14
Mumps IgM	EL1-1180	Low Risk	C	33908	2020-04-14
Mycoplasma pneumonia IgG	EL1-1181	Low Risk	C	30657	2020-04-14
Mycoplasma pneumonia IgM	EL1-1182	Low Risk	C	30657	2020-04-14
Syphilis (TPA) IgG	EL1-1195	Low Risk	C	30685	2020-04-14
Syphilis (TPA) IgM	EL1-1197	Low Risk	C	30685	2020-04-14
Legionela urine Ag detection	EL16-1175	Low Risk	C	30692	2020-04-14
H. pylori IgG	EL1-1140	Low Risk	B	30691	2020-04-14
H. pylori IgA	EL1-1139	Low Risk	B	30691	2020-04-14
H-Pylori IgM	EL1-1141	Low Risk	B	30691	2020-04-14
H. pylori Antigen	EL2-1138,	Low Risk	B	30691	2020-04-14

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	EL32-1138				
Varicella-Zoster IgG	EL1-1209	Low Risk	C	44027	2020-04-14
Varicella-Zoster IgM	EL1-1210	Low Risk	C	44027	2020-04-14
HEV IgG	EL13-1156	Low Risk	C	30757	2020-04-14
HEV IgM	EL13-1161	Low Risk	C	30758	2020-04-14
HAV Ab	EL7-1142	Low Risk	C	30721	2020-04-14
HAV IgM	EL7-1143	Low Risk	C	30722	2020-04-14
HDV IgG	EL7-1153	Low Risk	D	30750	2020-04-14
HDV IgM	EL7-1155	Low Risk	D	30752	2020-04-14
HDV Ab	EL13-1315	Low Risk	D	30750	2020-04-14
HDV Ag	EL13-1316, EL7-1154	Low Risk	D	30747	2020-04-14
HTLV 1 + 2 Ab	EL7-1160	Low Risk	C	30789	2020-04-14
Lyme Disease IgG	EL10-1171	Low Risk	C	30697	2020-04-14
Lyme Disease IgM	EL10-1172	Low Risk	C	30697	2020-04-14
Lyme Disease IgG, M	EL10-1173	Low Risk	C	30697	2020-04-14
Bordetella Pertussis IgA	EL15-1110	Low Risk	C	37723	2020-04-14
Bordetella Pertussis IgG	EL15-1111	Low Risk	C	37723	2020-04-14
Bordetella Pertussis IgM	EL15-1112	Low Risk	C	37723	2020-04-14
RSV IgA	EL15-1186	Low Risk	B	30814	2020-04-14
RSV IgG	EL15-1187	Low Risk	B	30814	2020-04-14
RSV IgM	EL15-1188	Low Risk	B	30814	2020-04-14
Tetanus	EL5-1205	Low Risk	C	38876	2020-04-14
Diphtheria IgG	EL5-1124	Low Risk	D	33499	2020-04-14
Salmonella typhi IgG	EL1-1193	Low Risk	C	30709	2020-04-14
Salmonella typhi IgM	EL1-1194	Low Risk	C	30709	2020-04-14
Salmonella Antigen detection	EL4-1192	Low Risk	C	30709	2020-04-14
Anthrax IgG	EL1-1105	Low Risk	C	32481	2020-04-14
Babesia IgG	EL4-1109	Low Risk	C	32481	2020-04-14
Dengue IgM	EL5-1127	Low Risk	C	32481	2020-04-14
Dengue IgG/IgM	EL5-1125	Low Risk	C	32481	2020-04-14
Dengue IgG	EL5-1126	Low Risk	C	32481	2020-04-14
Dengue NS1 Antigen	EL4-1128	Low Risk	C	32481	2020-04-14
Japanese Encephalitis IgG	EL4-1169	Low Risk	C	44321	2020-04-14
Japanese Encephalitis IgM	EL4-1170	Low Risk	C	44321	2020-04-14
Leprosy IgG/IgM	EL4-1176	Low Risk	C	32481	2020-04-14
Parvovirus B19 IgG	EL30-1183	Low Risk	C	40443	2020-04-14
Parvovirus B19 IgM	EL30-1184	Low Risk	C	40444	2020-04-14
Rotavirus (fecal)	EL16-1185	Low Risk	C	30815	2020-04-14
Scrub Typhus IgG	EL4-1199	Low Risk	C	44028	2020-04-14
Scrub Typhus IgM	EL4-1200	Low Risk	C	44028	2020-04-14
TB IgA	EL15-1317	Low Risk	C	30635	2020-04-14
TB IgG	EL15-1201	Low Risk	C	30635	2020-04-14
TB IgM	EL15-1202	Low Risk	C	30635	2020-04-14
Zika Virus IgG	EL1-1203	Low Risk	C	32481	2020-04-14
Zika Virus IgM	EL1-1204	Low Risk	C	32481	2020-04-14

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West Nile IgG	EL4-1211	Low Risk	C	42926	2020-04-14
West Nile IgM	EL4-1212	Low Risk	C	42926	2020-04-14
Parasitology					
Schistosoma IgG	EL5-1227	Low Risk	C	30824	2020-04-14
Chagas	EL5-1213	Low Risk	D	30820	2020-04-14
Cysticercosis IgG (T. solium)	EL5-1220	Low Risk	B	39979	2020-04-14
Campylobacter	EL16-1229	Low Risk	B	33948	2020-04-14
E. coli 0157 Ag detection	EL16-1232	Low Risk	B	37727	2020-04-14
E. histolytica IgG (Amebiasis)	EL5-1221	Low Risk	B	39979	2020-04-14
E. histolytica Dispar	EL16-1233	Low Risk	B	39979	2020-04-14
Echinococcus IgG	EL5-1222	Low Risk	B	30822	2020-04-14
Fasciola IgG	EL5-1216	Low Risk	B	34068	2020-04-14
Fasciola gigantica	EL5-1217	Low Risk	B	34068	2020-04-14
Filaria IgG4	EL4-1218	Low Risk	B	34068	2020-04-14
Leishmania	EL5-1223	Low Risk	C	30823	2020-04-14
Leptospira IgG	EL5-1224	Low Risk	C	30716	2020-04-14
Leptospira IgM	EL5-1226	Low Risk	C	30716	2020-04-14
Leptospira IgG/IgM	EL5-1225	Low Risk	C	30716	2020-04-14
Toxocara IgG	EL5-1228	Low Risk	C	34068	2020-04-14
Trichinella IgG	EL5-1215	Low Risk	C	33379	2020-04-14
Ascaris IgG	EL5-1219	Low Risk	B	39979	2020-04-14
Strongyloides IgG	EL5-1214	Low Risk	C	34068	2020-04-14
Crypto/Giardia Ag detection	EL16-1230	Low Risk	B	30675	2020-04-14
Cryptosporidium Ag detection	EL16-1231	Low Risk	B	30675	2020-04-14
Giardia antigen	EL16-1235	Low Risk	B	36173	2020-04-14
Giardia coprpantigen in stool	EL5-1361	Low Risk	B	36173	2020-04-14
Anti-Giardia IgA ELISA in saliva	EL5-1362	Low Risk	B	36173	2020-04-14
Entamoeba histolytica coproantigen in stool	EL5-1363	Low Risk	B	39979	2020-04-14
Adenovirus Antigen	EL16-1104	Low Risk	C	41274	2020-04-14
Steroid					
Aldosterone	EL3-1247	Low Risk	C	31428	2020-04-14
Cortisol	EL1-1249	Low Risk	C	31394	2020-04-14
Aldosterone	EL3-1247	Low Risk	B	31428	2020-04-14
Cortisol	EL1-1249	Low Risk	C	31394	2020-04-14
Cortisol Saliva	EL9-1250	Low Risk	C	31394	2020-04-14
Estradiol	EL1-1254	Low Risk	B	30321	2020-04-14
DHEA-S	EL1-1251	Low Risk	C	30320	2020-04-14
DHEA	EL3-1252	Low Risk	C	39894	2020-04-14
Progesterone	EL1-1259	Low Risk	C	30323	2020-04-14
Progesterone Saliva	EL9-1260	Low Risk	C	30294	2020-04-14
Testosterone	EL1-1263	Low Risk	B	30327	2020-04-14
Testosterone Saliva	EL9-1265	Low Risk	B	30327	2020-04-14
Free Testosterone	EL1-1264	Low Risk	B	30327	2020-04-14
Androstenedione	EL1-1248	Low Risk	C	30321	2020-04-14
Free Estriol	EL1-1257	Low Risk	B	30330	2020-04-14
Dihydrotestosterones (DHT)	EL9-1253	Low Risk	C	30327	2020-04-14

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17-OH Progesterone	EL1-1245	Low Risk	C	30324	2020-04-14
5a-Androstane-3a, 17b-diol Glucuronide (3a- Diol G)	EL9-1246	Low Risk	C	31533	2020-04-14
Total Estrogen	EL9-1255	Low Risk	B	38858	2020-04-14
Estrone	EL3-1256	Low Risk	B	33293	2020-04-14
Pregnenolone	EL9-1258	Low Risk	B	33301	2020-04-14
Total Estriol	EL8-1266	Low Risk	B	30330	2020-04-14
Thyroid					
T3	EL1-1270	Low Risk	C	30314	2020-04-14
T4	EL1-1271	Low Risk	C	30312	2020-04-14
TSH	EL1-1273	Low Risk	C	30489	2020-04-14
U-TSH	EL6-1275	Low Risk	C	30489	2020-04-14
Free T4	EL1-1268	Low Risk	C	30308	2020-04-14
Free T3	EL1-1267	Low Risk	C	30309	2020-04-14
Reverse T3	EL9-1274	Low Risk	C	30311	2020-04-14
T Uptake	EL3-1269	Low Risk	C	30313	2020-04-14
Tg (Thyroglobulin)	EL1-1272	Low Risk	C	30490	2020-04-14
TBG (Thyroxine-Binding Globulin)	EL3-1262	Low Risk	C	30316	2020-04-14
Neo-Natal Panel					
Neo-Natal T4	EL1-1240	Low Risk	C	30273	2020-04-14
Neo-Natal TSH	EL1-1239	Low Risk	C	30310	2020-04-14
Neo-Natal TBG	EL3-1242	Low Risk	C	30316	2020-04-14
Neo-Natal 17-OH Progesterone	EL1-1236	Low Risk	C	30324	2020-04-14
Neo-Natal MSUD	EL1-1237	Low Risk	C	30273	2020-04-14
Neo-Natal PKU	EL1-1238	Low Risk	C	30273	2020-04-14
Neo-Natal IRT	EL1-1241	Low Risk	C	30273	2020-04-14
Neo-Natal Total Galactose	EL1-1243	Low Risk	C	30273	2020-04-14
G6PD	EL1-1303	Low Risk	C	30273	2020-04-14
Neo-Natal Biotinidase	EL1-1244	Low Risk	C	30273	2020-04-14
Others					
Procalcitonin	EL3-1309	Low Risk	C	12069016	2020-04-14
Calcitonin	EL3-1292	Low Risk	C	30342	2020-04-14
Renin	EL9-1300	Low Risk	B	43444	2020-04-14

IFA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Autoimmune Diseases and others					
ANA Rat Liver IFA Kit	IF17-4002, IF17-4019	Low Risk	C	41420	2020-04-14
ANA Mouse Kidney IFA Kit	IF17-4003	Low Risk	C	41420	2020-04-14
ANA Hep-2 IFA Kit	IF17-4004, IF17-4005, IF17-4018	Low Risk	C	17269	2020-04-14
AMA IFA Kit	IF17-4022, IF17-4023	Low Risk	C	17267	2020-04-14
AAS Rat Kidney Stomach Liver Tissue	IF17-4000	Low Risk	C	30274	2020-04-14

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IFA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
ASMA IFA Kit	IF17-4006, IF17-4015	Low Risk	C	30274	2020-04-14
ATA IFA Kit	IF17-4030, IF174031	Low Risk	C	30274	2020-04-14
ASA IFA Kit	IF17-4008, IF17-4034	Low Risk	C	30274	2020-04-14
nDNA IFA Kit	IF17-4007, IF17-4051, IF17-4052	Low Risk	C	30274	2020-04-14
Endomysial (Primate Endomysial)	IF17-4032, IF17-4033	Low Risk	C	12109016	2020-04-14
Anti-Reticulin IgA	IF17-4041, IF17-4042	Low Risk	C	30526	2020-04-14
Anti-Reticulin IgG	IF17-4043, IF17-4044	Low Risk	C	30526	2020-04-14
C-ANCA	IF17-4059	Low Risk	C	30484	2020-04-14
P-ANCA	IF17-4060	Low Risk	C	30483	2020-04-14
Bacterial Diseases					
Legionella pneumophila 1-6 IFA Poly (HT)	IF17-4063, IF17-4064	Low Risk	C	30694	2020-04-14
Legionella pneumophila 1-6/bdglmj/C Specimen	IF17-4061	Low Risk	C	30694	2020-04-14
Legionella pneumophila 1-6/bdglmj DFA Screen	IF17-4062	Low Risk	C	30694	2020-04-14
FTA-ABS Double Stain (Syphilis) IFA Kit	IF17-4013, IF17-4066	Low Risk	C	32455	2020-04-14
FTA-ABS (T. pallidum)	IF17-4012, IF17-4067	Low Risk	C	32455	2020-04-14
FTA-ABS (Syphilis) Titrable IFA Kit	IF17-4014	Low Risk	C	32455	2020-04-14
Viral diseases					
HSV-1 IgG IFA Kit	IF17-4016	Low Risk	C	39502	2020-04-14
HSV-2 IgG IFA Kit	IF17-4080	Low Risk	C	39502	2020-04-14
HSV-1 IgM IFA Kit	IF17-4017	Low Risk	C	39502	2020-04-14
HSV-2 IgM IFA Kit	IF17-4081	Low Risk	C	39502	2020-04-14
HSV 1&2 IgG	IF17-4078	Low Risk	C	39502	2020-04-14
HSV 1&2 IgM	IF17-4079	Low Risk	C	39502	2020-04-14
EBV-VCA IgG IFA Kit	IF17-4074	Low Risk	C	33971	2020-04-14
EBV-VCA IgM IFA Kit	IF17-4075	Low Risk	C	33971	2020-04-14
EBV-EA IFA Kit	IF17-4077	Low Risk	C	33971	2020-04-14
EBNA IFA Kit	IF17-4076	Low Risk	C	33971	2020-04-14
RMSF Rocky Mountain Spotted Fever (R. ricketsii)	IF17-4065	Low Risk	C	32473	2020-04-14
Measles IgG IFA Kit	IF17-4092	Low Risk	C	44019	2020-04-14
Measles IgM IFA Kit	IF17-4093	Low Risk	C	44019	2020-04-14
Mumps IgG IFA Kit	IF17-4094	Low Risk	C	33908	2020-04-14
Mumps IgM IFA Kit	IF17-4095	Low Risk	C	33908	2020-04-14
RSV IgG (Respiratory Syncytial Virus)	IF17-4096	Low Risk	C	30814	2020-04-14

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IFA Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
RSV IgM (Respiratory Syncytial Virus)	IF17-4097	Low Risk	C	30814	2020-04-14
Varicella-Zoster Virus IgG IFA Kit	IF17-4098	Low Risk	C	44027	2020-04-14
Varicella-Zoster Virus IgM IFA Kit	IF17-4099	Low Risk	C	44027	2020-04-14
West Nile Virus IgG	IF17-4100	Low Risk	C	42926	2020-04-14
West Nile Virus IgG	IF17-4101	Low Risk	C	42926	2020-04-14

RT-PCR	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
SARS-CoV-2	PR31-8000	Low Risk	D	42994	2020-04-14
SARS-CoV-2	PR4-8000	Low Risk	D	42994	2020-04-14
SARS-CoV-2 pap-PCR	PR45-8000	Low Risk	D	42994	2020-12-06
SARS-CoV-2/Flu/RSV RT-PCR	PR31-8001	Low Risk	D	42994	2020-12-06

Rapid Tests Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Tumor Markers Tests					
FOB Cassette	RT27-2182	Low Risk	C	38217	2020-04-14
FOB Strip	RT27-2181	Low Risk	C	38217	2020-04-14
CEA	RT27-2180	Low Risk	C	30288	2020-04-14
AFP	RT27-2179	Low Risk	C	30295	2020-04-14
Cardiac markers					
CK-MB Cassette (Serum/Plasma/Whole Blood)	RT27-2001	Low Risk	C	30499	2020-04-14
C-Reactive Protein (CRP) Cassette (Serum/Plasma/Whole Blood)	RT27-2003	Low Risk	C	30507	2020-04-14
C-Reactive Protein (CRP) Strip (Serum/Plasma/Whole Blood)	RT27-2002	Low Risk	C	30507	2020-04-14
D-Dimer Cassette (Plasma/Whole Blood)	RT27-2004	Low Risk	C	30576	2020-04-14
Myoglobin Cassette (Serum/Plasma/Whole Blood)	RT27-2005	Low Risk	C	30264	2020-04-14
Troponin I Cassette (Serum/Plasma/Whole Blood)	RT27-2007	Low Risk	C	30509	2020-04-14
3 in 1 Troponin I/Myoglobin/CKMB Cassette (Serum/Plasma/Whole Blood)	RT27-2006	Low Risk	C	42649	2020-04-14
Drug Test					
Alcohol Urine Strip	RT27-2010	Low Risk	B	30443	2020-04-14
Alcohol Saliva Strip	RT27-2009	Low Risk	B	30443	2020-04-14
Amphetamine Urine Cassette	RT27-2012	Low Risk	C	30516	2020-04-14
Amphetamine Urine Strip	RT27-2011	Low Risk	C	30516	2020-04-14
Barbiturates Urine Cassette	RT27-2014	Low Risk	C	30517	2020-04-14
Barbiturates Urine Strip	RT27-2013	Low Risk	C	30517	2020-04-14
Buprenorphine Urine Cassette	RT27-2016	Low Risk	C	31584	2020-04-14
Buprenorphine Urine Strip	RT27-2015	Low Risk	C	31584	2020-04-14
Benzodiazepine Urine Cassette	RT27-2018	Low Risk	C	30518	2020-04-14
Benzodiazepine Urine Strip	RT27-2017	Low Risk	C	30518	2020-04-14
Cocaine Urine Cassette	RT27-2022	Low Risk	C	30520	2020-04-14
Cocaine Urine Strip	RT27-2021	Low Risk	C	30520	2020-04-14

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Rapid Tests Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Cotinine Cassette	RT27-2024	Low Risk	C	37270	2020-04-14
Cotinine Strip	RT27-2023	Low Risk	C	37270	2020-04-14
EDDP Urine Cassette	RT27-2028	Low Risk	C	30521	2020-04-14
EDDP Urine Strip	RT27-2027	Low Risk	C	30521	2020-04-14
Fentanyl Urine Cassette	RT27-2030	Low Risk	C	31582	2020-04-14
Fentanyl Urine Strip	RT27-2029	Low Risk	C	31582	2020-04-14
Ketamine Urine Cassette	RT27-2032	Low Risk	C	31582	2020-04-14
Ketamine Urine Strip	RT27-2031	Low Risk	C	31582	2020-04-14
MDMA(Ecstasy) Cassette	RT27-2038	Low Risk	C	30423	2020-04-14
MDMA(Ecstasy) Strip	RT27-2037	Low Risk	C	30423	2020-04-14
Methadone (MTD) Urine Urine Cassette	RT27-2040	Low Risk	C	30521	2020-04-14
Methadone (MTD) Urine Urine Strip	RT27-2039	Low Risk	C	30521	2020-04-14
Methamphetamine Urine Cassette	RT27-2042	Low Risk	C	30423	2020-04-14
Methamphetamine Urine Strip	RT27-2041	Low Risk	C	30423	2020-04-14
Marijuana (THC) Urine Cassette	RT27-2057	Low Risk	C	30519	2020-04-14
Marijuana (THC) Urine Strip	RT27-2056	Low Risk	C	30519	2020-04-14
Opiates Urine Cassette	RT27-2044	Low Risk	C	30522	2020-04-14
Opiates Urine Strip	RT27-2043	Low Risk	C	30522	2020-04-14
Oxycodone Urine Cassette	RT27-2047	Low Risk	C	31584	2020-04-14
Oxycodone Urine Strip	RT27-2046	Low Risk	C	31584	2020-04-14
Phencyclidine (PCP) Urine Cassette	RT27-2049	Low Risk	C	30523	2020-04-14
Phencyclidine (PCP) Urine Strip	RT27-2048	Low Risk	C	30435	2020-04-14
Tricyclic Antidepressants (TCA) Cassette	RT27-2055	Low Risk	C	30524	2020-04-14
Tricyclic Antidepressants (TCA) Strip	RT27-2054	Low Risk	C	30523	2020-04-14
Tramadol Urine Cassette	RT27-2059	Low Risk	C	31582	2020-04-14
Tramadol Urine Strip	RT27-2058	Low Risk	C	31582	2020-04-14
2-Drug Cassette (Any Combination)	RT27-2060	Low Risk	C	30261	2020-04-14
3-Drug Cassette (Any Combination)	RT27-2061	Low Risk	C	30261	2020-04-14
4-Drug Cassette (Any Combination)	RT27-2062	Low Risk	C	30261	2020-04-14
5-Drug Cassette (Any Combination)	RT27-2063	Low Risk	C	30261	2020-04-14
6-Drug Cassette (Any Combination)	RT27-2064	Low Risk	C	30261	2020-04-14
7-Drug Cassette (Any Combination)	RT27-2065	Low Risk	C	30261	2020-04-14
8-Drug Cassette (Any Combination)	RT27-2066	Low Risk	C	30261	2020-04-14
9-Drug Cassette (Any Combination)	RT27-2067	Low Risk	C	30261	2020-04-14
10-Drug Cassette (Any Combination)	RT27-2068	Low Risk	C	30261	2020-04-14
11-Drug Cassette (Any Combination)	RT27-2069	Low Risk	C	30261	2020-04-14
12-Drug Cassette (Any Combination)	RT27-2070	Low Risk	C	30261	2020-04-14
2-Drug Strip (Any Combination)	RT27-2071	Low Risk	C	30261	2020-04-14
3-Drug Strip (Any Combination)	RT27-2072	Low Risk	C	30261	2020-04-14
4-Drug Strip (Any Combination)	RT27-2073	Low Risk	C	30261	2020-04-14
5-Drug Strip (Any Combination)	RT27-2074	Low Risk	C	30261	2020-04-14
6-Drug Strip (Any Combination)	RT27-2075	Low Risk	C	30261	2020-04-14
7-Drug Strip (Any Combination)	RT27-2076	Low Risk	C	30261	2020-04-14
8-Drug Strip (Any Combination)	RT27-2077	Low Risk	C	30261	2020-04-14
9-Drug Strip (Any Combination)	RT27-2078	Low Risk	C	30261	2020-04-14
10-Drug Strip (Any Combination)	RT27-2079	Low Risk	C	30261	2020-04-14

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11-Drug Strip (Any Combination)	RT27-2080	Low Risk	C	30261	2020-04-14
12-Drug Strip (Any Combination)	RT27-2081	Low Risk	C	30261	2020-04-14
Drug Test/Cup					
2-Drug Cup (Any Combination)	RT27-2082	Low Risk	C	30261	2020-04-14
3-Drug Cup (Any Combination)	RT27-2083	Low Risk	C	30261	2020-04-14
4-Drug Cup (Any Combination)	RT27-2084	Low Risk	C	30261	2020-04-14
5-Drug Cup (Any Combination)	RT27-2085	Low Risk	C	30261	2020-04-14
6-Drug Cup (Any Combination)	RT27-2086	Low Risk	C	30261	2020-04-14
7-Drug Cup (Any Combination)	RT27-2087	Low Risk	C	30261	2020-04-14
8-Drug Cup (Any Combination)	RT27-2088	Low Risk	C	30261	2020-04-14
9-Drug Cup (Any Combination)	RT27-2089	Low Risk	C	30261	2020-04-14
10-Drug Cup (Any Combination)	RT27-2090	Low Risk	C	30261	2020-04-14
11-Drug Cup (Any Combination)	RT27-2091	Low Risk	C	30261	2020-04-14
12-Drug Cup (Any Combination)	RT27-2092	Low Risk	C	30261	2020-04-14
Infectious Diseases and others					
Legionella Urinary Antigen Cassette	RT27-2147	Low Risk	C	30692	2020-04-14
Legionella Urinary Antigen Strip	RT27-2146	Low Risk	C	30692	2020-04-14
Adeno/Rotavirus Antigen Cassette	RT27-2131	Low Risk	C	42994	2020-04-14
Adeno Antigen Cassette	RT27-2132	Low Risk	C	42994	2020-04-14
Rotavirus Antigen Cassette	RT27-2161	Low Risk	C	30815	2020-04-14
Chagas Cassette	RT27-2133	Low Risk	C	30820	2020-04-14
Chikungunya IgG/IgM Cassette	RT27-2135	Low Risk	C	42994	2020-04-14
Gonorrhoea Cassette	RT27-2140	Low Risk	C	38851	2020-04-14
Influenza A&B Cassette	RT27-2145	Low Risk	C	39466	2020-04-14
Leishmania IgG/IgM Cassette	RT27-2149	Low Risk	C	30823	2020-04-14
Leishmania Cutaneous Strip	RT27-2148	Low Risk	C	30823	2020-04-14
Leptospira IgG/IgM	RT27-2150	Low Risk	C	30716	2020-04-14
Syphilis Cassette	RT27-2172	Low Risk	C	30687	2020-04-14
Syphilis Strip	RT27-2173, RT24-2173	Low Risk	C	30687	2020-04-14
Mononucleosis Cassette (Mono) (S/P)	RT27-2177	Low Risk	C	30826	2020-04-14
Strep A Cassette	RT27-2169	Low Risk	C	30826	2020-04-14
Strep A Strip	RT27-2168	Low Risk	C	30826	2020-04-14
Strep B Cassette	RT27-2171	Low Risk	C	30827	2020-04-14
Strep B Strip	RT27-2170	Low Risk	C	30827	2020-04-14
H1N1 Strip	RT40-2209	Low Risk	C	39461	2020-04-14
H. Pylori Ab Cassette (Serum/Plasma)	RT27-2141	Low Risk	B	30825	2020-04-14
H. Pylori Ab Cassette (Serum/Plasma/Whole Blood)	RT27-2142, RT24-2142	Low Risk	B	30825	2020-04-14
H. Pylori Antigen Cassette	RT27-2143, RT24-2203	Low Risk	B	30689	2020-04-14
HAV IgM	RT27-2108	Low Risk	C	30720	2020-04-14
Dengue IgG&IgM	RT27-2138, RT24-2197	Low Risk	C	42994	2020-04-14
Dengue NS1	RT24-2139	Low Risk	C	42994	2020-04-14
Dengue IgG/IgM/NS1	RT24-2208	Low Risk	C	42994	2020-04-14

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Rapid Tests Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
Malaria P.f./Pv	RT24-2204	Low Risk	C	30674	2020-04-14
Malaria Pan	RT24-2206	Low Risk	C	30674	2020-04-14
Malaria P.f./Pan	RT24-2205, RT27-2154	Low Risk	C	30674	2020-04-14
Malaria P.f. Cassette	RT24-2207, RT27-2151	Low Risk	C	30674	2020-04-14
Malaria P.f. Strip	RT27-2152	Low Risk	C	30674	2020-04-14
Malaria P.f./vivax	RT27-2153	Low Risk	C	30674	2020-04-14
Norovirus	RT27-2156	Low Risk	C	32459	2020-04-14
Salmonella typhi Antigen Cassette	RT27-2163	Low Risk	C	30709	2020-04-14
Salmonella typhi IgG/IgM Cassette	RT27-2164	Low Risk	C	30709	2020-04-14
Salmonella typhi/paratyphi antigen	RT27-2165	Low Risk	C	30709	2020-04-14
Scrub typhus IgG Strip	RT4-2166	Low Risk	C	30717	2020-04-14
Scrub typhus IgM Strip	RT4-2167	Low Risk	C	30717	2020-04-14
Zika Virus IgG/IgM Cassette	RT27-2178	Low Risk	C	42994	2020-04-14
COVID-19 IgG/IgM	RT24-2198, RT28-2198, RT45-2198	Low Risk	D	44022	2020-04-14
SARS-CoV2 Antigen Rapid Test	RT45-2214	Low Risk	D	44022	2020-08-24
Tuberculosis (TB) Cassette	RT27-2175	Low Risk	C	44020	2020-04-14
Tuberculosis (TB) Strip	RT27-2174	Low Risk	C	44020	2020-04-14
HEV IgG/IgM	RT27-2119	Low Risk	D	30756	2020-04-14
Cryptococcus Ag	RT27-2137	Low Risk	C	37746	2020-04-14
Hantavirus IgG/IgM	RT27-2144	Low Risk	C	15048014	2020-04-14
Mycoplasma pneumoniae Ag	RT27-2155	Low Risk	C	17311	2020-04-14
Rickettsia IgG/IgM	RT24-2160	Low Risk	C	30717	2020-04-14
RSV	RT27-2162	Low Risk	C	30814	2020-04-14
Tetanus	RT27-2176	Low Risk	C	38876	2020-04-14
Fertility					
FSH Urine Cassette	RT27-2094	Low Risk	B	30512	2020-04-14
FSH Urine Strip	RT27-2093	Low Risk	B	30512	2020-04-14
Ovulation					
LH Urine Cassette	RT27-2106	Low Risk	B	30515	2020-04-14
LH Urine Strip	RT27-2105	Low Risk	B	30515	2020-04-14
Pregnancy					
hCG 10 mIU/ml Midstream	RT27-2099	Low Risk	B	30513	2020-04-14
hCG 20 mIU/ml Midstream	RT27-2102	Low Risk	B	30513	2020-04-14
hCG 10mIU/ml urine Cassette	RT27-2095	Low Risk	B	30513	2020-04-14
hCG 10mIU/ml urine Strip	RT27-2097	Low Risk	B	30513	2020-04-14
hCG 10mIU/ml urine/serum	RT27-2098	Low Risk	B	30513	2020-04-14
hCG 20 mIU/ml urine Cassette	RT27-2101	Low Risk	B	30513	2020-04-14
hCG 20 mIU/ml urine Strip	RT27-2100	Low Risk	B	30513	2020-04-14
hCG 10mIU/ml urine/serum/p	RT27-2096	Low Risk	B	30513	2020-04-14
hCG 20 mIU/ml urine/serum/p Cassette	RT27-2104	Low Risk	B	30513	2020-04-14
hCG 20 mIU/ml urine/serum/p Strip	RT27-2103	Low Risk	B	30513	2020-04-14
Others					

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Micro-Albumin (HAS) Strip	RT27-2197	Low Risk	C	30246	2020-04-14
Ferritin	RT27-2196	Low Risk	C	30377	2020-04-14
H-FABP	RT27-2107	Low Risk	C	1230190	2020-04-14
Nt-proBNP	RT27-1157	Low Risk	C	12130190	2020-04-14
Procalcitonin (S/P/WB)	RT27-2158	Low Risk	C	12069016	2020-04-14
Procalcitonin (S/P)	RT27-2159	Low Risk	C	12069016	2020-04-14
Urine Reagent Strips					
URS-1G	RT27-2185	Low Risk	B	17419	2020-04-14
URS-2PK	RT27-2186	Low Risk	B	30226	2020-04-14
URS-3 GKpH	RT27-2187	Low Risk	B	30226	2020-04-14
URS-4 GKpHB	RT27-2188	Low Risk	B	30226	2020-04-14
URS-5GKpHBP	RT27-2189	Low Risk	B	30226	2020-04-14
URS-6GKpHBPBili	RT27-2190	Low Risk	B	30226	2020-04-14
URS-7GKpHBPBiliU	RT27-2191	Low Risk	B	30226	2020-04-14
URS-8GKpHBPBiliUN	RT27-2192	Low Risk	B	30226	2020-04-14
URS-9GKpHBPBiliUNS	RT27-2193	Low Risk	B	30226	2020-04-14
URS-10GKpHBPBiliUNSL	RT27-2194	Low Risk	B	30226	2020-04-14
URS-11	RT27-2195	Low Risk	B	30226	2020-04-14

Serology Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
C- Reactive Protein (CRP)	SL25-3002, SL25-3003	Low Risk	C	30499	2020-04-14
RF	SL25-3008, SL25-3009	Low Risk	C	30500	2020-04-14
Anti- Streptolysin O(ASO)	SL25-3000, SL25-3001	Low Risk	C	30495	2020-04-14
Infectious Mononucleosis Screening (Mono)	SL25-3004, SL25-3005	Low Risk	C	30810	2020-04-14
RPR	SL25-3011, SL25-3012	Low Risk	C	17393	2020-04-14
Lupus Erythematosus (SLE)	SL25-3007	Low Risk	C	30487	2020-04-14
TPHA	SL25-3016	Low Risk	C	32453	2020-04-14
Rotavirus	SL25-3010	Low Risk	C	17381	2020-04-14
S. Aureus	SL25-3013	Low Risk	C	33887	2020-04-14
Streptococci Lancefield grouping	SL25-3015	Low Risk	C	17389	2020-04-14
VDRL Antigen	SL25-3017	Low Risk	C	17395	2020-04-14
PARATYPHOID A (Salmonella, flagellar a antigen)	SL25-3022	Low Risk	C	39453	2020-04-14
PARATYPHOID B (Salmonella, flagellar b antigen)	SL25-3023	Low Risk	C	39453	2020-04-14
PARATYPHOID C (Salmonella typhi, flagellar c antigen)	SL25-3024	Low Risk	C	39453	2020-04-14
SALMONELLA Group A Antigen (somatic antigen)	SL25-3028	Low Risk	C	39453	2020-04-14
SALMONELLA Group B Antigen (somatic antigen)	SL25-3029	Low Risk	C	39453	2020-04-14

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Serology Device Group	Ref. No.	IVDD Risk class	IVDR Risk class	GMDN code	First CE-marking
SALMONELLA Group C Antigen (somatic antigen)	SL25-3030	Low Risk	C	39453	2020-04-14
TYPHOID H (Salmonella typhi, flagellar d antigen)	SL25-3031	Low Risk	C	39453	2020-04-14
TYPHOID O (Salmonella typhi, somatic Group D antigen)	SL25-3032	Low Risk	C	39453	2020-04-14
Brucella Melitensis	SL25-3018	Low Risk	C	39536	2020-04-14
Brucella Abortus	SL25-3019	Low Risk	C	39536	2020-04-14
PROTEUS OX2 (somatic antigen)	SL25-3026	Low Risk	C	39543	2020-04-14
PROTEUS OX19 (somatic antigen)	SL25-3025	Low Risk	C	39543	2020-04-14
PROTEUS OXK (somatic antigen)	SL25-3027	Low Risk	C	39543	2020-04-14

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CE DECLARATION OF CONFORMITY

Document Ref: **CE DoC 2020 vs. 2**

1) Manufacturer: **Monocent Inc.**
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2) European authorized representative: **CEpartner4U BV,**

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;**
(on product labels printed as:
CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.com)

3) Product(s) *(name, type or model/batch number, etc.)*:

- **CLIA Test Kits**
- **ELISA Test Kits**
- **IFA Test Kits**
- **Instruments**
- **PCR Test Kits**
- **Rapid Tests**
- **Serology Test Kits**

4) The product(s) described above is in conformity with:

Title	Document No.
In vitro Diagnostic Medical Devices Directive	98/79/EC

5) Additional information *(Conformity procedure, Notified Body, CE certificate, Registration nr., etc.)*:
Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex III.
Registration nr. **: CLIA Test Kits (NL-CA002-2020-50897), ELISA Test Kits (NL-CA002-2020-50898), IFA Test Kits (NL-CA002-2020-50899), Instruments (NL-CA002-2020-50900), PCR Test Kits (NL-CA002-2020-50901), Rapid Tests (NL-CA002-2020-50902), Serology Test Kits (NL-CA002-2020-50903)**

Canoga Park, USA 2020/12/06

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CLIA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
Allergy Assays				
IgE	CL3-5055	Low Risk	30275	2020-04-14
Thyroid Assays				
T3	CL3-5028	Low Risk	30312	2020-04-14
T4	CL3-5029	Low Risk	30314	2020-04-14
TSH	CL2-5030	Low Risk	30318	2020-04-14
T3 Uptake	CL3-5072	Low Risk	30313	2020-04-14
FT3	CL3-5026	Low Risk	30309	2020-04-14
FT4	CL3-5027	Low Risk	30308	2020-04-14
Tg (Thyroglobulin)	CL3-5073	Low Risk	30490	2020-04-14
TBG	CL3-5074	Low Risk	30316	2020-04-14
Anti-Tg	CL3-5075	Low Risk	30490	2020-04-14
Anti-TPO	CL3-5076	Low Risk	30317	2020-04-14
Ultra-Sensitive TSH	CL2-5077	Low Risk	30318	2020-04-14
Fertility Assays				
LH	CL3-5006	Low Risk	38965	2020-04-14
FSH	CL3-5004	Low Risk	30322	2020-04-14
Prolactin	CL3-5008	Low Risk	30325	2020-04-14
hCG	CL2-5005	Low Risk	30513	2020-04-14
AMH	CL3-5069	Low Risk	43148	2020-04-14
Beta hCG	CL2-5055	Low Risk	30332	2020-04-14
HGH	CL3-5007	Low Risk	30333	2020-04-14
PAPP-A	CL3-5068	Low Risk	31533	2020-04-14

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CLIA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
Diabetes Assays				
Insulin	CL2-5003	Low Risk	30338	2020-04-14
C-peptide	CL2-5002	Low Risk	30336	2020-04-14
Tumor Markers Assays				
AFP	CL3-5031	Low Risk	30295	2020-04-14
CEA	CL3-5036	Low Risk	30288	2020-04-14
Free Beta hCG	CL2-5037	Low Risk	30333	2020-04-14
Beta 2 Microglobulin	CL2-5032	Low Risk	30296	2020-04-14
NSE	CL2-5039	Low Risk	30301	2020-04-14
CA-12-5	CL3-5034	Low Risk	30283	2020-04-14
CA-19-9	CL2-5035	Low Risk	30280	2020-04-14
CA-15-3	CL2-5033	Low Risk	30279	2020-04-14
Ferritin	CL3-5001	Low Risk	30377	2020-04-14
Cyfra21-1	CL2-5079	Low Risk	44431	2020-04-14
Pro-GRP	CL2-5080	Low Risk	44438	2020-04-14
PAP	CL2-5081	Low Risk	34226	2020-04-14
Steroid Assays				
Progesterone	CL3-5021	Low Risk	30294	2020-04-14
Estradiol	CL3-5016	Low Risk	30321	2020-04-14
Testosterone	CL3-5022	Low Risk	30327	2020-04-14
Free Testosterone	CL9-5023	Low Risk	30327	2020-04-14
Testosterone (Saliva)	CL9-5025	Low Risk	30327	2020-04-14
5a-Androstane-3a, 17b-diol Glucuronide (3a-Diol G)	CL9-5009	Low Risk	31533	2020-04-14

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CLIA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
17 OH Progesterone	CL3-5010	Low Risk	30324	2020-04-14
Androstenedione	CL3-5070	Low Risk	30319	2020-04-14
Aldosterone	CL3-5011	Low Risk	31428	2020-04-14
Cortisol	CL3-5012	Low Risk	31394	2020-04-14
DHEA	CL3-5013	Low Risk	39894	2020-04-14
DHEA-S	CL3-5014	Low Risk	39894	2020-04-14
uE3	CL3-5041	Low Risk	30330	2020-04-14
Estriol (Saliva)	CL9-5018	Low Risk	30329	2020-04-14
Estrone (Saliva)	CL9-5019	Low Risk	33293	2020-04-14
Estrone	CL3-5020	Low Risk	33293	2020-04-14
Plasma Renin Activity (PRA)	CL9-5024	Low Risk	43444	2020-04-14
SHBG	CL3-5071	Low Risk	30326	2020-04-14
Procalcitonin	CL3-5067	Low Risk	12069016	2020-04-14

Infectious Disease Assays

Digoxin	CL3-5059	Low Risk	30386	2020-04-14
hs-CRP	CL2-5060	Low Risk	30499	2020-04-14
CK-MB	CL3-5061	Low Risk	30499	2020-04-14
Myoglobin	CL3-5062	Low Risk	30264	2020-04-14
cTn I	CL2-5063	Low Risk	30266	2020-04-14

Bone Metabolism

ACTH	CL3-5017	Low Risk	39005	2020-04-14
Calcitonin	CL3-5064	Low Risk	30342	2020-04-14
PTH	CL3-5065	Low Risk	30353	2020-04-14

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CLIA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
Vitamin D	CL3-5066	Low Risk	30350	2020-04-14
Autoimmune Disease				
Cardiolipin IgA	CL2-5051	Low Risk	30475	2020-04-14
Cardiolipin IgG	CL2-5052	Low Risk	30475	2020-04-14
Cardiolipin IgM	CL2-5053	Low Risk	30475	2020-04-14
ds-DNA	CL2-5054	Low Risk	30458	2020-04-14
RF IgM	CL2-5114	Low Risk	30500	2020-04-14
B2GP1 IgA	CL2-5115	Low Risk	30478	2020-04-14
B2GP1 IgG	CL2-5116	Low Risk	30478	2020-04-14
B2GP1 IgM	CL2-5117	Low Risk	30478	2020-04-14
Thyroglobulin IgG	CL2-5118	Low Risk	30315	2020-04-14
Anti-CCP	CL2-5119	Low Risk	44202	2020-04-14
Anemia Assays				
Folate	CL3-5056	Low Risk	30378	2020-04-14
Vitamin B12	CL3-5057	Low Risk	30384	2020-04-14
Transferrin Soluble Receptor (sTfR)	CL3-5058	Low Risk	30253	2020-04-14
NeoNatal Assays				
Neonatal TSH	CL2-5078	Low Risk	30310	2020-04-14
Infectious Disease Assays				
H. pylori IgA	CL2-5048	Low Risk	30691	2020-04-14
H. pylori IgG	CL2-5049	Low Risk	30691	2020-04-14
H. pylori IgM	CL2-5050	Low Risk	30691	2020-04-14
H. pylori IgG (Quantitative)	CL2-5082	Low Risk	30691	2020-04-14

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CLIA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
H. pylori Antigen	CL2-5083	Low Risk	30691	2020-04-14
EBV VCA IgA	CL2-5084	Low Risk	30809	2020-04-14
EBV VCA IgG	CL2-5085	Low Risk	30809	2020-04-14
EBV VCA IgM	CL2-5086	Low Risk	30809	2020-04-14
EBV EA-D IgA	CL2-5087	Low Risk	30809	2020-04-14
EBV EA-D IgG	CL2-5088	Low Risk	30809	2020-04-14
EBV EA-D IgM	CL2-5089	Low Risk	30809	2020-04-14
EBNA IgA	CL2-5090	Low Risk	30808	2020-04-14
EBNA IgG	CL2-5091	Low Risk	30808	2020-04-14
EBNA IgM	CL2-5092	Low Risk	30808	2020-04-14
Measles IgG	CL2-5093	Low Risk	44019	2020-04-14
Measles IgM	CL2-5094	Low Risk	44019	2020-04-14
VZV IgG	CL2-5095	Low Risk	44027	2020-04-14
VZV IgM	CL2-5096	Low Risk	44027	2020-04-14
Mumps IgG	CL2-5097	Low Risk	33908	2020-04-14
Mumps IgM	CL2-5098	Low Risk	33908	2020-04-14
Dengue IgG	CL2-5099	Low Risk	32481	2020-04-14
Dengue IgM	CL2-5100	Low Risk	32481	2020-04-14
HSV 1/2 IgG	CL2-5101	Low Risk	40176	2020-04-14
HSV 1/2 IgM	CL2-5102	Low Risk	40176	2020-04-14
HSV 1 IgA	CL2-5103	Low Risk	38870	2020-04-14
HSV 1 IgG	CL2-5104	Low Risk	38870	2020-04-14
HSV 1 IgM	CL2-5105	Low Risk	38870	2020-04-14

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CLIA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
HSV 2 IgA	CL2-5106	Low Risk	38875	2020-04-14
HSV 2 IgG	CL2-5107	Low Risk	38875	2020-04-14
HSV 2 IgM	CL2-5108	Low Risk	38875	2020-04-14

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ELISA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
Allergy				
Total Human IgE	EL1-1000, EL2-1000	Low Risk	30275	2020-04-14
Human Specific IgG	EL15-1001	Low Risk	44211	2020-04-14
Human Specific IgG4	EL15-1002	Low Risk	44211	2020-04-14
Histamine	EL30-1003	Low Risk	30274	2020-04-14
Anemia				
Vitamin B12	EL1-1007	Low Risk	30384	2020-04-14
Folate	EL1-1005	Low Risk	30378	2020-04-14
sTfR-Transferrin Soluble Receptor	EL3-1006	Low Risk	30253	2020-04-14
Ferritin	EL1-1004	Low Risk	30377	2020-04-14
Hepcidin	EL1-1008	Low Risk	12070190	2020-04-14
Autoimmune Disease				
Anti-CCP	EL2-1011	Low Risk	44202	2020-04-14
Anti-CP IgG	EL20-1288	Low Risk	44202	2020-04-14
Beta 2 Glycoprotein 1 IgA	EL2-1017	Low Risk	30478	2020-04-14
Beta 2 Glycoprotein 1 IgG	EL2-1018	Low Risk	30478	2020-04-14
Beta 2 Glycoprotein 1 IgM	EL2-1019	Low Risk	30478	2020-04-14
Anti-Tissue Transglutaminase IgG	EL20-1015	Low Risk	44385	2020-04-14
Anti-Tissue Transglutaminase IgA	EL20-1014	Low Risk	44385	2020-04-14
ANA Screen IgG	EL1-1009	Low Risk	30454	2020-04-14
ENA IgG Profile-6	EL10-1024	Low Risk	30455	2020-04-14
ENA Screen IgG	EL20-1025	Low Risk	30455	2020-04-14
Rheumatoid Factor (RF) IgA	EL15-1034	Low Risk	30500	2020-04-14

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ELISA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
Rheumatoid Factor (RF) IgG	EL15-1035	Low Risk	30500	2020-04-14
Rheumatoid Factor (RF) IgM	EL2-1038	Low Risk	30500	2020-04-14
Sm/RNP IgG	EL1-1040	Low Risk	30464	2020-04-14
Sm IgG	EL1-1041	Low Risk	17276	2020-04-14
Jo-1 IgG	EL21-1029	Low Risk	30461	2020-04-14
Scl-70 IgG	EL1-1039	Low Risk	30463	2020-04-14
SS-A (Ro)	EL1-1042	Low Risk	44202	2020-04-14
SS-B (La)	EL1-1043	Low Risk	44202	2020-04-14
dsDNA	EL1-1023	Low Risk	30458	2020-04-14
Cardiolipin IgG	EL1-1021	Low Risk	30475	2020-04-14
Cardiolipin IgM	EL1-1022	Low Risk	30475	2020-04-14
Cardiolipin IgA	EL1-1020	Low Risk	30475	2020-04-14
Cardiolipin Total Ab	EL1-1044	Low Risk	30475	2020-04-14
Mitochondrial Antibody (MA)	EL1-1031	Low Risk	30476	2020-04-14
Thyroglobulin Antigen (Anti-Tg)	EL3-1016	Low Risk	30315	2020-04-14
PR3 (c-ANCA)	EL20-1033	Low Risk	30484	2020-04-14
ANCA screen IgG	EL10-1010	Low Risk	30483	2020-04-14
MPO, Myeloperoxidase (p-ANCA)	EL20-1032	Low Risk	30483	2020-04-14
Gliadin IgG	EL36-1026	Low Risk	30480	2020-04-14
Gliadin IgA	EL36-1027	Low Risk	30480	2020-04-14
TPO	EL1-1012	Low Risk	30317	2020-04-14
Anti-Phospholipids Screen	EL20-1013	Low Risk	30582	2020-04-14
ASMA	EL29-1302	Low Risk	30274	2020-04-14

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ELISA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
Beta-2-Glycoprotein IgA	EL2-1017	Low Risk	30478	2020-04-14
Beta-2-Glycoprotein IgG	EL2-1018	Low Risk	30478	2020-04-14
Beta-2-Glycoprotein IgM	EL2-1019	Low Risk	30478	2020-04-14
Tumor markers				
Prostatic Acid Phosphatase (PAP)	EL2-1289	Low Risk	34226	2020-04-14
Beta-2-Microglobulin	EL2-1277	Low Risk	30296	2020-04-14
AFP (Alpha Fetoprotein)	EL1-1276	Low Risk	43480	2020-04-14
CEA	EL1-1283	Low Risk	30288	2020-04-14
CA-15-3	EL1-1279	Low Risk	30279	2020-04-14
CA-12-5	EL1-1278	Low Risk	30283	2020-04-14
CA-19-9	EL1-1280	Low Risk	30280	2020-04-14
NSE	EL2-1286	Low Risk	30301	2020-04-14
Free Beta HCG	EL1-1284	Low Risk	30333	2020-04-14
Pro-GRP (Gastrin-Releasing Peptide)	EL2-1290	Low Risk	44438	2020-04-14
Chromogranin A	EL1-1281	Low Risk	30289	2020-04-14
HE4	EL1-1306	Low Risk	30289	2020-04-14
Cyfra21-1	EL2-1034	Low Risk	30289	2020-04-14
Bone Metabolism				
Intact PTH	EL3-1048	Low Risk	30353	2020-04-14
25-OH Vitamin D	EL1-1045	Low Risk	30350	2020-04-14
ACTH	EL3-1046	Low Risk	39005	2020-04-14
Cardiac				
Digoxin	EL3-1051	Low Risk	30386	2020-04-14

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ELISA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
CK-MB	EL3-1050	Low Risk	30499	2020-04-14
Troponin I	EL1-1054	Low Risk	30266	2020-04-14
Myoglobin	EL6-1053	Low Risk	30264	2020-04-14
C-Reactive Protein (CRP)	EL1-1049	Low Risk	30499	2020-04-14

Diabetes

Insulin	EL1-1058	Low Risk	30338	2020-04-14
C-peptide	EL1-1055	Low Risk	30336	2020-04-14
Leptin	EL9-1059	Low Risk	12069017	2020-04-14
Adiponectin	EL9-1056	Low Risk	12069017	2020-04-14
(IGFBP-1) Insulin-Like Growth Factor Binding Protein-1	EL9-1057	Low Risk	42852	2020-04-14
Anti-GAD	EL8-1060	Low Risk	30340	2020-04-14
IAA	EL8-1061	Low Risk	30339	2020-04-14
IGF-1	EL8-1062	Low Risk	30361	2020-04-14
Pro-Insulin	EL1-1063	Low Risk	42852	2020-04-14

Fertility

Human Growth Hormone (HGH)	EL1-1083	Low Risk	30333	2020-04-14
hCG Visual	EL6-1082	Low Risk	30513	2020-04-14
Beta hCG (Total)	EL2-1078	Low Risk	30332	2020-04-14
FSH	EL1-1080	Low Risk	31533	2020-04-14
LH	EL1-1084	Low Risk	38246	2020-04-14
Prolactin	EL1-1086	Low Risk	30325	2020-04-14
PAPP-A	EL3-1085	Low Risk	31533	2020-04-14
SHBG	EL3-1261	Low Risk	30326	2020-04-14

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ELISA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
AMH	EL3-1079	Low Risk	43148	2020-04-14
hCG	EL1-1081	Low Risk	30332	2020-04-14
Sperm Ab	EL8-1087	Low Risk	30486	2020-04-14

Infectious Diseases

Adenovirus IgG	EL15-1102	Low Risk	39468	2020-04-14
Adenovirus IgA	EL15-1101	Low Risk	39468	2020-04-14
Adenovirus IgM	EL15-1103	Low Risk	39468	2020-04-14
Influenza A IgA	EL15-1365	Low Risk	39463	2020-04-14
Influenza A IgG	EL15-1366	Low Risk	39463	2020-04-14
Influenza A IgM	EL15-1367	Low Risk	39463	2020-04-14
Influenza B IgA	EL15-1368	Low Risk	39463	2020-04-14
Influenza B IgG	EL15-1369	Low Risk	39463	2020-04-14
Influenza B IgM	EL15-1370	Low Risk	39463	2020-04-14
Chikungunya IgG	EL4-1114	Low Risk	32481	2020-04-14
Chikungunya IgM	EL4-1113	Low Risk	32481	2020-04-14
COVID-19 IgA	EL45-1373	Low Risk	42994	2020-04-14
COVID-19 IgG	EL1-1360	Low Risk	42994	2020-04-14
COVID-19 IgM	EL1-1361	Low Risk	42994	2020-04-14
COVID-19 IgG	EL45-1360	Low Risk	42994	2020-04-14
COVID-19 IgM	EL45-1361	Low Risk	42994	2020-04-14
COVID-19 Total Ab	EL45-1379	Low Risk	42994	2020-12-06
Mycobacterium Tuberculosis (TB) IgA	EL15-1317	Low Risk	30635	2020-04-14
Mycobacterium Tuberculosis (TB) IgG	EL15-1201	Low Risk	30635	2020-04-14

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ELISA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
Mycobacterium Tuberculosis (TB) IgM	EL15-1202	Low Risk	30635	2020-04-14
Herpes Simplex 1 IgG (HSV1 IgA)	EL2-1162	Low Risk	38870	2020-04-14
Herpes Simplex 1 IgG (HSV1 IgG)	EL1-1163	Low Risk	38870	2020-04-14
Herpes Simplex 1 IgM (HSV1 IgM)	EL1-1164	Low Risk	38870	2020-04-14
Herpes Simplex 2 IgG (HSV2 IgG)	EL1-1165	Low Risk	38875	2020-04-14
Herpes Simplex 2 IgM (HSV2 IgM)	EL1-1166	Low Risk	38875	2020-04-14
Herpes Simplex 1,2 IgG (HSV1,2 IgG)	EL1-1167	Low Risk	40176	2020-04-14
Herpes Simplex 1,2 IgM (HSV1,2 IgM)	EL1-1168	Low Risk	40176	2020-04-14
Epstein Barr Virus VCA IgA (EBV, VCA IgA)	EL2-1135	Low Risk	30809	2020-04-14
Epstein Barr Virus VCA IgG (EBV, VCA IgG)	EL1-1136	Low Risk	30809	2020-04-14
Epstein Barr Virus VCA IgM (EBV, VCA IgM)	EL1-1137	Low Risk	30809	2020-04-14
Epstein Barr Virus Early Antigen (EA) IgM	EL2-1134	Low Risk	30809	2020-04-14
Epstein Barr Virus Early Antigen (EA) IgG	EL2-1133	Low Risk	30809	2020-04-14
Epstein Barr Virus Early Antigen (EA) IgA	EL2-1132	Low Risk	30809	2020-04-14
Epstein Barr Virus Nuclear Antigen (EBNA) IgG	EL2-1130	Low Risk	30808	2020-04-14
Epstein Barr Virus Nuclear Antigen (EBNA) IgM	EL2-1131	Low Risk	30808	2020-04-14
Epstein Barr Virus Nuclear Antigen (EBNA) IgA	EL2-1129	Low Risk	30808	2020-04-14
Measles IgG	EL1-1177	Low Risk	44019	2020-04-14
Measles IgM	EL1-1178	Low Risk	44019	2020-04-14
Mumps IgG	EL1-1179	Low Risk	33908	2020-04-14
Mumps IgM	EL1-1180	Low Risk	33908	2020-04-14
Mycoplasma pneumonia IgG	EL1-1181	Low Risk	30657	2020-04-14
Mycoplasma pneumonia IgM	EL1-1182	Low Risk	30657	2020-04-14

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ELISA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
Syphilis (TPA) IgG	EL1-1195	Low Risk	30685	2020-04-14
Syphilis (TPA) IgM	EL1-1197	Low Risk	30685	2020-04-14
Legionela urine Ag detection	EL16-1175	Low Risk	30692	2020-04-14
H. pylori IgG	EL1-1140	Low Risk	30691	2020-04-14
H. pylori IgA	EL1-1139	Low Risk	30691	2020-04-14
H-Pylori IgM	EL1-1141	Low Risk	30691	2020-04-14
H. pylori Antigen	EL2-1138, EL32-1138	Low Risk	30691	2020-04-14
Varicella-Zoster IgG	EL1-1209	Low Risk	44027	2020-04-14
Varicella-Zoster IgM	EL1-1210	Low Risk	44027	2020-04-14
HEV IgG	EL13-1156	Low Risk	30757	2020-04-14
HEV IgM	EL13-1161	Low Risk	30758	2020-04-14
HAV Ab	EL7-1142	Low Risk	30721	2020-04-14
HAV IgM	EL7-1143	Low Risk	30722	2020-04-14
HDV IgG	EL7-1153	Low Risk	30750	2020-04-14
HDV IgM	EL7-1155	Low Risk	30752	2020-04-14
HDV Ab	EL13-1315	Low Risk	30750	2020-04-14
HDV Ag	EL13-1316, EL7-1154	Low Risk	30747	2020-04-14
HTLV 1 + 2 Ab	EL7-1160	Low Risk	30789	2020-04-14
Lyme Disease IgG	EL10-1171	Low Risk	30697	2020-04-14
Lyme Disease IgM	EL10-1172	Low Risk	30697	2020-04-14
Lyme Disease IgG, M	EL10-1173	Low Risk	30697	2020-04-14
Brucella IgM	EL1-1108	Low Risk	37723	2020-04-14
Brucella IgG	EL1-1107	Low Risk	37723	2020-04-14

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ELISA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
Rubella IgG	EL46-1190	Low Risk	37723	2020-04-14
RSV IgA	EL15-1186	Low Risk	30814	2020-04-14
RSV IgG	EL15-1187	Low Risk	30814	2020-04-14
RSV IgM	EL15-1188	Low Risk	30814	2020-04-14
Tetanus	EL5-1205	Low Risk	38876	2020-04-14
Diphtheria IgG	EL5-1124	Low Risk	33499	2020-04-14
Salmonella typhi IgG	EL1-1193	Low Risk	30709	2020-04-14
Salmonella typhi IgM	EL1-1194	Low Risk	30709	2020-04-14
Salmonella Antigen detection	EL4-1192	Low Risk	30709	2020-04-14
Anthrax IgG	EL1-1105	Low Risk	32481	2020-04-14
Babesia IgG	EL4-1109	Low Risk	32481	2020-04-14
Dengue IgM	EL5-1127	Low Risk	32481	2020-04-14
Dengue IgG/IgM	EL5-1125	Low Risk	32481	2020-04-14
Dengue IgG	EL5-1126	Low Risk	32481	2020-04-14
Dengue NS1 Antigen	EL4-1128	Low Risk	32481	2020-04-14
Japanese Encephalitis IgG	EL4-1169	Low Risk	44321	2020-04-14
Japanese Encephalitis IgM	EL4-1170	Low Risk	44321	2020-04-14
Leprosy IgG/IgM	EL4-1176	Low Risk	32481	2020-04-14
Parvovirus B19 IgG	EL30-1183	Low Risk	40443	2020-04-14
Parvovirus B19 IgM	EL30-1184	Low Risk	40444	2020-04-14
Rotavirus (fecal)	EL16-1185	Low Risk	30815	2020-04-14
Scrub Typhus IgG	EL4-1199	Low Risk	44028	2020-04-14
Scrub Typhus IgM	EL4-1200	Low Risk	44028	2020-04-14

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ELISA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
TB IgA	EL15-1317	Low Risk	30635	2020-04-14
TB IgG	EL15-1201	Low Risk	30635	2020-04-14
TB IgM	EL15-1202	Low Risk	30635	2020-04-14
Zika Virus IgG	EL1-1203	Low Risk	32481	2020-04-14
Zika Virus IgM	EL1-1204	Low Risk	32481	2020-04-14
West Nile IgG	EL4-1211	Low Risk	42926	2020-04-14
West Nile IgM	EL4-1212	Low Risk	42926	2020-04-14

Parasitology

Schistosoma IgG	EL5-1227	Low Risk	30824	2020-04-14
Chagas	EL5-1213	Low Risk	30820	2020-04-14
Cysticercosis IgG (T. solium)	EL5-1220	Low Risk	39979	2020-04-14
Campylobacter	EL16-1229	Low Risk	33948	2020-04-14
E. coli 0157 Ag detection	EL16-1232	Low Risk	37727	2020-04-14
E. histolytica IgG (Amebiasis)	EL5-1221	Low Risk	39979	2020-04-14
E. histolytica Dispar	EL16-1233	Low Risk	39979	2020-04-14
Echinococcus IgG	EL5-1222	Low Risk	30822	2020-04-14
Fasciola IgG	EL5-1216	Low Risk	34068	2020-04-14
Fasciola gigantica	EL5-1217	Low Risk	34068	2020-04-14
Filaria IgG4	EL4-1218	Low Risk	34068	2020-04-14
Leishmania	EL5-1223	Low Risk	30823	2020-04-14
Leptospira IgG	EL5-1224	Low Risk	30716	2020-04-14
Leptospira IgM	EL5-1226	Low Risk	30716	2020-04-14
Leptospira IgG/IgM	EL5-1225	Low Risk	30716	2020-04-14

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ELISA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
Toxocara IgG	EL5-1228	Low Risk	34068	2020-04-14
Trichinella IgG	EL5-1215	Low Risk	33379	2020-04-14
Ascaris IgG	EL5-1219	Low Risk	39979	2020-04-14
Strongyloides IgG	EL5-1214	Low Risk	34068	2020-04-14
Crypto/Giardia Ag detection	EL16-1230	Low Risk	30675	2020-04-14
Cryptosporidium Ag detection	EL16-1231	Low Risk	30675	2020-04-14
Giardia antigen	EL16-1235	Low Risk	36173	2020-04-14
Giardia coprpantigen in stool	EL5-1361	Low Risk	36173	2020-04-14
Anti-Giardia IgA ELISA in saliva	EL5-1362	Low Risk	36173	2020-04-14
Entamoeba histolytica coproantigen in stool	EL5-1363	Low Risk	39979	2020-04-14
Adenovirus Antigen	EL16-1104	Low Risk	41274	2020-04-14

Steroid

Aldosterone	EL3-1247	Low Risk	31428	2020-04-14
Cortisol	EL1-1249	Low Risk	31394	2020-04-14
Cortisol Saliva	EL9-1250	Low Risk	31394	2020-04-14
Estradiol	EL1-1254	Low Risk	30321	2020-04-14
DHEA-S	EL1-1251	Low Risk	30320	2020-04-14
DHEA	EL3-1252	Low Risk	39894	2020-04-14
Progesterone	EL1-1259	Low Risk	30323	2020-04-14
Progesterone Saliva	EL9-1260	Low Risk	30294	2020-04-14
Testosterone	EL1-1263	Low Risk	30327	2020-04-14
Testosterone Saliva	EL9-1265	Low Risk	30327	2020-04-14
Free Testosterone	EL1-1264	Low Risk	30327	2020-04-14

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ELISA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
Androstenedione	EL1-1248	Low Risk	30321	2020-04-14
Free Estriol	EL1-1257	Low Risk	30330	2020-04-14
Dihydrotestosterones (DHT)	EL9-1253	Low Risk	30327	2020-04-14
17-OH Progesterone	EL1-1245	Low Risk	30324	2020-04-14
5a-Androstane-3a, 17b-diol Glucuronide (3a-Diol G)	EL9-1246	Low Risk	31533	2020-04-14
Total Estrogen	EL9-1255	Low Risk	38858	2020-04-14
Estrone	EL3-1256	Low Risk	33293	2020-04-14
Pregnenolone	EL9-1258	Low Risk	33301	2020-04-14
Total Estriol	EL8-1266	Low Risk	30330	2020-04-14

Thyroid

T3	EL1-1270	Low Risk	30314	2020-04-14
T4	EL1-1271	Low Risk	30312	2020-04-14
TSH	EL1-1273	Low Risk	30489	2020-04-14
U-TSH	EL6-1275	Low Risk	30489	2020-04-14
Free T4	EL1-1268	Low Risk	30308	2020-04-14
Free T3	EL1-1267	Low Risk	30309	2020-04-14
Reverse T3	EL9-1274	Low Risk	30311	2020-04-14
T Uptake	EL3-1269	Low Risk	30313	2020-04-14
Tg (Thyroglobulin)	EL1-1272	Low Risk	30490	2020-04-14
TBG (Thyroxine-Binding Globulin)	EL3-1262	Low Risk	30316	2020-04-14

Neo-Natal Panel

Neo-Natal T4	EL1-1240	Low Risk	30273	2020-04-14
Neo-Natal TSH	EL1-1239	Low Risk	30310	2020-04-14

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ELISA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
Neo-Natal TBG	EL3-1242	Low Risk	30316	2020-04-14
Neo-Natal 17-OH Progesterone	EL1-1236	Low Risk	30324	2020-04-14
Neo-Natal MSUD	EL1-1237	Low Risk	30273	2020-04-14
Neo-Natal PKU	EL1-1238	Low Risk	30273	2020-04-14
Neo-Natal IRT	EL1-1241	Low Risk	30273	2020-04-14
Neo-Natal Total Galactose	EL1-1243	Low Risk	30273	2020-04-14
G6PD	EL1-1303	Low Risk	30273	2020-04-14
Neo-Natal Biotinidase	EL1-1244	Low Risk	30273	2020-04-14

Others

Procalcitonin	EL3-1309	Low Risk	12069016	2020-04-14
Calcitonin	EL3-1292	Low Risk	30342	2020-04-14
Renin	EL9-1300	Low Risk	43444	2020-04-14

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IFA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
Autoimmune Diseases and others:				
ANA Rat Liver IFA Kit	IF17-4002, IF17-4019	Low Risk	41420	2020-04-14
ANA Mouse Kidney IFA Kit	IF17-4003	Low Risk	41420	2020-04-14
ANA Hep-2 IFA Kit	IF17-4004, IF17-4005, IF17-4018	Low Risk	17269	2020-04-14
AMA IFA Kit	IF17-4022, IF17-4023	Low Risk	17267	2020-04-14
AAS Rat Kidney Stomach Liver Tissue	IF17-4000	Low Risk	30274	2020-04-14
ASMA IFA Kit	IF17-4006, IF17-4015	Low Risk	30274	2020-04-14
ATA IFA Kit	IF17-4030, IF174031	Low Risk	30274	2020-04-14
ASA IFA Kit	IF17-4008, IF17-4034	Low Risk	30274	2020-04-14
nDNA IFA Kit	IF17-4007, IF17-4051, IF17-4052	Low Risk	30274	2020-04-14
Endomysial (Primate Endomysial)	IF17-4032, IF17-4033	Low Risk	12109016	2020-04-14
Anti-Reticulin IgA	IF17-4041, IF17-4042	Low Risk	30526	2020-04-14
Anti-Reticulin IgG	IF17-4043, IF17-4044	Low Risk	30526	2020-04-14
C-ANCA	IF17-4059	Low Risk	30484	2020-04-14
P-ANCA	IF17-4060	Low Risk	30483	2020-04-14
Bacterial Diseases:				
Legionella pneumophila 1-6 IFA Poly (HT)	IF17-4063, IF17-4064	Low Risk	30694	2020-04-14
Legionella pneumophila 1-6/bdglmj/C Specimen	IF17-4061	Low Risk	30694	2020-04-14
Legionella pneumophila 1-6/bdglmj DFA Screen	IF17-4062	Low Risk	30694	2020-04-14
FTA-ABS Double Stain (Syphilis) IFA Kit	IF17-4013, IF17-4066	Low Risk	32455	2020-04-14
FTA-ABS (T. pallidum)	IF17-4012, IF17-4067	Low Risk	32455	2020-04-14
FTA-ABS (Syphilis) Titrable IFA Kit	IF17-4014	Low Risk	32455	2020-04-14

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IFA Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
Viral diseases				
HSV-1 IgG IFA Kit	IF17-4016	Low Risk	39502	2020-04-14
HSV-2 IgG IFA Kit	IF17-4080	Low Risk	39502	2020-04-14
HSV-1 IgM IFA Kit	IF17-4017	Low Risk	39502	2020-04-14
HSV-2 IgM IFA Kit	IF17-4081	Low Risk	39502	2020-04-14
HSV 1&2 IgG	IF17-4078	Low Risk	39502	2020-04-14
HSV 1&2 IgM	IF17-4079	Low Risk	39502	2020-04-14
EBV-VCA IgG IFA Kit	IF17-4074	Low Risk	33971	2020-04-14
EBV-VCA IgM IFA Kit	IF17-4075	Low Risk	33971	2020-04-14
EBV-EA IFA Kit	IF17-4077	Low Risk	33971	2020-04-14
EBNA IFA Kit	IF17-4076	Low Risk	33971	2020-04-14
RMSF Rocky Mountain Spotted Fever (R. ricketsii)	IF17-4065	Low Risk	32473	2020-04-14
Measles IgG IFA Kit	IF17-4092	Low Risk	44019	2020-04-14
Measles IgM IFA Kit	IF17-4093	Low Risk	44019	2020-04-14
Mumps IgG IFA Kit	IF17-4094	Low Risk	33908	2020-04-14
Mumps IgM IFA Kit	IF17-4095	Low Risk	33908	2020-04-14
RSV IgG (Respiratory Syncytial Virus)	IF17-4096	Low Risk	30814	2020-04-14
RSV IgM (Respiratory Syncytial Virus)	IF17-4097	Low Risk	30814	2020-04-14
Varicella-Zoster Virus IgG IFA Kit	IF17-4098	Low Risk	44027	2020-04-14
Varicella-Zoster Virus IgM IFA Kit	IF17-4099	Low Risk	44027	2020-04-14
West Nile Virus IgG	IF17-4100	Low Risk	42926	2020-04-14
West Nile Virus IgG	IF17-4101	Low Risk	42926	2020-04-14

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Instruments	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
ELISA/CLIA Combo Analyzer-- One plate	IN38-6003	low risk	36415	2020-04-14
ELISA/CLIA Combo Analyzer-- two plates	IN38-6004	low risk	36415	2020-04-14
Microplate Incubator & Shaker	IN34-6006	low risk	36418	2020-04-14
Microplate Luminometer	IN18-6005	low risk	36415	2020-04-14
Urine Analyzer	IN18-6000	low risk	39887	2020-04-14
Microplate reader	IN18-6001	low risk	36415	2020-04-14
Microplate washer	IN18-6002	low risk	36407	2020-04-14

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RT-PCR	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
SARS-CoV-2 RT-PCR	PR31-8000	low risk	42994	2020-04-14
SARS-CoV-2 RT-PCR	PR4-8000	low risk	42994	2020-04-14
SARS-CoV-2 pap-PCR	PR45-8000	low risk	42994	2020-12-06
SARS-CoV-2/Flu/RSV RT-PCR	PR31-8001	low risk	42994	2020-12-06

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Rapid Tests Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
Tumor Markers Tests				
FOB Cassette	RT27-2182	Low Risk	38217	2020-04-14
FOB Strip	RT27-2181	Low Risk	38217	2020-04-14
CEA	RT27-2180	Low Risk	30288	2020-04-14
AFP	RT27-2179	Low Risk	30295	2020-04-14
Cardiac markers				
CK-MB Cassette (Serum/Plasma/Whole Blood)	RT27-2001	Low Risk	30499	2020-04-14
C-Reactive Protein (CRP) Cassette (Serum/Plasma/Whole Blood)	RT27-2003	Low Risk	30507	2020-04-14
C-Reactive Protein (CRP) Strip (Serum/Plasma/Whole Blood)	RT27-2002	Low Risk	30507	2020-04-14
D-Dimer Cassette (Plasma/Whole Blood)	RT27-2004	Low Risk	30576	2020-04-14
Myoglobin Cassette (Serum/Plasma/Whole Blood)	RT27-2005	Low Risk	30264	2020-04-14
Troponin I Cassette (Serum/Plasma/Whole Blood)	RT27-2007	Low Risk	30509	2020-04-14
3 in 1 Troponin I/Myoglobin/CKMB Cassette (Serum/Plasma/Whole Blood)	RT27-2006	Low Risk	42649	2020-04-14
Drug Test				
Alcohol Urine Strip	RT27-2010	Low Risk	30443	2020-04-14
Alcohol Saliva Strip	RT27-2009	Low Risk	30443	2020-04-14
Amphetamine Urine Cassette	RT27-2012	Low Risk	30516	2020-04-14
Amphetamine Urine Strip	RT27-2011	Low Risk	30516	2020-04-14
Barbiturates Urine Cassette	RT27-2014	Low Risk	30517	2020-04-14
Barbiturates Urine Strip	RT27-2013	Low Risk	30517	2020-04-14
Buprenorphine Urine Cassette	RT27-2016	Low Risk	31584	2020-04-14
Buprenorphine Urine Strip	RT27-2015	Low Risk	31584	2020-04-14
Benzodiazepine Urine Cassette	RT27-2018	Low Risk	30518	2020-04-14

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Rapid Tests Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
Benzodiazepine Urine Strip	RT27-2017	Low Risk	30518	2020-04-14
Cocaine Urine Cassette	RT27-2022	Low Risk	30520	2020-04-14
Cocaine Urine Strip	RT27-2021	Low Risk	30520	2020-04-14
Cotinine Cassette	RT27-2024	Low Risk	37270	2020-04-14
Cotinine Strip	RT27-2023	Low Risk	37270	2020-04-14
EDDP Urine Cassette	RT27-2028	Low Risk	30521	2020-04-14
EDDP Urine Strip	RT27-2027	Low Risk	30521	2020-04-14
Fentanyl Urine Cassette	RT27-2030	Low Risk	31582	2020-04-14
Fentanyl Urine Strip	RT27-2029	Low Risk	31582	2020-04-14
Ketamine Urine Cassette	RT27-2032	Low Risk	31582	2020-04-14
Ketamine Urine Strip	RT27-2031	Low Risk	31582	2020-04-14
MDMA(Ecstasy) Cassette	RT27-2038	Low Risk	30423	2020-04-14
MDMA(Ecstasy) Strip	RT27-2037	Low Risk	30423	2020-04-14
Methadone (MTD) Urine Urine Cassette	RT27-2040	Low Risk	30521	2020-04-14
Methadone (MTD) Urine Urine Strip	RT27-2039	Low Risk	30521	2020-04-14
Methamphetamine Urine Cassette	RT27-2042	Low Risk	30423	2020-04-14
Methamphetamine Urine Strip	RT27-2041	Low Risk	30423	2020-04-14
Marijuana (THC) Urine Cassette	RT27-2057	Low Risk	30519	2020-04-14
Marijuana (THC) Urine Strip	RT27-2056	Low Risk	30519	2020-04-14
Opiates Urine Cassette	RT27-2044	Low Risk	30522	2020-04-14
Opiates Urine Strip	RT27-2043	Low Risk	30522	2020-04-14
Oxycodone Urine Cassette	RT27-2047	Low Risk	31584	2020-04-14
Oxycodone Urine Strip	RT27-2046	Low Risk	31584	2020-04-14

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Phencyclidine (PCP) Urine Cassette	RT27-2049	Low Risk	30523	2020-04-14
Phencyclidine (PCP) Urine Strip	RT27-2048	Low Risk	30435	2020-04-14
Tricyclic Antidepressants (TCA) Cassette	RT27-2055	Low Risk	30524	2020-04-14
Tricyclic Antidepressants (TCA) Strip	RT27-2054	Low Risk	30523	2020-04-14
Tramadol Urine Cassette	RT27-2059	Low Risk	31582	2020-04-14
Tramadol Urine Strip	RT27-2058	Low Risk	31582	2020-04-14
2-Drug Cassette (Any Combination)	RT27-2060	Low Risk	30261	2020-04-14
3-Drug Cassette (Any Combination)	RT27-2061	Low Risk	30261	2020-04-14
4-Drug Cassette (Any Combination)	RT27-2062	Low Risk	30261	2020-04-14
5-Drug Cassette (Any Combination)	RT27-2063	Low Risk	30261	2020-04-14
6-Drug Cassette (Any Combination)	RT27-2064	Low Risk	30261	2020-04-14
7-Drug Cassette (Any Combination)	RT27-2065	Low Risk	30261	2020-04-14
8-Drug Cassette (Any Combination)	RT27-2066	Low Risk	30261	2020-04-14
9-Drug Cassette (Any Combination)	RT27-2067	Low Risk	30261	2020-04-14
10-Drug Cassette (Any Combination)	RT27-2068	Low Risk	30261	2020-04-14
11-Drug Cassette (Any Combination)	RT27-2069	Low Risk	30261	2020-04-14
12-Drug Cassette (Any Combination)	RT27-2070	Low Risk	30261	2020-04-14
2-Drug Strip (Any Combination)	RT27-2071	Low Risk	30261	2020-04-14
3-Drug Strip (Any Combination)	RT27-2072	Low Risk	30261	2020-04-14
4-Drug Strip (Any Combination)	RT27-2073	Low Risk	30261	2020-04-14
5-Drug Strip (Any Combination)	RT27-2074	Low Risk	30261	2020-04-14
6-Drug Strip (Any Combination)	RT27-2075	Low Risk	30261	2020-04-14
7-Drug Strip (Any Combination)	RT27-2076	Low Risk	30261	2020-04-14

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Rapid Tests Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
8-Drug Strip (Any Combination)	RT27-2077	Low Risk	30261	2020-04-14
9-Drug Strip (Any Combination)	RT27-2078	Low Risk	30261	2020-04-14
10-Drug Strip (Any Combination)	RT27-2079	Low Risk	30261	2020-04-14
11-Drug Strip (Any Combination)	RT27-2080	Low Risk	30261	2020-04-14
12-Drug Strip (Any Combination)	RT27-2081	Low Risk	30261	2020-04-14
Drug Test/Cup				
2-Drug Cup (Any Combination)	RT27-2082	Low Risk	30261	2020-04-14
3-Drug Cup (Any Combination)	RT27-2083	Low Risk	30261	2020-04-14
4-Drug Cup (Any Combination)	RT27-2084	Low Risk	30261	2020-04-14
5-Drug Cup (Any Combination)	RT27-2085	Low Risk	30261	2020-04-14
6-Drug Cup (Any Combination)	RT27-2086	Low Risk	30261	2020-04-14
7-Drug Cup (Any Combination)	RT27-2087	Low Risk	30261	2020-04-14
8-Drug Cup (Any Combination)	RT27-2088	Low Risk	30261	2020-04-14
9-Drug Cup (Any Combination)	RT27-2089	Low Risk	30261	2020-04-14
10-Drug Cup (Any Combination)	RT27-2090	Low Risk	30261	2020-04-14
11-Drug Cup (Any Combination)	RT27-2091	Low Risk	30261	2020-04-14
12-Drug Cup (Any Combination)	RT27-2092	Low Risk	30261	2020-04-14
Infectious Diseases and others				
Legionella Urinary Antigen Cassette	RT27-2147	Low Risk	30692	2020-04-14
Legionella Urinary Antigen Strip	RT27-2146	Low Risk	30692	2020-04-14
Adeno/Rotavirus Antigen Cassette	RT27-2131	Low Risk	42994	2020-04-14
Adeno Antigen Cassette	RT27-2132	Low Risk	42994	2020-04-14
Rotavirus Antigen Cassette	RT27-2161	Low Risk	30815	2020-04-14

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Chagas Cassette	RT27-2133	Low Risk	30820	2020-04-14
Chikungunya IgG/IgM Cassette	RT27-2135	Low Risk	42994	2020-04-14
Gonorrhea Cassette	RT27-2140	Low Risk	38851	2020-04-14
Influenza A&B Cassette	RT27-2145	Low Risk	39466	2020-04-14
Leishmania IgG/IgM Cassette	RT27-2149	Low Risk	30823	2020-04-14
Leishmania Cutaneous Strip	RT27-2148	Low Risk	30823	2020-04-14
Leptospira IgG/IgM	RT27-2150	Low Risk	30716	2020-04-14
Syphilis Cassette	RT27-2172	Low Risk	30687	2020-04-14
Syphilis Strip	RT27-2173, RT24-2173	Low Risk	30687	2020-04-14
Mononucleosis Cassette (Mono) (S/P)	RT27-2177	Low Risk	30826	2020-04-14
Strep A Cassette	RT27-2169	Low Risk	30826	2020-04-14
Strep A Strip	RT27-2168	Low Risk	30826	2020-04-14
Strep B Cassette	RT27-2171	Low Risk	30827	2020-04-14
Strep B Strip	RT27-2170	Low Risk	30827	2020-04-14
H1N1 Strip	RT40-2209	Low Risk	39461	2020-04-14
H. Pylori Ab Cassette (Serum/Plasma)	RT27-2141	Low Risk	30825	2020-04-14
H. Pylori Ab Cassette (Serum/Plasma/Whole Blood)	RT27-2142, RT24-2142	Low Risk	30825	2020-04-14
H. Pylori Antigen Cassette	RT27-2143, RT24-2203	Low Risk	30689	2020-04-14
HAV IgM	RT27-2108	Low Risk	30720	2020-04-14
Dengue IgG&IgM	RT27-2138, RT24-2197	Low Risk	42994	2020-04-14
Dengue NS1	RT24-2139	Low Risk	42994	2020-04-14
Dengue IgG/IgM/NS1	RT24-2208	Low Risk	42994	2020-04-14
Malaria P.f./Pv	RT24-2204	Low Risk	30674	2020-04-14
Malaria Pan	RT24-2206	Low Risk	30674	2020-04-14

List of devices.

Appendix

Date: 2020-12-06

Rapid Tests Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
Malaria P.f./Pan	RT24-2205, RT27-2154	Low Risk	30674	2020-04-14
Malaria P.f. Cassette	RT24-2207, RT27-2151	Low Risk	30674	2020-04-14
Malaria P.f. Strip	RT27-2152	Low Risk	30674	2020-04-14
Malaria P.f./vivax	RT27-2153	Low Risk	30674	2020-04-14
Norovirus	RT27-2156	Low Risk	32459	2020-04-14
Salmonella typhi Antigen Cassette	RT27-2163	Low Risk	30709	2020-04-14
Salmonella typhi IgG/IgM Cassette	RT27-2164	Low Risk	30709	2020-04-14
Salmonella typhi/paratyphi antigen	RT27-2165	Low Risk	30709	2020-04-14
Scrub typhus IgG Strip	RT4-2166	Low Risk	30717	2020-04-14
Scrub typhus IgM Strip	RT4-2167	Low Risk	30717	2020-04-14
Zika Virus IgG/IgM Cassette	RT27-2178	Low Risk	42994	2020-04-14
COVID-19 IgG/IgM	RT45-2198	Low Risk	44022	2020-04-14
SARS-CoV2 Antigen	RT45-2214	Low Risk	44022	2020-08-24
Tuberculosis (TB) Cassette	RT27-2175	Low Risk	44020	2020-04-14
Tuberculosis (TB) Strip	RT27-2174	Low Risk	44020	2020-04-14
HEV IgG/IgM	RT27-2119	Low Risk	30756	2020-04-14
Cryptococcus Ag	RT27-2137	Low Risk	37746	2020-04-14
Hantavirus IgG/IgM	RT27-2144	Low Risk	15048014	2020-04-14
Mycoplasma pneumoniae Ag	RT27-2155	Low Risk	17311	2020-04-14
Rickettsia IgG/IgM	RT24-2160	Low Risk	30717	2020-04-14
RSV	RT27-2162	Low Risk	30814	2020-04-14
Tetanus	RT27-2176	Low Risk	38876	2020-04-14

Fertility

FSH Urine Cassette	RT27-2094	Low Risk	30512	2020-04-14

List of devices.

Appendix

Date: 2020-12-06

Rapid Tests Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
FSH Urine Strip	RT27-2093	Low Risk	30512	2020-04-14
Ovulation				
LH Urine Cassette	RT27-2106	Low Risk	30515	2020-04-14
LH Urine Strip	RT27-2105	Low Risk	30515	2020-04-14
Pregnancy				
hCG 10 mIU/ml Midstream	RT27-2099	Low Risk	30513	2020-04-14
hCG 20 mIU/ml Midstream	RT27-2102	Low Risk	30513	2020-04-14
hCG 10mIU/ml urine Cassette	RT27-2095	Low Risk	30513	2020-04-14
hCG 10mIU/ml urine Strip	RT27-2097	Low Risk	30513	2020-04-14
hCG 10mIU/ml urine/serum	RT27-2098	Low Risk	30513	2020-04-14
hCG 20 mIU/ml urine Cassette	RT27-2101	Low Risk	30513	2020-04-14
hCG 20 mIU/ml urine Strip	RT27-2100	Low Risk	30513	2020-04-14
hCG 10mIU/ml urine/serum/p	RT27-2096	Low Risk	30513	2020-04-14
hCG 20 mIU/ml urine/serum/p Cassette	RT27-2104	Low Risk	30513	2020-04-14
hCG 20 mIU/ml urine/serum/p Strip	RT27-2103	Low Risk	30513	2020-04-14
Others				
Micro-Albumin (HAS) Strip	RT27-2197	Low Risk	30246	2020-04-14
Ferritin	RT27-2196	Low Risk	30377	2020-04-14
H-FABP	RT27-2107	Low Risk	1230190	2020-04-14
Nt-proBNP	RT27-1157	Low Risk	12130190	2020-04-14
Procalcitonin (S/P/WB)	RT27-2158	Low Risk	12069016	2020-04-14
Procalcitonin (S/P)	RT27-2159	Low Risk	12069016	2020-04-14

List of devices.

Appendix

Date: 2020-12-06

Rapid Tests Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
Urine Reagent Strips				
URS-1G	RT27-2185	Low Risk	17419	2020-04-14
URS-2PK	RT27-2186	Low Risk	30226	2020-04-14
URS-3 GKpH	RT27-2187	Low Risk	30226	2020-04-14
URS-4 GKpHB	RT27-2188	Low Risk	30226	2020-04-14
URS-5GKpHBP	RT27-2189	Low Risk	30226	2020-04-14
URS-6GKpHBPBili	RT27-2190	Low Risk	30226	2020-04-14
URS-7GKpHBPBiliU	RT27-2191	Low Risk	30226	2020-04-14
URS-8GKpHBPBiliUN	RT27-2192	Low Risk	30226	2020-04-14
URS-9GKpHBPBiliUNS	RT27-2193	Low Risk	30226	2020-04-14
URS-10GKpHBPBiliUNSL	RT27-2194	Low Risk	30226	2020-04-14
URS-11	RT27-2195	Low Risk	30226	2020-04-14

List of devices.

Appendix

Date: 2020-12-06

Serology Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
C- Reactive Protein (CRP)	SL25-3002, SL25-3003	Low Risk	30499	2020-04-14
RF	SL25-3008, SL25-3009	Low Risk	30500	2020-04-14
Anti- Streptolysin O(ASO)	SL25-3000, SL25-3001	Low Risk	30495	2020-04-14
Infectious Mononucleosis Screening (Mono)	SL25-3004, SL25-3005	Low Risk	30810	2020-04-14
RPR	SL25-3011, SL25-3012	Low Risk	17393	2020-04-14
Lupus Erythematosus (SLE)	SL25-3007	Low Risk	30487	2020-04-14
TPHA	SL25-3016	Low Risk	32453	2020-04-14
Rotavirus	SL25-3010	Low Risk	17381	2020-04-14
S. Aureus	SL25-3013	Low Risk	33887	2020-04-14
Streptococci Lancefield grouping	SL25-3015	Low Risk	17389	2020-04-14
VDRL Antigen	SL25-3017	Low Risk	17395	2020-04-14
PARATYPHOID A (Salmonella, flagellar a antigen)	SL25-3022	Low Risk	39453	2020-04-14
PARATYPHOID B (Salmonella, flagellar b antigen)	SL25-3023	Low Risk	39453	2020-04-14
PARATYPHOID C (Salmonella typhi, flagellar c antigen)	SL25-3024	Low Risk	39453	2020-04-14
SALMONELLA Group A Antigen (somatic antigen)	SL25-3028	Low Risk	39453	2020-04-14
SALMONELLA Group B Antigen (somatic antigen)	SL25-3029	Low Risk	39453	2020-04-14
SALMONELLA Group C Antigen (somatic antigen)	SL25-3030	Low Risk	39453	2020-04-14
TYPHOID H (Salmonella typhi, flagellar d antigen)	SL25-3031	Low Risk	39453	2020-04-14
TYPHOID O (Salmonella typhi, somatic Group D antigen)	SL25-3032	Low Risk	39453	2020-04-14
Brucella Melitensis	SL25-3018	Low Risk	39536	2020-04-14
Brucella Abortus	SL25-3019	Low Risk	39536	2020-04-14
PROTEUS OX2 (somatic antigen)	SL25-3026	Low Risk	39543	2020-04-14
PROTEUS OX19 (somatic antigen)	SL25-3025	Low Risk	39543	2020-04-14

List of devices.

Appendix

Date: 2020-12-06

Serology Device Group	Document / Ref. No.	Risk classification	GMDN code	First CE-marking
PROTEUS OXK (somatic antigen)	SL25-3027	Low Risk	39543	2020-04-14

Certificate of Registration

This is to certify the Quality Management System of:

MONOCENT, INC.
9237 Eton Avenue
Chatsworth, CA 91311

has been assessed and found to be in compliance with the requirements of

ISO 9001:2015

for the following scope:

Manufacturing and Distribution of IVD Products
(Serology, Rapid, ELISA, CLIA, IFA Test Systems and Instrumentation)

IAF Code: 31 & 35

Certificate Number: **SARA-2019-CA-0253-01-A**

Originally Registered:
January 10, 2020

Latest Issue:
December 20, 2022

Certification Cycle:
January 10, 2023 – January 9, 2026

Expiration Date:
January 9, 2026

President, SARA Registrar

MSCB-194

Certificate of Registration

This is to certify the Quality Management System of:

MONOCENT, INC.
9237 Eton Avenue
Chatsworth, CA 91311

has been assessed and found to be in compliance with the requirements of

ISO 13485:2016

for the following scope:

Manufacturing and Distribution of IVD Products
(Serology, Rapid, ELISA, CLIA, IFA Test Systems and Instrumentation)

ISO 13485:2016

Medical Device Code: In Vitro Dianostics (IVD) & Non-active Medical Device

Certificate Number: **SARA-2019-CA-0253-02-A**

Originally Registered:
January 10, 2020

Latest Issue:
December 20, 2022

Certification Cycle:
January 10, 2023 – January 9, 2026

Expiration Date:
January 9, 2026

President, SARA Registrar

MSCB-194

This registration is subject to the company maintaining its system to the required standard which will be monitored annually by SARA Registrar.
This certificate remains the property of Standards American Registrations Authority (SARA Registrar) and shall be returned immediately upon request.
SARA Registrar Headquarter Mailing: 1807H Santa Rita Road, #175, Pleasanton, CA 94566

MONOCENT
Innovation & Excellence

ENGLISH

Brucella IgG ELISA TEST SYSTEM

CE

REF EL1-1107 | Σ 96 TESTS | IVD

INTENDED USE

The Monocent, Inc.'s Brucella IgG ELISA Test System is intended for the detection of IgG antibody to Brucella in human serum or plasma.

SUMMARY AND EXPLANATION

Brucella is a gram negative coccobacilli capable of infecting a wide range of animal and man. Of the three species causing human infection, *B. melitensis* is the most patogenic followed by *B. suis* and *B. abortus* . Brucellosis is transmitted through contaminated and untreated milk and milk products and by direct contact with infected animals (cattle, sheep, goats, pigs, camels, buffaloes, and, very recently, seals), animal carcasses, and abortion materials. Worldwide, millions of individuals are at risk, especially in developing countries where the infection in animals has not been brought under control, heat treatment procedures of milk (e.g. pasteurization) are not routinely applied, and food habits such as consumption of raw milk. The incubation period of brucellosis is usually one to three weeks, but sometimes may be several months. The illness may be mild and self-limiting or severe. The disease is accompanied by continued, intermittent, or irregular fever, headache, weight loss and generalized aching and fatigue. Urogenital symptoms may dominate the clinical presentation in some patients.

This method uses *B. abortus* outer membrane, which is shared by the other species. Brucella IgG and IgA antibodies persist for many years after infection. A significant increase in Brucella IgG level is in patients with symptoms of brucellosis is indicative of recent exposure. IgM antibodies are present in acute brucellosis and also found in about 33% of patients with chronic brucellosis.

PRINCIPLE OF THE TEST

Diluted patient serum is added to wells coated with purified antigen. IgG specific antibody, if present, binds to the antigen. All unbound materials are washed away and the enzyme conjugate is added to bind to the antibody-antigen complex, if present. Excess enzyme conjugate is washed off and substrate is added. The plate is incubated to allow the hydrolysis of the substrate by the enzyme. The intensity of the color generated is proportional to the amount of IgG specific antibody in the sample.

MATERIALS AND COMPONENTS

• Microwell coated with Brucella abortus antigen	12x8x1
• Sample Diluent: 1 bottle (ready to use)	22 ml
• Calibrator: 1 Vial (ready to use)	1ml
• Positive Control: 1 vial (ready to use)	1ml
• Negative Control: 1 vial (ready to use)	1ml
• Enzyme conjugate: 1 bottle (ready to use)	12ml
• TMB Substrate: 1 bottle (ready to use)	12ml
• Stop Solution: 1 bottle (ready to use)	12ml
• Wash concentrate 20X: 1 bottle	25ml

MATERIALS REQUIRED BUT NOT PROVIDED

- Distilled or deionized water
- Precision pipettes
- Disposable pipette tips
- ELISA reader capable of reading absorbance at 450nm
- Absorbance paper or paper towel
- Graph paper

STORAGE CONDITIONS

- Store the kit at 2 - 8 °C.
- Keep microwells sealed in a dry bag with desiccants.
- The reagents are stable until expiration of the kit.
- Do not expose test reagents to heat, sun, or strong light.

PRECAUTIONS

1. Potential biohazardous materials:
   The calibrator and controls contain human source components which have been tested and found non-reactive for hepatitis B surface antigen as well as HIV antibody with FDA licensed reagents. However, there is no test method that can offer complete assurance that HIV, Hepatitis B virus or other infectious agents are absent. These reagents should be handled at the Biosafety Level 2, as recommended in the Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories." 1984.
2. Optimal results will be obtained by strict adherence to the test protocol. Precise pipetting as well as following the exact time and temperature requirements is essential.
3. Do not pipette by mouth. Do not smoke, eat, or drink in the areas in which specimens or kit reagents are handled.
4. The components in this kit are intended for use as an integral unit. The components of different lots should not be mixed.
5. Control sera and sample diluent contain preserved with sodium azide. Sodium azide may react with lead and copper plumbing to form explosive metal azide. On disposal, flush with a large volume of water.

SPECIMEN COLLECTION

1. Collect blood specimens and separate the serum.
2. Specimens may be refrigerated at 2–8°C for up to seven days or frozen for up to six months. Avoid repetitive freezing and thawing.

REAGENT PREPARATION

Prepare 1X Wash buffer by adding the contents of the bottle (25 ml, 20X) to 475 ml of distilled or deionized water. Store at room temperature (20-25°C).

TEST PROCEDURE

Prior to assay, allow reagents to reach room temperature. Gently mix all reagents before use.

1. Bring all specimens and kit reagents to room temperature (20-25°C) and gently mix.
2. Place the desired number of coated strips into the holder.
3. Negative control, positive control, and calibrator are ready to use. Prepare 1:21 dilution of test samples, by adding 10 µl of the sample to 200 µl f sample diluent. Mix well.
4. Dispense 100 µl f diluted sera, calibrator and controls into the appropriate wells. For the reagent blank, dispense 100µl ample diluent in 1A well position. Tap the holder to remove air bubbles from the liquid and mix well. Incubate for 20 minutes at room temperature.
5. Remove liquid from all wells. Wash wells three times with 300µl of 1X wash buffer. Blot on absorbance paper or paper towel.
6. Dispense 100 µl of enzyme conjugate to each well and incubate for 20 minutes at room temperature.
7. Remove enzyme conjugate from all wells. Wash wells three times with 300 µl of 1X wash buffer. Blot on absorbance paper or paper towel.
8. Dispense 100 µl of TMB substrate and incubate for 10 minutes at room temperature.
9. Add 100 µl of stop solution.
10. Read O.D. at 450 nm using ELISA reader within 15 min. A dual wavelength is recommended with reference filter of 600-650 nm.

CALCULATION OF RESULTS

1. Check Calibrator Factor (CF) value on the calibrator bottle. This value might vary from lot to lot. Make sure you check the value on every kit.

2. Calculate the cut-off value: Calibrator OD x Calibrator Factor (CF).
3. Calculate the Ab (Antibody) Index of each determination by dividing the O.D. value of each sample by cut-off value.

Example of typical results:
Calibrator mean OD = 0.8
Calibrator Factor (CF) = 0.5
Cut-off Value = 0.8 x 0.5= 0.400
Positive control O.D. = 1.2
Ab Index = 1.2 / 0.4 = 3
Patient sample O.D. = 1.6
Ab Index = 1.6 / 0.4 = 4.0

QUALITY CONTROL

The test run may be considered valid provided the following criteria are met:

1. The O.D. of the Calibrator should be greater than 0.250.
2. The Ab index for Negative control should be less than 0.9.
3. The Ab Index for Positive control should fall within the range specified on the COA/label.

INTERPRETATION

The following is intended as a guide to interpretation of Brucella IgG test results; each laboratory is encouraged to establish its own criteria for test interpretation based on sample populations encountered.

Antibody Index Interpretation

<0.9	No detectable antibody to Brucella IgG by ELISA.
0.9-1.1	Borderline positive. Follow-up testing is recommended if clinically indicated.
>1.1	Detectable antibody to Brucella IgG by ELISA.

LIMITATIONS OF THE TEST

1. The test results obtained using this kit serve only as an aid to diagnosis and should be interpreted inrelation to the patient's history, physical findings and other diagnostic procedures.
2. Lipemic or hemolyzed samples may cause erroneous results.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

92 patient sera were tested by this Brucella IgG ELISA and a reference ELISA method. 14 sera were positive and 77 were negative by both methods (99% agreement). The results are summarized below:

		Brucella IgG ELISA		
		+	-	Total
Reference ELISA Kit	+	14	0	14
	-	1	77	78
	Total	15	77	92

Precision

Intra Assay Study

Serum	No. of Replicates	Mean	Standard Deviation	Coefficient of Variation %
1	16	1.31	0.071	5.41
2	16	0.86	0.052	6.04
3	16	0.24	0.015	6.25

Inter Assay Study

Serum	No. of Replicates	Mean	Standard Deviation	Coefficient of Variation %
1	10	1.92	0.21	10.93
2	10	1.44	0.17	11.80
3	10	0.25	0.032	12.80

REFERENCE

1. Gad El-Rab MO; Kambal AM. Evaluation of a Brucella enzyme immunoassay test (ELISA) in comparison withbacteriological culture and agglutination. J Infect 1998; 36(2):197-201.
2. Mikolon AB; Gardner IA; Hietala SK; Hernandez de Anda J; Chamizo Pestana E; Hennager SG; Edmondson AJ. Evaluation of North American antibody detection tests for diagnosis of brucellosis in goats. J Clin Microbiol 1998; 36(6):1716-22.
3. Bowden RA; Cloeckaert A; Zygmunt MS; Bernard S; Dubray G. Surface exposure of outer membrane protein and lipopolysaccharide epitopes in Brucella species studied by enzyme-linked immunosorbent assay and flow cytometry. Infect Immun 1995; 63(10):3945-52.
4. Baldi PC; Miguel SE; Fossati CA; Wallach JC. Serological follow-up of human brucellosis by measuring IgG antibodies to lipopolysaccharide and cytoplasmic proteins of Brucella species. Clin Infect Dis 1996;22(3):446-55
5. Casao MA; Leiva J; Diaz R; Gamazo C. Anti-phosphatidylcholine antibodies in patients with brucellosis. J MedMicrobiol 1998; 47(1):49-54.

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www.cepartner4u.com

Revision Date: 2016-07-06

MONOCENT
Innovation & Excellence

ENGLISH

Brucella IgM ELISA TEST SYSTEM

CE

REF EL1-1108 | 96 TESTS | IVD

INTENDED USE

The Monocent, Inc.'s Brucella IgM ELISA Test System is intended for the detection of IgM antibody to Brucella in human serum or plasma.

SUMMARY AND EXPLANATION

Brucella is a gram negative coccobacilli capable of infecting a wide range of animal and man. Of the three species causing human infection, *B. melitensis* is the most patogenic followed by *B. suis* and *B. abortus* . Brucellosis is transmitted through contaminated and untreated milk and milk products and by direct contact with infected animals (cattle, sheep, goats, pigs, camels, buffaloes, and, very recently, seals), animal carcasses, and abortion materials. Worldwide, millions of individuals are at risk, especially in developing countries where the infection in animals has not been brought under control, heat treatment procedures of milk (e.g. pasteurization) are not routinely applied, and food habits such as consumption of raw milk. The incubation period of brucellosis is usually one to three weeks, but sometimes may be several months. The illness may be mild and self-limiting or severe. The disease is accompanied by continued, intermittent, or irregular fever, headache, weight loss and generalized aching and fatigue. Urogenital symptoms may dominate the clinical presentation in some patients.

This method uses *B. abortus* outer membrane, which is shared by the other species. Brucella IgG and IgA antibodies persist for many years after infection. A significant increase in Brucella IgG level is in patients with symptoms of brucellosis is indicative of recent exposure. IgM antibodies are present in acute brucellosis and also found in about 33% of patients with chronic brucellosis.

PRINCIPLE OF THE TEST

Diluted patient serum (serum diluent contains sorbent to remove Rheumatoid Factor and human IgG interference) is added to wells coated with purified antigen. IgM specific antibody, if present, binds to the antigen. All unbound materials are washed away and the enzyme conjugate is added to bind to the antibody-antigen complex, if present. Excess enzyme conjugate is washed off and substrate is added. The plate is incubated to allow the hydrolysis of the substrate by the enzyme. The intensity of the color generated is proportional to the amount of IgM specific antibody in the sample.

MATERIALS AND COMPONENTS

• Microwell coated with Brucella antigen	12x8x1
• Sample Diluent: 1 bottle (ready to use)	22 ml
• Calibrator: 1 Vial (ready to use)	1ml
• Positive Control: 1 vial (ready to use)	1ml
• Negative Control: 1 vial (ready to use)	1ml
• Enzyme conjugate: 1 bottle (ready to use)	12ml
• TMB Substrate: 1 bottle (ready to use)	12ml
• Stop Solution: 1 bottle (ready to use)	12ml
• Wash concentrate 20X: 1 bottle	25ml

MATERIALS REQUIRED BUT NOT PROVIDED

- Distilled or deionized water
- Precision pipettes
- Disposable pipette tips
- ELISA reader capable of reading absorbance at 450nm
- Absorbance paper or paper towel
- Graph paper

STORAGE CONDITIONS

- Store the kit at 2 - 8 °C.
- Keep microwells sealed in a dry bag with desiccants.
- The reagents are stable until expiration of the kit.
- Do not expose test reagents to heat, sun, or strong light.

PRECAUTIONS

1. Potential biohazardous materials:
   The calibrator and controls contain human source components which have been tested and found non-reactive for hepatitis B surface antigen as well as HIV antibody with FDA licensed reagents. However, there is no test method that can offer complete assurance that HIV, Hepatitis B virus or other infectious agents are absent. These reagents should be handled at the Biosafety Level 2, as recommended in the Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories." 1984.
2. Optimal results will be obtained by strict adherence to the test protocol. Precise pipetting as well as following the exact time and temperature requirements is essential.
3. Do not pipette by mouth. Do not smoke, eat, or drink in the areas in which specimens or kit reagents are handled.
4. The components in this kit are intended for use as an integral unit. The components of different lots should not be mixed.
5. Control sera and sample diluent contain preserved with sodium azide. Sodium azide may react with lead and copper plumbing to form explosive metal azide. On disposal, flush with a large volume of water.

SPECIMEN COLLECTION

1. Collect blood specimens and separate the serum.
2. Specimens may be refrigerated at 2–8°C for up to seven days or frozen for up to six months. Avoid repetitive freezing and thawing.

REAGENT PREPARATION

Prepare 1X Wash buffer by adding the contents of the bottle (25 ml, 20X) to 475 ml of distilled or deionized water. Store at room temperature (20-25°C).

TEST PROCEDURE

Bring all specimens and kit reagents to room temperature (20-25°C) and gently mix.

1. Place the desired number of coated strips into the holder.
2. Negative control, positive control, and calibrator are ready to use. Prepare 1:21 dilution of test samples, by adding 10 µl of the sample to 200 µl of sample diluent. Mix well.
3. Dispense 100 µl of diluted sera, calibrator and controls into the appropriate wells. For the reagent blank, dispense 100µl sample diluent in 1A well position. Tap the holder to remove air bubbles from the liquid and mix well. Incubate for 20 minutes at room temperature.
4. Remove liquid from all wells. Wash wells three times with 300µl of 1X wash buffer. Blot on absorbance paper or paper towel.
5. Dispense 100 µl of enzyme conjugate to each well and incubate for 20 minutes at room temperature.
6. Remove enzyme conjugate from all wells. Wash wells three times with 300µl of 1X wash buffer. Blot on absorbance paper or paper towel.
7. Dispense 100 µl of TMB substrate and incubate for 10 minutes at room temperature.
8. Add 100 µl of stop solution.
9. Read O.D. at 450 nm using ELISA reader within 15 min. A dual wavelength is recommended with reference filter of 600-650 nm.

CALCULATION OF RESULTS

1. Check Calibrator Factor (CF) value on the calibrator bottle. This value might vary from lot to lot. Make sure you check the value on every kit.

2. Calculate the cut-off value: Calibrator OD x Calibrator Factor (CF).
3. Calculate the Ab (Antibody) Index of each determination by dividing the O.D. value of each sample by cut-off value.

Example of typical results:
Calibrator mean OD = 0.8
Calibrator Factor (CF) = 0.5
Cut-off Value = 0.8 x 0.5= 0.400
Positive control O.D. = 1.2
Ab Index = 1.2 / 0.4 = 3
Patient sample O.D. = 1.6
Ab Index = 1.6 / 0.4 = 4.0

QUALITY CONTROL

The test run may be considered valid provided the following criteria are met:

1. The O.D. of the Calibrator should be greater than 0.250.
2. The Ab index for Negative control should be less than 0.9.
3. The Ab Index for Positive control should fall within the range specified on the COA/label.

INTERPRETATION

The following is intended as a guide to interpretation of Brucella IgG test results; each laboratory is encouraged to establish its own criteria for test interpretation based on sample populations encountered.

Antibody Index Interpretation

<0.9	No detectable antibody to Brucella IgM by ELISA.
0.9-1.1	Borderline positive. Follow-up testing is recommended if clinically indicated.
>1.1	Detectable antibody to Brucella IgM by ELISA.

LIMITATIONS OF THE TEST

1. To enhance sensitivity and specificity of this IgM test provided sample diluent has been formulated to block IgG and Rheumatoid Factor (RF) interferences. Turbidity could be seen after diluting serum with sample diluent. This turbidity is due to the blocking of serum IgG and shows no interference with test results. It can be removed by centrifugation.
2. In specimens with high RF and high autoimmune antibodies, the possibility of eliminating the interferences cannot be ruled out entirely.
3. The test results obtained using this kit serve only as an aid to diagnosis and should be interpreted in relation to the patient's history, physical findings and other diagnostic procedures.
4. Lipemic or hemolyzed samples may cause erroneous results.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

178 patient sera were tested by this Brucella IgM ELISA and a reference ELISA method. 26 sera were positive and 149 were negative by both methods (98% agreement). The results are summarized below:

		Brucella IgM ELISA		
		+	-	Total
Reference ELISA Kit	+	23	2	25
	-	1	152	153
	Total	24	154	178

Precision

Intra Assay Study

Serum	No. of Replicates	Mean	Standard Deviation	Coefficient of Variation %
1	16	1.49	0.066	4.43
2	16	1.01	0.051	5.50
3	16	0.19	0.012	6.31

Inter Assay Study

Serum	No. of Replicates	Mean	Standard Deviation	Coefficient of Variation %
1	10	1.41	0.139	09.85
2	10	0.97	0.100	10.30
3	10	0.20	0.022	11.00

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5. Casao MA; Leiva J; Diaz R; Gamazo C. Anti-phosphatidylcholine antibodies in patients with brucellosis. J Med Microbiol 1998; 47(1):49-54.

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ENGLISH

EBNA IgG ELISA TEST SYSTEM

CE

REF EL2-1130 | Σ 96 TESTS | IVD

INTENDED USE

The Monocent, Inc.'s Epstein Barr Virus (EBV) EBNA IgG ELISA Test System is an Enzyme-Linked Immunosorbent Assay kit providing material for the detection of IgG-class antibodies to the nuclear antigen of EBV in human serum or plasma. This assay is intended for *in vitro* use only.

SUMMARY AND EXPLANATION

Epstein Barr Virus (EBV) is a herpes virus, which causes infectious mononucleosis (IM). It is also associated with Burkitt's lymphoma, nasopharyngeal carcinoma and lymphatic proliferative syndromes in immunodepressed patients. The virus is widespread throughout the world and 80-90% of the population is serum-positive.
The laboratory diagnosis of IM is traditionally performed by detecting heterophile antibodies which develop in the serum during the course of the infection, and which agglutinate horse erythrocytes. However, these antibodies may not always be present in patients affected by IM, particularly if below 14 years of age; furthermore, they may also persist for over a year after the infection. The determination of heterophile antibodies alone may therefore lead to an erroneous diagnosis. It is therefore important to determine the presence of antibodies towards the viral antigens. The detection of antibodies directed to the "Viral Capsid Antigen" (VCA) and the nuclear antigen (EBNA) is particularly useful. During the course of IM, the IgM- and IgA -class antibodies to VCA appear early and a little later IgG-class antibodies to VCA, while the IgG to EBNA develop later during the infection. The presence of IgA/IgM against VCA in the absence of IgG against EBNA therefore indicates that there is a current infection, while the presence of IgG against both VCA and EBNA is indicative of a prior infection.

PRINCIPLE OF THE TEST

The EBV EBNA IgG ELISA Test System is based on the ELISA technique. In the assay, controls and unknowns are incubated in microtitration wells coated with recombinant protein of Epstein Barr Virus nuclear antigen (EBNA). After incubation and washing, the wells are treated with the conjugate, composed of anti-human IgG antibodies labelled with peroxidase. After a second incubation and washing step, the wells are incubated with the substrate tetramethylbenzidine (TMB). An acidic stopping solution is then added and the degree of enzymatic turnover of the substrate is determined by wavelength absorbance measurement at 450 nm. The absorbance measured is directly proportional to the concentration of anti-EBV EBNA IgG antibodies present.

MATERIALS AND COMPONENTS PROVIDED

• EBV nuclear Antigen-Coated Microtitration Strip	One Plate
• Wash Concentrate	One Bottle
• Sample Diluent	One Bottle
• TMB-Substrate	One Bottle
• Negative control	One Vial
• Cut off control	One Vial
• Positive control	One Vial
• 2nd Antibody Conjugate	One Bottle
• Stopping Solution	One Bottle

MATERIALS REQUIRED BUT NOT PROVIDED

- Microtitration plate reader capable of absorbance measurement at 450 nm
- Deionized/Distilled water
- Precision pipette to deliver 10 µl, 100 µl and 1 ml
- Semi-automatic pipette to deliver 100 µl
- Automatic microtitration plate washer
- Absorbent material for blotting the strips
- Incubator

REAGENTS PROVIDED

- **Antigen-Coated Microtitration Strips:**
  One stripholder containing 12x8 (96) microtitration wells coated with EBV nuclear antigen. Store at 2-8°C until expiration date. Remove the support and strips to be used from the foil package and place the unused strips in the polythene bag with the silica gel, expel the air and seal by pressing the closure. Once opened, the product is stable for 4 weeks at 2-8°C.
- **Wash Concentrate:**
  One bottle, 100 mL, containing a phosphate buffered saline, concentrated 10-fold containing 0.5% Brij weight by volume (w/v). Dilute with deionized/distilled water prior to use. Store at 2-8°C until expiration date.
- **Sample Diluent:**
  One bottle, 100 ml, containing a BSA solution with 0.09% sodium azide as a preservative. Store at 2-8°C until expiration date.
- ***EBV EBNA* IgG Controls:**
  Three vials, negative, cut off and positive, each 2 mL of human serum in a 0.01 M phosphate buffer containing BSA with 0.09% sodium azide as a preservative. Store at 2-8°C until expiration date.
- **2nd Antibody Conjugate:**
  One bottle, 12 mL, containing anti-human IgG monoclonal antibodies labelled with peroxidase, in a phosphate buffer solution with 0.02% Proclin™. Store at 2-8°C until expiration date.
- **TMB-Substrate:**
  One bottle, 12 mL, containing tetramethylbenzidine (TMB) and hydrogen peroxide stabilized in citrate buffer, pH 3.8. Store at 2-8°C until expiration date.
- **Stopping Solution:**
  One bottle, 15 mL, containing 0.3 M H_2SO_4 in solution. Store at 2-8°C until expiration date.

PRECAUTIONS

For *in vitro* use

The following universal Good Laboratory Practices should be observed:
Do not eat, drink, smoke or apply cosmetics where immunodiagnostic material is being handled. Do not pipet by mouth. Wear lab coats and disposable gloves when handling immunodiagnostic material. Wash hands thoroughly afterwards. Cover working area with disposable absorbent paper. Wipe up spills immediately and decontaminate affected surfaces. Avoid generation of aerosols. Provide adequate ventilation. Handle and dispose all reagents and material in compliance with applicable regulations.

WARNING: POTENTIAL BIOHAZARDOUS MATERIAL
This kit may contain some reagents made with human and animal source material (e.g. serum, plasma or bovine albumin) or used in conjunction with human and animal source material. The human material in this kit has been tested by CE recommended methods and found to be non-reactive for HIV-1/2 Antibodies, HCV and HbsAg; the material of animal source is also free from infection. No available test method can offer complete assurance of eliminating potential biohazardous risk. Handle all reagents and patient samples at a Biosafety Level 2, as recommended for any potentially infectious human material in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories," 4th Edition, April 1999.

WARNING AND PRECAUTION:
Some of the reagents in this kit contain sodium azide as a preservative at concentrations below the regulatory limit of < 0.1%. Although significantly diluted, concentrated sodium azide is an irritant to skin and mucous membranes and may react with lead and copper plumbing to form explosive metal azides, especially if accumulated. Additionally, TMB and Sulfuric Acid, in concentrated amounts are also irritants to skin and mucous membranes. These substances are in diluted form and therefore may minimize exposure risks significantly but not completely. Provide adequate ventilation. Avoid contact with skin, eyes and clothing. In case of contact with any of these reagents, wash thoroughly with water and seek medical advice. Dispose all nonhazardous reagents by flushing with large volumes of water to prevent buildup of chemical hazards in the plumbing system.
For further information regarding hazardous substances in the kit, please refer to the component specific MSDS by request.

SPECIMEN COLLECTION AND HANDLING

Serum should be used, and the usual precautions for venepuncture should be observed. Specimens may be stored at 2-8°C for 2 days. For longer periods, store at –20°C. Do not use haemolyzed or lipemic specimens. Avoid repeated freezing and thawing of samples.

ASSAY PREPARATION

A thorough understanding of this package insert is necessary for successful use of the product. Reliable results will only be obtained by using precise laboratory techniques and accurately following the package insert. Bring all kit reagents and specimens to room temperature (~25°C) before use. Thoroughly mix the reagents and samples before use by gentle inversion. Do not mix various lots of any kit component within an individual assay. Do not use any component beyond the expiration date shown on its label. Incomplete washing will adversely affect the outcome and assay precision. To minimize potential assay drift due to variation in the substrate incubation time, care should be taken to add the stopping solution into the wells in the same order and speed to add the TMB Chromogen Solution. Avoid microbial contamination of reagents, especially of the conjugate, wash buffer and diluent. Avoid contamination of the TMB Chromogen Solution with the Conjugate. Use a clean disposable pipette tip for each reagent. Avoid pipettes with metal parts. Containers and semi-automatic pipette tips used for the Conjugate and TMB can be reused provided they are thoroughly rinsed with deionized/distilled water and dried prior to and after each usage. The enzyme used as the label is inactivated by oxygen, and is highly sensitive to microbial contamination, sodium azide, hypochlorous acid and aromatic chlorohydrocarbons often found in laboratory water supplies. Use high quality water. Avoid exposure of the reagents to excessive heat or sunlight during storage and incubation.

REAGENT PREPARATION

- **Wash Solution:**
  Dilute 1:10 with deionized/distilled water prior to use. If crystals are present, they should be dissolved at 37°C before dilution. Pour 100 mL of the Wash Concentrate into a clean container and dilute by adding 900 mL of deionized/distilled water. Mix thoroughly by inversion. The wash solution is stable for 5 days at room temperature and 2 weeks at 2-8°C when stored in a tightly sealed bottle.
- **Microtitration Strips:**
  Select the number of coated strips required for the assay. The remaining unused wells should be placed in the resealable pouch with a desiccant pack. The pouch must be resealed to protect from moisture.

TEST PROCEDURE

All specimens and reagents to reach room temperature (~25°C) before use. Serum Samples and Controls should be assayed in duplicate.

1. Mark the microtitration strips to be used.
2. Dilute serum samples 1:101 distributing 10 µL of serum into 1 mL of Sample Diluent.
3. Pipette 100 µL of each diluted serum sample and ready to use controls to the appropriate wells.
4. Incubate for 45 minutes at 37°C.
5. Aspirate and wash each well four (4) times for 30 seconds with Washing Solution using an automatic microplate washer or manually using a dispenser. Blot and dry by inverting plate on absorbent material.

NOTE: *Use of an automatic microplate washer is strongly recommended. Incomplete washing will adversely affect assay precision. If a microplate washer is not available, (a) completely aspirate the liquid from each well, (b) dispense 0.35 mL of the Wash Solution into each well. (c) repeat step (a) and (b) four times.*

6. Add 100 µL of Enzyme-Labeled 2nd Antibody into each well.
7. Incubate for 45 minutes at 37°C.
8. Aspirate and wash each well four times for 30 seconds with Washing Solution using an automatic microplate washer or manually using a dispenser. Blot and dry by inverting plate on absorbent material.
9. Add 100 µL of TMB Chromogen Solution to each well using a dispenser.
10. Incubate for 15 minutes at room temperature. Avoid exposure to direct sunlight.
11. Add 100 µL of Stopping Solution to each well using a dispenser.
12. Read the absorbance of the solution in the wells within 30 minutes, using a microplate reader set to 450 nm. If wavelength correction is available, set the instrument to dual wavelength measurement at 450 nm with background wavelength correction set at 600 or 620 nm.

CALCULATION OF RESULTS

Calculate the mean absorbance for each control and unknown.

Qualitative results:

If the absorbance of the sample is higher than that of the Cut-Off, the sample is positive for the presence of specific IgG.

Calculate the ratio between the average OD value of the sample and that of the Cut-Off. The sample is considered:

Positive: if the ratio is > 1.1.
Doubtful: if +/- 10% of the Cut-Off.
Negative: if the ratio is < 0.9.

If the result is doubtful, repeat the test. If it remains doubtful, collect a new serum sample.

LIMITATIONS OF THE PROCEDURE

- A serum sample obtained during the early phase of infection, when only IgM antibodies are present, may be negative by this procedure.
- The test result should be used in conjunction with information available from the evaluation of other clinical and diagnostic procedures.
- Avoid repeated freezing and thawing of reagents and specimens.
- Grossly haemolyzed, icteric or lipemic specimens should be avoided.
- Heat inactivated sera should be avoided.

QUALITY CONTROL

The OD values of Cut-Off control must be at least 0.2.
Positive control must have an OD at least 1.5 times that of Cut-Off.

PERFORMANCE CHARACTERISTICS

1. Sensitivity and Specificity

100 human sera were analysed by this EBV EBNA IgG ELISA Test System and an Elisa reference method. Out of 100 samples, 69 were positive for the presence of IgG antibodies to EBV EBNA IgG by Monocent, Inc.'s ELISA Test System, and reference Elisa also showed 69 of them as positive. The results are summarized below:

	Positive	Negative	FN (false negative)	FP (false positive)
Monocent	69	31	0	0
Test A	69	31	0	0

2. Precision

1. Inter-assay Study			
No of Replicates 10	Serum 1	Serum 2	Serum 3
Mean	0.42	0.95	2.5
SD	0.032	0.046	0.046
CV%	**7.6**	**4.9**	**3.16**

2. Intra-assay study			
No of Replicates 16	Serum 1	Serum 2	Serum 3
Mean	1.3	1.17	0.23
SD	0.094	0.082	0.021
CV%	**7.01**	**7.0**	**9.13**

3. Interferences Study

Interferences with lipemic, hemolytic or icteric sera are not observed up to a concentration of 5 mg/ml hemoglobin, 5 mg/ml triglycerides and 0.2 mg/ml bilirubin.

REFERENCES

1. A. Andersson, V. Vetter et al. Avidities of IgG directed against viral capsid antigen or early antigen: useful markers for significant Epstein-Barr Virus serology. J. Med. Virology 43: 238 (1994).
2. J. Middeldorp and P. Herbrink: Epstein Barr Virus specific marker molecules for early diagnosis of infectious mononucleosis. J. Virol. Methods 21: 133 (1988).
3. C. Valent Sumaya: Serological testing for Epstein Barr Virus - developments in interpretation. J. Inf. Dis. 151: 984 (1985).
4. J. Luka, R.C. Chase and G. Pearson: A sensitive enzyme-linked immunosorbent assay (ELISA) against the major EBV-associated antigens. I. Correlation between ELISA and immunofluorescence titers using purified antigens. J. Immunol. Methods 67: 145 (1984).

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ENGLISH

EBV EA IgG ELISA TEST SYSTEM

CE

REF EL2-1133 | Σ 96 TESTS | IVD

INTENDED USE

The Monocent, Inc.'s Epstein Barr Virus EBV Early IgG Elisa test system is an Enzyme-Linked Immunosorbent Assay kit providing material for the detection of IgG-class antibodies to the Early Antigen of EBV in human serum or plasma. This assay is intended for *in vitro* use only.

SUMMARY AND EXPLANATION

Epstein Barr Virus (EBV) is a herpes virus, which causes infectious mononucleosis (IM). It is also associated with Burkitt's lymphoma, nasopharyngeal carcinoma and lymphatic proliferative syndromes in immunodepressed patients. The virus is widespread throughout the world and 80-90% of the population is serum-positive.
The laboratory diagnosis of IM is traditionally performed by detecting heterophile antibodies which develop in the serum during the course of the infection and which agglutinate horse erythrocytes. However, these antibodies may not always be present in patients affected by IM, particularly if below 14 years of age; furthermore, they may also persist for over a year after the infection. The determination of heterophile antibodies alone may therefore lead to an erroneous diagnosis. It is therefore important to determine the presence of antibodies towards the viral antigens. The detection of antibodies directed to the "Viral Capsid Antigen" (VCA), to Early Antigen as well as the Nuclear Antigen (EBNA) is particularly useful. During the course of IM, the IgM-class antibodies to VCA and Early Antigen appear very early, followed by IgG-class antibodies to VCA and Early Antigen, while the IgG antibodies to EBNA develop later during the infection. The presence of IgM against VCA and Early in the absence of IgG against EBNA therefore indicates that there is a current infection, while the presence of IgG against VCA, Early and EBNA is indicative of a prior infection.

PRINCIPLE OF THE TEST

EBV Early IgG kit is based on the ELISA technique. In the assay, controls and unknowns are incubated in microtitration wells coated with recombinant derived Epstein Barr Virus early antigen. After incubation and washing, the wells are treated with the conjugate, composed of anti-human IgG antibodies labeled with peroxidase. After a second incubation and washing step, the wells are incubated with the substrate tetramethylbenzidine (TMB). An acidic stopping solution is then added and the degree of enzymatic turnover of the substrate is determined by wavelength absorbance measurement at 450 nm. The absorbance measured is directly proportional to the concentration of anti-EBV Early IgG antibodies present.

MATERIALS AND COMPONENTS PROVIDED

• EBV Early Antigen-Coated Microtitration Strip	One Plate
• Wash Concentrate	One Bottle
• Sample Diluent	One Bottle
• TMB-Substrate	One Bottle
• Negative control	One Vial
• Cut off control	One Vial
• Positive control	One Vial
• 2nd Antibody Conjugate	One Bottle
• Stopping Solution	One Bottle

MATERIALS REQUIRED BUT NOT PROVIDED

- Microtitration plate reader capable of absorbance measurement at 450 nm
- Deionized/Distilled water
- Precision pipette to deliver 10 µl, 100 µl and 1 ml
- Semi-automatic pipette to deliver 100 µl
- Automatic microtitration plate washer
- Absorbent material for blotting the strips
- Incubator

REAGENTS PROVIDED

- **Antigen-Coated Microtitration Strips:**
  One stripholder containing 12x8 (96) microtitration wells coated with recombinant derived EBV early antigen. Store at 2-8°C until expiration date. Remove the support and strips to be used from the foil package and place the unused strips in the polythene bag with the silica gel, expel the air and seal by pressing the closure. Once opened, the product is stable for 4 weeks at 2-8°C.
- **Wash Concentrate:**
  One bottle, 100 mL, containing a phosphate buffered saline, concentrated 10-fold containing 0.5% Brij weight by volume (w/v). Dilute with deionized/distilled water prior to use. Store at 2-8°C until expiration date.
- **Sample Diluent:**
  One bottle, 100 ml, containing a BSA solution with 0.09% sodium azide as a preservative. Store at 2-8°C until expiration date.
- ***EBV Early* IgG Controls:**
  Three vials, negative, cut off and positive, each 2 mL of human serum in a 0.01 M phosphate buffer containing BSA with 0.09% sodium azide as a preservative. Store at 2-8°C until expiration date.
- **2nd Antibody Conjugate:**
  One bottle, 12 mL, containing anti-human IgG monoclonal antibodies labeled with peroxidase, in a phosphate buffer solution with 0.02% Proclin. Store at 2-8°C until expiration date.
- **TMB-Substrate:**
  One bottle, 12 mL, containing tetramethylbenzidine (TMB) and hydrogen peroxide stabilized in citrate buffer, pH 3.8. Store at 2-8°C until expiration date.
- **Stopping Solution:**
  One bottle, 15 mL, containing 0.3 M H_2SO_4 in solution. Store at 2-8°C until expiration date.

PRECAUTIONS

For *in vitro* use
The following universal Good Laboratory Practices should be observed: Do not eat, drink, smoke or apply cosmetics where immunodiagnostic material is being handled. Do not pipet by mouth. Wear lab coats and disposable gloves when handling immunodiagnostic material. Wash hands thoroughly afterwards. Cover working area with disposable absorbent paper. Wipe up spills immediately and decontaminate affected surfaces. Avoid generation of aerosols. Provide adequate ventilation. Handle and dispose all reagents and material in compliance with applicable regulations.

WARNING: POTENTIAL BIOHAZARDOUS MATERIAL
This kit may contain some reagents made with human ad animal source material (e.g. serum, plasma or bovine albumin) or used in conjunction with human and animal source materials. The material in this kit has been tested by CE recommended methods and found to be non-reactive for HIV-1/2 Antibodies, HCV and HbsAg; the animal source material is also free from infection. No available test method can offer complete assurance of eliminating potential biohazardous risk. Handle all reagents and patient samples at a Biosafety Level 2, as recommended for any potentially infectious human material in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories," 4th Edition, April 1999.

WARNING AND PRECAUTION:
Some of the reagents in this kit contain sodium azide as a preservative at concentrations below the regulatory limit of < 0.1%. Although significantly diluted, concentrated sodium azide is an irritant to skin and mucous membranes and may react with lead and copper plumbing to form explosive metal azides, especially if accumulated. Additionally, TMB and Sulfuric Acid, in concentrated amounts are also irritants to skin and mucous membranes. These substances are in diluted form and therefore may minimize exposure risks significantly but not completely. Provide adequate ventilation. Avoid contact with skin, eyes and clothing. In case of contact with any of these reagents, wash thoroughly with water and seek medical advice. Dispose all nonhazardous reagents by flushing with large volumes of water to prevent buildup of chemical hazards in the plumbing system.
For further information regarding hazardous substances in the kit, please refer to the component specific MSDS by request.

SPECIMEN COLLECTION AND HANDLING

Serum should be used, and the usual precautions for venepuncture should be observed. Specimens may be stored at 2-8°C for 2 days. For longer periods, store at –20°C. Do not use hemolyzed or lipemic specimens. Avoid repeated freezing and thawing of samples.

ASSAY PREPARATION

A thorough understanding of this package insert is necessary for successful use of the product. Reliable results will only be obtained by using precise laboratory techniques and accurately following the package insert. Bring all kit reagents and specimens to room temperature (~25°C) before use. Thoroughly mix the reagents and samples before use by gentle inversion. Do not mix various lots of any kit component within an individual assay. Do not use any component beyond the expiration date shown on its label. Incomplete washing will adversely affect the outcome and assay precision. To minimize potential assay drift due to variation in the substrate incubation time, care should be taken to add the stopping solution into the wells in the same order and speed to add the TMB Chromogen Solution. Avoid microbial contamination of reagents, especially of the conjugate, wash buffer and diluent. Avoid contamination of the TMB Chromogen Solution with the Conjugate. Use a clean disposable pipette tip for each reagent. Avoid pipettes with metal parts. Containers and semi-automatic pipette tips used for the Conjugate and TMB can be reused provided they are thoroughly rinsed with deionized/distilled water and dried prior to and after each usage. The enzyme used as the label is inactivated by oxygen, and is highly sensitive to microbial contamination, sodium azide, hypochlorous acid and aromatic chlorohydrocarbons often found in laboratory water supplies. Use high quality water. Avoid exposure of the reagents to excessive heat or sunlight during storage and incubation.

REAGENT PREPARATION

- **Wash Solution:**
  Dilute 1:10 with deionized/distilled water prior to use. If crystals are present, they should be dissolved at 37°C before dilution. Pour 100 mL of the Wash Concentrate into a clean container and dilute by adding 900 mL of deionized/distilled water. Mix thoroughly by inversion. The wash solution is stable for 5 days at room temperature and 2 weeks at 2-8°C when stored in a tightly sealed bottle.
- **Microtitration Strips:**
  Select the number of coated strips required for the assay. The remaining unused wells should be placed in the resealable pouch with a desiccant pack. The pouch must be resealed to protect from moisture.

TEST PROCEDURE

All specimens and reagents to reach room temperature (~25°C) before use. Serum Samples and Controls should be assayed in duplicate.

1. Mark the microtitration strips to be used.
2. Dilute serum samples 1:101 distributing 10 µL of serum into 1 mL of Sample Diluent.
3. Pipette 100 µL of each diluted serum sample and ready to use controls to the appropriate wells.
4. Incubate for 45 minutes at 37°C.
5. Aspirate and wash each well four (4) times for 30 seconds with Washing Solution using an automatic microplate washer or manually using a dispenser. Blot and dry by inverting plate on absorbent material.

NOTE: Use of an automatic microplate washer is strongly recommended. Incomplete washing will adversely affect assay precision. If a microplate washer is not available, (a) completely aspirate the liquid from each well, (b) dispense 0.35 mL of the Wash Solution into each well, and (c) repeat step (a) and (b) four times.

6. Add 100 µL of Enzyme-Labeled 2nd Antibody into each well.
7. Incubate for 45 minutes at 37°C.
8. Aspirate and wash each well four times for 30 seconds with Washing Solution using an automatic microplate washer or manually using a dispenser. Blot and dry by inverting plate on absorbent material.
9. Add 100 µL of TMB Chromogen Solution to each well using a dispenser.
10. Incubate for 15 minutes at room temperature. Avoid exposure to direct sunlight.
11. Add 100 µL of Stopping Solution to each well using a dispenser.
12. Read the absorbance of the solution in the wells within 30 minutes, using a microplate reader set to 450 nm. If wavelength correction is available, set the instrument to dual wavelength measurement at 450 nm with background wavelength correction set at 600 or 620 nm.

CALCULATION OF RESULTS

Calculate the mean absorbance for each control and unknown.

Qualitative results:

If the absorbance of the sample is higher than that of the Cut-Off, the sample is positive for the presence of specific IgG.

Calculate the ratio between the average OD value of the sample and that of the Cut-Off. The sample is considered:

Positive: if the ratio is > 1.1.
Doubtful: if +/- 10% of the Cut-Off.
Negative: if the ratio is < 0.9.

If the result is doubtful, repeat the test. If it remains doubtful, collect a new serum sample.

LIMITATIONS OF THE PROCEDURE

- A serum sample obtained during the early phase of infection, when only IgM antibodies are present, may be negative by this procedure.
- The test result should be used in conjunction with information available from the evaluation of other clinical and diagnostic procedures.
- Avoid repeated freezing and thawing of reagents and specimens.
- Grossly hemolyzed, icteric or lipemic specimens should be avoided.
- Heat inactivated sera should be avoided.

QUALITY CONTROL

The OD values of Cut-Off control must be at least 0.2. Positive control must have an OD at least 1.5 times that of Cut-Off.

PERFORMANCE CHARACTERISTICS

1. Sensitivity and Specificity

95 human sera were analysed by this EBV Early IgG Elisa and an Elisa reference method. Out of 95 samples, 41 were positive for the presence of IgG antibodies to EBV Early by Monocent, Inc.'s ELISA Test System and reference Elisa showed 41 of them as positive. The results are summarized below.

	Positive	Negative	FN (false negative)	FP (false positive)
Monocent	41	54	0	0
Reference	41	54	0	0

2. Precision

1. Inter-assay Study			
No of Replicates 10	Serum 1	Serum 2	Serum 3
Mean	0.912	0.554	0.036
SD	0.023	0.028	0.034
CV%	**2.5**	**5.1**	**9.6**

2. Intra-assay study			
No of Replicates 16	Serum 1	Serum 2	Serum 3
Mean	1.07	0.700	0.044
SD	0.016	0.013	0.002
CV%	**1.5**	**1.85**	**4.9**

3. Interferences Study

Interferences with lipemic, hemolytic or icteric sera are not observed up to a concentration of 5 mg/ml hemoglobin, 5 mg/ml triglycerides and 0.2 mg/ml bilirubin.

REFERENCES

1. A. Andersson, V. Vetter et al. Avidities of IgG directed against viral capsid antigen or early antigen: useful markers for significant Epstein-Barr Virus serology. J. Med. Virology 43: 238 (1994).
2. J. Middeldorp and P. Herbrink: Epstein Barr Virus specific marker molecules for early diagnosis of infectious mononucleosis. J. Virol. Methods 21: 133 (1988).
3. C. Valent Sumaya: Serological testing for Epstein Barr Virus - developments in interpretation. J. Inf. Dis. 151: 984 (1985).
4. J. Luka, R.C. Chase and G. Pearson: A sensitive enzyme-linked immunosorbent assay (ELISA) against the major EBV-associated antigens. I. Correlation between ELISA and immunofluorescence titers using purified antigens. J. Immunol. Methods 67: 145 (1984).

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EBV VCA IgG ELISA TEST SYSTEM

CE

REF EL1-1136 Σ 96 TESTS IVD

INTENDED USE

The Monocent, Inc.'s Epstein Barr Virus EBV VCA IgG ELISA Test System is an Enzyme-Linked Immunosorbent Assay kit providing material for the detection of IgG-class antibodies to the capsid antigen of EBV in human serum or plasma. This assay is intended for *in vitro* use only.

SUMMARY AND EXPLANATION

Epstein Barr Virus (EBV) is a herpes virus, which causes infectious mononucleosis (IM). It is also associated with Burkitt's lymphoma, nasopharyngeal carcinoma and lymphatic proliferative syndromes in immunodepressed patients. The virus is widespread throughout the world and 80-90% of the population is serum-positive.
The laboratory diagnosis of IM is traditionally performed by detecting heterophile antibodies which develop in the serum during the course of the infection and which agglutinate horse erythrocytes. However, these antibodies may not always be present in patients affected by IM, particularly if below 14 years of age; furthermore, they may also persist for over a year after the infection. The determination of heterophile antibodies alone may therefore lead to an erroneous diagnosis. It is therefore important to determine the presence of antibodies towards the viral antigens. The detection of antibodies directed to the "Viral Capsid Antigen" (VCA) and the nuclear antigen (EBNA) is particularly useful. During the course of IM, the IgM- and IgG-class antibodies to VCA appear early, while the IgG to EBNA develop later during the infection. The presence of IgM against VCA in the absence of IgG against EBNA therefore indicates that there is a current infection, while the presence of IgG against both VCA and EBNA is indicative of a prior infection.

PRINCIPLE OF THE TEST

The EBV VCA IgG kit is based on the ELISA technique. In the assay, controls and unknowns are incubated in microtitration wells coated with purified and inactivated Epstein Barr Virus antigen. After incubation and washing, the wells are treated with the conjugate, composed of anti-human IgG antibodies labelled with peroxidase. After a second incubation and washing step, the wells are incubated with the substrate tetramethylbenzidine (TMB). An acidic stopping solution is then added and the degree of enzymatic turnover of the substrate is determined by wavelength absorbance measurement at 450 nm. The absorbance measured is directly proportional to the concentration of anti-EBV VCA IgG antibodies present.

MATERIALS AND COMPONENTS PROVIDED

• EBV Capsid Antigen-Coated Microtitration Strip	One Plate
• Wash Concentrate	One Bottle
• Sample Diluent	One Bottle
• TMB-Substrate	One Bottle
• Negative control	One Vial
• Cut off control	One Vial
• Positive control	One Vial
• 2nd Antibody Conjugate	One Bottle
• Stopping Solution	One Bottle

MATERIALS REQUIRED BUT NOT PROVIDED

- Microtitration plate reader capable of absorbance measurement at 450 nm
- Deionized/Distilled water
- Precision pipette to deliver 10 µl, 100 µl and 1 ml
- Semi-automatic pipette to deliver 100 µl
- Automatic microtitration plate washer
- Absorbent material for blotting the strips
- Incubator

REAGENTS PROVIDED

- **Antigen-Coated Microtitration Strips:**
  One stripholder containing 12x8 (96) microtitration wells coated with EBV capsid antigen. Store at 2-8°C until expiration date. Remove the support and strips to be used from the foil package and place the unused strips in the polythene bag with the silica gel, expel the air and seal by pressing the closure. Once opened, the product is stable for 4 weeks at 2-8°C.
- **Wash Concentrate:**
  One bottle, 100 mL, containing a phosphate buffered saline, concentrated 10-fold containing 0.5% Brij weight by volume (w/v). Dilute with deionized/distilled water prior to use. Store at 2-8°C until expiration date.
- **Sample Diluent:**
  One bottle, 100 ml, containing a BSA solution with 0.09% sodium azide as a preservative. Store at 2-8°C until expiration date.
- ***EBV VCA* IgG Controls:**
  Three vials, negative, cut off and positive, each 2 mL of human serum in a 0.01 M phosphate buffer containing BSA with 0.09% sodium azide as a preservative. Store at 2-8°C until expiration date.
- **2nd Antibody Conjugate:**
  One bottle, 12 mL, containing anti-human IgG monoclonal antibodies labelled with peroxidase, in a phosphate buffer solution with 0.02% Proclin™. Store at 2-8°C until expiration date.
- **TMB-Substrate:**
  One bottle, 12 mL, containing tetramethylbenzidine (TMB) and hydrogen peroxide stabilized in citrate buffer, pH 3.8. Store at 2-8°C until expiration date.
- **Stopping Solution:**
  One bottle, 15 mL, containing 0.3 M H_2SO_4 in solution. Store at 2-8°C until expiration date.

PRECAUTIONS

For *in vitro* use
The following universal Good Laboratory Practices should be observed: Do not eat, drink, smoke or apply cosmetics where immunodiagnostic material is being handled. Do not pipet by mouth. Wear lab coats and disposable gloves when handling immunodiagnostic material. Wash hands thoroughly afterwards. Cover working area with disposable absorbent paper. Wipe up spills immediately and decontaminate affected surfaces. Avoid generation of aerosols. Provide adequate ventilation. Handle and dispose all reagents and material in compliance with applicable regulations.

WARNING: POTENTIAL BIOHAZARDOUS MATERIAL
This kit may contain some reagents made with human or animal source material (e.g. serum, plasma or bovine albumin) or used in conjunction with human ans animal source material. The material in this kit has been tested by CE recommended methods and found to be non-reactive for HIV-1/2 Antibodies, HCV and HbsAg; the animal source material is also free from infection. No available test method can offer complete assurance of eliminating potential biohazardous risk. Handle all reagents and patient samples at a Biosafety Level 2, as recommended for any potentially infectious human material in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories," 4th Edition, April 1999.

WARNING AND PRECAUTION:
Some of the reagents in this kit contain sodium azide as a preservative at concentrations below the regulatory limit of < 0.1%. Although significantly diluted, concentrated sodium azide is an irritant to skin and mucous membranes and may react with lead and copper plumbing to form explosive metal azides, especially if accumulated. Additionally, TMB and Sulfuric Acid, in concentrated amounts are also irritants to skin and mucous membranes. These substances are in diluted form and therefore may minimize exposure risks significantly but not completely. Provide adequate ventilation. Avoid contact with skin, eyes and clothing. In case of contact with any of these reagents, wash thoroughly with water and seek medical advice. Dispose all nonhazardous reagents by flushing with large volumes of water to prevent buildup of chemical hazards in the plumbing system.
For further information regarding hazardous substances in the kit, please refer to the component specific MSDS by request.

SPECIMEN COLLECTION AND HANDLING

Serum should be used, and the usual precautions for venepuncture should be observed. Specimens may be stored at 2-8°C for 2 days. For longer periods, store at –20°C. Do not use haemolyzed or lipemic specimens. Avoid repeated freezing and thawing of samples.

ASSAY PREPARATION

A thorough understanding of this package insert is necessary for successful use of the product. Reliable results will only be obtained by using precise laboratory techniques and accurately following the package insert. Bring all kit reagents and specimens to room temperature (~25°C) before use. Thoroughly mix the reagents and

samples before use by gentle inversion. Do not mix various lots of any kit component within an individual assay. Do not use any component beyond the expiration date shown on its label. Incomplete washing will adversely affected the outcome and assay precision. To minimize potential assay drift due to variation in the substrate incubation time, care should be taken to add the stopping solution into the wells in the same order and speed to add the TMB Chromogen Solution. Avoid microbial contamination of reagents, especially of the conjugate, wash buffer and diluent. Avoid contamination of the TMB Chromogen Solution with the Conjugate. Use a clean disposable pipette tip for each reagent. Avoid pipettes with metal parts. Containers and semi-automatic pipette tips used for the Conjugate and TMB can be reused provided they are thoroughly rinsed with deionized/distilled water and dried prior to and after each usage. The enzyme used as the label is inactivated by oxygen, and is highly sensitive to microbial contamination, sodium azide, hypochlorous acid and aromatic chlorohydrocarbons often found in laboratory water supplies. Use high quality water. Avoid exposure of the reagents to excessive heat or sunlight during storage and incubation.

REAGENT PREPARATION

- **Wash Solution:**
  Dilute 1:10 with deionized/distilled water prior to use. If crystals are present, they should be dissolved at 37°C before dilution. Pour 100 mL of the Wash Concentrate into a clean container and dilute by adding 900 mL of deionized/distilled water. Mix thoroughly by inversion. The wash solution is stable for 5 days at room temperature and 2 weeks at 2-8°C when stored in a tightly sealed bottle.
- **Microtitration Strips:**
  Select the number of coated strips required for the assay. The remaining unused wells should be placed in the resealable pouch with a desiccant pack. The pouch must be resealed to protect from moisture.

TEST PROCEDURE

All specimens and reagents to reach room temperature (~25°C) before use. Serum Samples and Controls should be assayed in duplicate.

1. Mark the microtitration strips to be used.
2. Dilute serum samples 1:101 distributing 10 µL of serum into 1 mL of Sample Diluent.
3. Pipette 100 µL of each diluted serum sample and ready to use controls to the appropriate wells.
4. Incubate for 45 minutes at 37°C.
5. Aspirate and wash each well four (4) times for 30 seconds with Washing Solution using an automatic microplate washer or manually using a dispenser. Blot and dry by inverting plate on absorbent material.

NOTE: *Use of an automatic microplate washer is strongly recommended. Incomplete washing will adversely affect assay precision. If a microplate washer is not available, (a) completely aspirate the liquid from each well, (b) dispense 0.35 mL of the Wash Solution into each well, and (c) repeat step (a) and (b) four times.*

6. Add 100 µL of Enzyme-Labeled 2nd Antibody into each well.
7. Incubate for 45 minutes at 37°C.
8. Aspirate and wash each well four times for 30 seconds with Washing Solution using an automatic microplate washer or manually using a dispenser. Blot and dry by inverting plate on absorbent material.
9. Add 100 µL of TMB Chromogen Solution to each well using a dispenser.
10. Incubate for 15 minutes at room temperature. Avoid exposure to direct sunlight.
11. Add 100 µL of Stopping Solution to each well using a dispenser.
12. Read the absorbance of the solution in the wells within 30 minutes, using a microplate reader set to 450 nm. If wavelength correction is available, set the instrument to dual wavelength measurement at 450 nm with background wavelength correction set at 600 or 620 nm.

CALCULATION OF RESULTS

Calculate the mean absorbance for each control and unknown.

Qualitative results:

If the absorbance of the sample is higher than that of the Cut-Off, the sample is positive for the presence of specific IgG.

Calculate the ratio between the average OD value of the sample and that of the Cut-Off. The sample is considered:

Positive: if the ratio is > 1.1.
Doubtful: if +/- 10% of the Cut-Off.
Negative: if the ratio is < 0.9.

If the result is doubtful, repeat the test. If it remains doubtful, collect a new serum sample.

LIMITATIONS OF THE PROCEDURE

- A serum sample obtained during the early phase of infection, when only IgM antibodies are present, may be negative by this procedure.
- The test result should be used in conjunction with information available from the evaluation of other clinical and diagnostic procedures.
- Avoid repeated freezing and thawing of reagents and specimens.
- Grossly haemolyzed, icteric or lipemic specimens should be avoided.
- Heat inactivated sera should be avoided.

QUALITY CONTROL

The OD values of Cut-Off control must be at least 3x> than the OD of the negative control.

Positive control must have an OD at least 1.5 times that of Cut-Off.

PERFORMANCE CHARACTERISTICS

1. Sensitivity and Specificity

100 human sera were analysed by this EBV VCA IgG Elisa and an Elisa reference method. Out of 100 samples, 81 were positive for the presence of IgG antibodies to EBV VCA by Monocent, Inc.'s ELISA Test System and reference Elisa showed 81 of them as positive. The results are summarized below.

	Positive	Negative	FN (false negative)	FP (false positive)
Monocent	81	19	0	0
Test A	81	19	0	0

2. Precision

Inter-assay Study			
No of Replicates 10	Serum 1	Serum 2	Serum 3
Mean	1.29	0.91	0.23
SD	0.121	0.089	0.025
CV%	**9.37**	**9.78**	**10.86**

Intra-assay study			
No of Replicates 16	Serum 1	Serum 2	Serum 3
Mean	1.43	0.98	0.26
SD	0.096	0.067	0.019
CV%	**6.71**	**6.83**	**7.30**

3. Interferences Study

Interferences with lipemic, hemolytic or icteric sera are not observed up to a concentration of 5 mg/ml hemoglobin, 5 mg/ml triglycerides and 0.2 mg/ml bilirubin.

REFERENCES

1. A. Andersson, V. Vetter et al. Avidities of IgG directed against viral capsid antigen or early antigen: useful markers for significant Epstein-Barr Virus serology. J. Med. Virology 43: 238 (1994).
2. J. Middeldorp and P. Herbrink: Epstein Barr Virus specific marker molecules for early diagnosis of infectious mononucleosis. J. Virol. Methods 21: 133 (1988).
3. C. Valent Sumaya: Serological testing for Epstein Barr Virus - developments in interpretation. J. Inf. Dis. 151: 984 (1 Methods 67: 145 (1984).

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ENGLISH

EBV VCA IgM ELISA

CE

REF **EL1-1137** Σ **96 TESTS** IVD

INTENDED USE

The Monocent EBV VCA IgM ELISA test system is an Enzyme-Linked Immunosorbent Assay kit provides material for the detection of IgM-class antibodies to the capsid antigen of EBV in human serum or plasma. This assay is intended for in vitro use only.

SUMMARY AND EXPLANATION

Epstein Barr Virus (EBV) is a herpes virus, which causes infectious mononucleosis (IM). It is also associated with Burkitt's lymphoma, nasopharyngeal carcinoma, and lymphatic proliferative syndromes in immunosuppressed patients. The virus is widespread throughout the world and 80-90% of the population is serum positive.
The laboratory diagnosis of IM is traditionally performed by detecting heterophile antibodies which develop in the serum during the course of the infection, and which agglutinate horse erythrocytes. However, these antibodies may not always be present in patients affected by IM, particularly if below 14 years of age; furthermore, they may also persist for over a year after the infection. The determination of heterophile antibodies alone may therefore lead to an erroneous diagnosis. It is therefore important to determine the presence of antibodies towards the viral antigens. The detection of antibodies directed to the "Viral Capsid Antigen" (VCA) and the nuclear antigen (EBNA) is particularly useful.
During the course of IM, the IgM-class antibodies to VCA appear early, and a little later IgG-class antibodies, while the IgG to EBNA develop later during the infection. The presence of IgM against VCA in the absence of IgG against EBNA therefore indicates that there is a current infection, while the presence of IgG against both VCA and EBNA is indicative of a prior infection.

PRINCIPLE OF THE TEST

The EBV VCA IgM ELISA kit is based on the ELISA technique. In the assay, controls and unknowns are incubated in microtitration wells coated with purified and inactivated Epstein Barr Virus antigen. After incubation and washing, the wells are treated with the conjugate, composed of anti-human IgM antibodies labeled with peroxidase. After a second incubation and washing step, the wells are incubated with the substrate tetramethylbenzidine (TMB). An acidic stopping solution is then added and the degree of enzymatic turnover of the substrate is determined by wavelength absorbance measurement at 450 nm. The absorbance measured is directly proportional to the concentration of anti-EBV VCA IgM antibodies present.

MATERIALS AND COMPONENTS

EBV Capsid Antigen-Coated Microtitration Strip	(12x8x1)
Wash Concentrate, One Bottle	100 mL
Sample Diluent, One Bottle	100 mL
TMB-Substrate, One Bottle	12 mL
Negative control, One Vial	2 mL
Cut off control, One Vial	2 mL
Positive control, One Vial	2 mL
2nd Antibody Conjugate, One Bottle	12 mL
Stop Solution, One Bottle	15 mL
Sorbent M, One Bottle	4 mL

MATERIALS REQUIRED BUT NOT PROVIDED

Microtitration plate reader capable of absorbance measurement at 450 nm
Deionized/Distilled water
Precision pipette to deliver 10 µL, 100 µL and 1 mL
Semi-automatic pipette to deliver 100 µL
Automatic microtitration plate washer
Absorbent materials for blotting the strips

REAGENTS

Antigen-Coated Microtitration Strips:
One strip holder containing 12x8 (96) microtitration wells coated with EBV capsid antigen. Store at 2-8°C until expiration date. Remove the support and strips to be used from the foil package and place the unused strips in the polythene bag with the silica gel, expel the air and seal by pressing the closure. Once opened, the product is stable for 4 weeks at 2-8°C.

Wash Concentrate:
One bottle, 100 mL, containing a phosphate buffered saline, concentrated 10-fold containing 0.5% Brij weight by volume (w/v). Dilute with deionized/distilled water prior to use. Store at 2-8°C until expiration date.

Sample Diluent:
One bottle, 100 ml, containing a BSA solution with 0.09% sodium azide as a preservative. Store at 2-8°C until expiration date.

EBV VCA IgM Controls:
Three vials, negative, cut off and positive, each 2 mL of human serum in a 0.01 M phosphate buffer containing BSA with 0.09% sodium azide as a preservative. Store at 2-8°C until expiration date.

2nd Antibody Conjugate:
One bottle, 12 mL, containing anti-human IgM monoclonal antibodies labeled with peroxidase, in a phosphate buffer solution with 0.02% Proclin. Store at 2-8°C until expiration date.

Sorbent M:
One Bottle, 4 ml, containing anti-human IgG, in a phosphate buffer solution with 0.02% proclin. Store at 2°- 8° C.

TMB-Substrate:
One bottle, 12 mL, containing tetramethylbenzidine (TMB) and hydrogen peroxide stabilized in citrate buffer, pH 3.8. Store at 2-8°C until expiration date.

Stopping Solution:
One bottle, 15 mL, containing 0.3 M H2SO4 in solution. Store at 2-8°C until expiration date.

SPECIMEN COLLECTION

Serum should be used, and the usual precautions for venipuncture should be observed. Specimens may be stored at 2-8°C for 2 days. For longer periods, store at -20°C. Do not use hemolyzed or lipemic specimens. Avoid repeated freezing and thawing of samples.

PRECAUTIONS

For *in vitro* use
The following universal Good Laboratory Practices should be observed:
Do not eat, drink, smoke or apply cosmetics where immunodiagnostic material is being handled. Do not pipet by mouth. Wear lab coats and disposable gloves when handling immunodiagnostic material. Wash hands thoroughly afterwards. Cover working area with disposable absorbent paper. Wipe up spills immediately and decontaminate affected surfaces. Avoid generation of aerosols. Provide adequate ventilation. Handle and dispose all reagents and materials in compliance with applicable regulations.

WARNING: POTENTIAL BIOHAZARDOUS MATERIAL
This kit may contain some reagents made with human source material (e.g., serum or plasma) or used in conjunction with human source materials. The material in this kit has been tested by CE recommended methods and found to be non-reactive for HIV-1/2 Antibodies, HCV and HBsAg. No available test method can offer complete assurance of eliminating potential biohazardous risk. Handle all reagents and patient samples at a Biosafety Level 2, as recommended for any potentially infectious human material in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories," 4th Edition, April 1999.

WARNING AND PRECAUTION:
Some of the reagents in this kit contain sodium azide as a preservative at concentrations below the regulatory limit of < 0.1%. Although significantly diluted, concentrated sodium azide is an irritant to skin and mucous membranes, and may react with lead and copper plumbing to form explosive metal azides, especially if accumulated. Additionally, TMB and Sulfuric Acid, in concentrated amounts are also irritants to skin and mucous membranes. These substances are in diluted form and therefore may minimize exposure risks significantly but not completely. Provide adequate ventilation. Avoid contact with skin, eyes and clothing. In case of contact with any of these reagents, wash thoroughly with water and seek medical advice. Dispose all nonhazardous reagents by flushing with large volumes of water to prevent buildup of chemical hazards in the plumbing system.
For further information regarding hazardous substances in the kit, please refer to the component specific MSDS by request.

PREPARATION FOR ASSAY

A thorough understanding of this package insert is necessary for successful use of the product. Reliable results will only be obtained by using precise laboratory techniques and accurately following the

package insert. Bring all kit reagents and specimens to room temperature (~25°C) before use. Thoroughly mix the reagents and samples before use by gentle inversion. Do not mix various lots of any kit component within an individual assay. Do not use any component beyond the expiration date shown on its label. Incomplete washing will adversely affected the outcome and assay precision. To minimize potential assay drift due to variation in the substrate incubation time, care should be taken to add the stopping solution into the wells in the same order and speed to add the TMB Chromogen Solution. Avoid microbial contamination of reagents, especially of the conjugate, wash buffer and diluent. Avoid contamination of the TMB Chromogen Solution with the Conjugate. Use a clean disposable pipette tip for each reagent. Avoid pipettes with metal parts. Containers and semi-automatic pipette tips used for the Conjugate and TMB can be reused provided they are thoroughly rinsed with deionized/distilled water and dried prior to and after each usage. The enzyme used as the label is inactivated by oxygen, and is highly sensitive to microbial contamination, sodium azide, hypochlorous acid and aromatic chlorohydrocarbons often found in laboratory water supplies. Use high quality water. Avoid exposure of the reagents to excessive heat or sunlight during storage and incubation.

REAGENT PREPARATION

Wash Solution:
Dilute 1:10 with deionized/distilled water prior to use. If crystals are present, they should be dissolved at 37°C before dilution. Pour 100 mL of the Wash Concentrate into a clean container and dilute by adding 900 mL of deionized/distilled water. Mix thoroughly by inversion. The wash solution is stable for 5 days at room temperature and 2 weeks at 2-8°C when stored in a tightly sealed bottle.

Microtitration Strips:
Select the number of coated strips required for the assay. The remaining unused wells should be placed in the resealable pouch with a desiccant pack. The pouch must be resealed to protect from moisture.

ASSAY PROCEDURE

All specimens and reagents to reach room temperature (~25°C) before use. Serum Samples and Controls should be assayed in duplicate.

- Mark the microtitration strips to be used.
- Dilute serum samples 1:101 distributing 10 µL of serum into 1 mL of Sample Diluent.
- Pipette 100 µL of each diluted serum sample and ready to use controls to the appropriate wells. Add 30 µL Sorbent M only in to the wells of diluted samples.
- Incubate for 45 minutes at 37°C.
- Aspirate and wash each well four (4) times for 30 seconds with Washing Solution using an automatic microplate washer or manually using a dispenser. Blot and dry by inverting plate on absorbent material.
  NOTE: Use of an automatic microplate washer is strongly recommended. Incomplete washing will adversely affect assay precision. If a microplate washer is not available, (a) completely aspirate the liquid from each well, (b) dispense 0.35 mL of the Wash Solution into each well and (c) repeat step (a) and (b) four times.
- Add 100 µL of Enzyme-Labeled 2nd Antibody into each well.
- Incubate for 45 minutes at 37°C.
- Aspirate and wash each well four times for 30 seconds with Washing Solution using an automatic microplate washer or manually using a dispenser. Blot and dry by inverting plate on absorbent material.
- Add 100 µL of TMB Chromogen Solution to each well using a dispenser.
- Incubate for 15 minutes at room temperature. Avoid exposure to direct sunlight.
- Add 100 µL of Stopping Solution to each well using a dispenser.
- Read the absorbance of the solution in the wells within 30 minutes, using a microplate reader set to 450 nm. If wavelength correction is available, set the instrument to dual wavelength measurement at 450 nm with background wavelength correction set at 600 or 620 nm.

RESULTS

Calculate the mean absorbance for each control and unknown.

Qualitative results:
If the absorbance of the sample is higher than that of the Cut-Off, the sample is positive for the presence of specific IgM. Calculate the ratio between the average OD value of the sample and that of the Cut-Off.

The sample is considered:

Positive: if the ratio is > 1.1.
Indeterminate: if +/- 10% of the Cut-Off.
Negative: if the ratio is < 0.9.
If the result is indeterminate, repeat the test. If it remains indeterminate, collect a new serum sample.

LIMITATIONS OF THE PROCEDURE

- A serum sample obtained during the late phase of infection, when only IgG antibodies are present, may be negative by this procedure.
- The test result should be used in conjunction with information available from the evaluation of other clinical and diagnostic procedures.
- Avoid repeated freezing and thawing of reagents and specimens.
- Grossly hemolyzed, icteric or lipemic specimens should be avoided.
- Heat inactivated sera should be avoided.

QUALITY CONTROL

The OD values of Cut-Off control must be at least 0.2.
Positive control must have an OD at least 1.5 times that of Cut-Off.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity
112 human sera were analyzed by this EBV VCA IgM ELISA and an ELISA reference method. Out of 112 samples, 12 were positive for the presence of IgM antibodies to EBV VCA by Monocent ELISA and reference ELISA showed 13 of them as positive. The results are summarized below.

	Positive	Negative	FN (false negative)	FP (false positive)
Monocent	12	100	1	0
Reference	13	99	0	0

Precision
Inter-assay Study

No of Replicates 10	Serum 1	Serum 2	Serum 3
Mean	1.29	0.91	0.23
SD	0.121	0.089	0.025
CV%	9.37	9.78	10.86

Intra-assay study

No of Replicates 16	Serum 1	Serum 2	Serum 3
Mean	1.43	0.98	0.26
SD	0.096	0.067	0.019
CV%	6.71	6.83	7.30

Interference study
Interferences with lipemic, hemolytic or icteric sera are not observed up to a concentration of 5 mg/ml hemoglobin, 5 mg/ml triglycerides and 0.2 mg/ml bilirubin.

REFERENCES

1. A. Andersson, V. Vetter et al. Avidities of IgG directed against viral capsid antigen or early antigen: useful markers for significant Epstein-Barr Virus serology. J. Med. Virology 43: 238 (1994).
2. J. Middeldorp and P. Herbrink: Epstein Barr Virus specific marker molecules for early diagnosis of infectious mononucleosis. J. Virol. Methods 21: 133 (1988).
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4. J. Luka, R.C. Chase and G. Pearson: A sensitive enzyme-linked immunosorbent assay (ELISA) against the major EBV- associated antigens. I. Correlation between ELISA and immunofluorescence titers using purified antigens. J. Immunol. Methods 67: 145 (1984).

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GIARDIA ANTIGEN ELISA TEST SYSTEM

CE

REF EL16-1235 Σ 96 TESTS IVD

INTENDED USE

The Monocent, Inc.'s Giardia Antigen ELISA Test System is an *in vitro* immunoassay for the qualitative determination of *Giardia* antigen in fecal specimens.

SUMMARY AND EXPLANATION

Giardia lamblia is the protozoan parasite responsible for the disease giardiasis. Symptoms of acute giardiasis include diarrhea, nausea, weight loss, malabsorption, abdominal cramps, flatulence and anemia.[1] The disease may manifest itself as an acute, chronic or as an asymptomatic infection. Giardiasis is the most prevalent parasitic disease in the United States and is responsible for an estimated 100 million mild infections and 1 million severe infections each year.[9]

The mode of transmission of *Giardia* is through fecal-oral ingestion of cysts. Epidemics of giardiasis have been documented in day care centers and by drinking contaminated water.[1,2] Day care centers may be directly or indirectly responsible for 45% of diagnosed *Giardia* infections in the United States.[4] One study found 54% of the children at a day care center were infected.[1]

Diagnosis of giardiasis has been done through a number of invasive and non-invasive techniques. Of the non-invasive techniques, microscopic examination of stools has been the most common. However, this method relies on an experienced technician and subsequent observation of intact organisms. Because of the historically low proficiency of correct microscopic examinations and intermittent excretion of organisms, alternative diagnostic methods have been investigated.[3,5,6,10,11] One important alternative has been the development of an antigen capture enzyme linked immunosorbent assay (ELISA) for use with stools. These tests have shown comparable sensitivity to experienced microscopic examinations, are fairly simple to perform and do not require the observation of intact organisms.[5,6,7,12]

PRINCIPLE OF THE TEST

During the first incubation, *Giardia* specific antigen present in the stool specimens are captured by monoclonal antibodies attached to the microwells. The wells are incubated and washed before anti-*Giardia* polyclonal antibodies conjugated to horseradish peroxidase are added. The enzyme conjugate will "sandwich" any antigen bound to the wells. After washings to remove unbound enzyme, a chromogen is added which develops a blue color in the presence of the enzyme complex. The stop solution ends the reaction and turns the blue color to yellow. If no antigen is captured, or if there is an insufficient level of antigen, no colored reaction will take place.

MATERIALS AND COMPONENTS

- Test Strips: Microwells containing anti-*Giardia* monoclonal antibodies: 96 test wells in a test strip holder.
- Enzyme Conjugate: One (1) bottle containing 11 ml of anti-*Giardia* polyclonal antibodies conjugated to horseradish peroxidase with preservative.
- Positive Control: One (1) vial containing 2 ml of a diluted *Giardia* positive antigen formalinized stool supernatant.
- Negative Control: One (1) vial containing 2 ml of dilution buffer.
- Chromogen: One (1) bottle containing 11 ml of tetramethylbenzidine (TMB) and peroxide.
- Wash Concentrate (20X): Two (2) bottles containing 30 ml of concentrated buffer with detergent and thimerosal.
- Dilution Buffer: Four (4) bottles containing 30 ml of a buffered protein solution with thimerosal.
- Stop Solution: One (1) bottle containing 11 ml of 5% phosphoric acid solution.

MATERIALS REQUIRED BUT NOT PROVIDED

- Transfer Pipettes
- Squeeze bottle for washing strips (narrow tip is recommended)
- Graduated Cylinder
- Micropipette
- Applicator sticks (recommended) or swabs for sample preparation
- Sample dilution tubes

Suggested Materials

- ELISA plate reader capable of reading bichromatically at 450/620-650 nm.

STORAGE CONDITIONS

- Reagents, strips and bottled components should be stored at 2-8°C.
- Squeeze bottle containing diluted wash buffer may be stored at room temperature (15-25°C).

PRECAUTIONS

- **Do not deviate from the specified procedures when performing this assay**. All specimen dilutions, incubation times/temperatures and washings have been optimized for the best performance characteristics. Deviations from the specified procedures may affect the sensitivity and specificity of the assay.
- For In Vitro Diagnostic Use Only.
- Do not interchange reagents between kits with different lot numbers.
- Do not use reagents that are beyond their expiration dates. Expiration dates are on each reagent label. Use of reagents beyond their expiration dates may affect results.
- Unused microwells should be stored in the desiccated pouch to protect them from moisture.
- Do not use solutions if they precipitate or become cloudy.

Exception: Wash concentrate may precipitate during refrigerated storage but will dissolve upon warming.

- Do not add azides to the samples or any of the reagents.
- Controls and some reagents contain thimerosal as a preservative, which may be irritating to skin, eyes and mucous membranes. In case of contact, flush eyes or rinse skin with copious amounts of water.
- Treat all reagents and samples as potentially infectious materials. Use care to prevent aerosols and decontaminate any spills of samples.
- Stop solution is a 5% solution of phosphoric acid in water. If spilled on the skin, wash with copious amounts of water. If acid gets into the eyes, wash with copious amounts of water and seek medical attention.
- Persons who are color blind or visually impaired may not be able to read the test visually and should use spectrophotometric readings to interpret results.

COLLECTION OF STOOL (FECES)

- No modification of collection techniques used for standard microscopic O&P examinations is needed.
- Stool samples may be used as unpreserved or frozen, in Cary-Blair Transport Medium or in preservation media of 10% formalin or SAF.
- Unpreserved samples should be kept at 2-8 ºC and tested within 24 hours of collection. Samples that cannot be tested within this time should be frozen at -20 ºC or lower until used. Avoid multiple freeze/thaw cycles.
- Formalinized and SAF preserved samples may be kept at room temperature (15-25 ºC) or at 2-8 °C and tested within 18 months of collection. DO NOT freeze preserved samples.
- Samples in Cary-Blair should be kept at 2-8 °C or -20 °C and tested within 1 week of collection. Avoid multiple freeze/thaw cycles.

REAGENT PREPARATION

- Before use, bring all reagents and samples to room temperature (15-25 °C) and mix.
- (20X) Wash Concentrate may precipitate during refrigerated storage but will go back into solution when brought to room temperature (15-25°C) and mixed. ***Ensure that (20X) wash concentrate is completely in solution before diluting to working concentration***. To dilute (20X) wash concentrate to working dilution, remove cap and add contents of one bottle of Wash Concentrate to a squeeze bottle containing 570 ml of DI water. Swirl to mix. Squeeze bottle should have a narrow tip to optimize washings.

PROCEDURAL NOTES

- All incubations are to be done at room temperature (15 to 25 °C)
- Ensure all samples and reagents are at room temperature (15-25°C) before use. Frozen samples must be thawed completely before use.
- All dilutions of stools must be made with the Dilution Buffer provided. Do not use dilution buffer from a kit with a different lot number.
- If needed, prepared samples can be centrifuged at 2000-3000 g for 5-10 minutes. Ensure supernatant is clear before use.
- When running the assay, try to avoid the formation of bubbles in the wells. Bubbles may affect overall performance and reading of end results. Slapping the wells out on a clean absorbent towel after each wash step should help to minimize bubbles in the wells.

- Controls must be included each time the kit is run. Controls are provided ready to use. DO NOT dilute further.
- **Unpreserved and Preserved specimens have different testing procedures. See below for specific instructions on how to run the assay using each procedure.**

PRESERVED SPECIMEN PROCEDURE

1. **For samples in SAF, 10% Formalin or Cary-Blair,** mix contents thoroughly inside container. No further processing is required.
2. Break off the required number of wells needed (number of samples plus 2 for controls) and place in holder.
3. Using a micropipette, add **100 µl** of negative control to well # 1 and **100 µl** of positive control to well # 2.
4. Using a micropipette, add **50 µl** of Dilution Buffer to each sample well. **DO NOT add Dilution Buffer to control wells.**
5. Add **50 µl** of sample to each sample well with Dilution Buffer.
6. Incubate for **60 minutes** at room temperature (15-25°C), then wash.* After last wash, slap the wells out on a clean absorbent towel to remove excess wash buffer.
7. Add **2 drops** of Enzyme Conjugate to each well.
8. Incubate for **30 minutes** at room temperature (15-25°C), then wash.* After last wash, slap the wells out on a clean absorbent towel to remove excess wash buffer.
9. Add **2 drops** of Chromogen to each well.
10. Incubate for **10 minutes** at room temperature (15-25°C).
11. Add **2 drops** of Stop Solution to each well. Mix wells by gently tapping the side of the strip holder with index finger for approximately **15 seconds**. Read reaction within **5 minutes** after adding stop solution.
12. Read results visually or using an ELISA plate reader (see instructions below).

UNPRESERVED SPECIMEN PROCEDURE

1. Prepare sample dilutions in tubes using **0.7 ml** of Dilution Buffer and **0.1 g**, about the size of a small pea, of fecal sample using an applicator stick. Mix thoroughly before using.

-IF USING SWABS, add **1 ml** of dilution buffer to dilution tube. Coat the swab with a thin layer of specimen and mix into dilution buffer, expressing as much fluid as possible. Mix thoroughly before using.

2. **For watery unpreserved specimens**, mix contents then add **0.1 ml** of sample to **0.7 ml** of Dilution Buffer in dilution tubes. Mix thoroughly before using.
3. Break off the required number of wells needed (number of samples plus 2 for controls) and place in holder.
4. Using a micropipette, add **100 µl** of negative control to well # 1.
5. Using a micropipette, add **100 µl** of positive control to well # 2.
6. Add **100 µl** of diluted sample to each well.
7. Incubate for **60 minutes** at room temperature (15-25°C), then wash.* After last wash, slap the wells out on a clean absorbent towel to remove excess wash buffer.
8. Add **2 drops** of Enzyme Conjugate to each well.
9. Incubate for **30 minutes** at room temperature (15-25°C), then wash.* After last wash, slap the wells out on a clean absorbent towel to remove excess wash buffer.
10. Add **2 drops** of Chromogen to each well.
11. Incubate for **10 minutes** at room temperature (15-25°C).
12. Add **2 drops** of Stop Solution to each well. Mix wells by gently tapping the side of the strip holder with index finger for approximately **15 seconds**. Read reaction within **5 minutes** after adding stop solution.
13. Read results visually or using an ELISA plate reader (see instructions below).

**** Washings consist of vigorously filling each well to overflowing and decanting contents five (5) separate times. When possible, avoid formation of bubbles in the wells as this may affect the end results.***

TEST LIMITATIONS

- Test results should be used as an aid in diagnosis and should not be interpreted as diagnostic by themselves.
- DO NOT concentrate stool samples. Assay will not give accurate results on a concentrated sample.
- A negative result can occur from an antigen level lower than the detection limits of this assay. Multiple samples over time may be indicated for those patients that are suspected of being positive for *Giardia*.

READING OF RESULTS

Visually:

- **Positive:** Any sample well that is obviously more yellow than the negative control well.
- **Negative:** Any sample well that is not obviously more yellow than the negative control well.

NOTE: The negative control, as well as some samples, may show some slight color. A sample well must be obviously darker than the negative control well to be called a positive result.

ELISA Reader:

- Zero reader on air. ***Read all wells using a bichromatic reading with filters at 450 nm and 620-650 nm.***
- **Positive:** Absorbance reading of 0.08 OD and above indicates the sample contains *Giardia* antigen.
- **Negative:** Absorbance reading less than 0.08 OD indicates the sample does not contain detectable levels of *Giardia* antigen.

EXPECTED RESULTS

- Normal healthy individuals should be free of *Giardia* and should test negative.
- A positive reaction indicates that the patient is shedding detectable amounts of *Giardia* antigen.
- Certain populations, such as children in day care settings, have shown higher rates of infection with *Giardia* than the normal population. Please refer to the Summary section for references.

QUALITY CONTROL

The positive and negative control must be included each time the assay is run. The use of a positive and negative control allows easy validation of kit stability.

- Negative control should appear colorless when read visually and should read less than 0.08 OD when read at a dual wavelength of 450/620-650 nm.
- Positive control should be a clearly visible yellow color and read at greater than 0.5 OD when read at a dual wavelength of 450/620-650 nm.

PERFORMANCE CHARACTERISTICS

Study 1:

A study was performed with the Monocent, Inc.'s *Giardia* ELISA Test System using fresh/frozen specimens, specimens preserved in 10% Formalin and SAF and specimens in Carey-Blair Transport Media. There was a total of 90 specimens used in the study that were identified positive or negative for *Giardia* by microscopy. Of the 90 specimens, 26 were determined to be positive for *Giardia* and 64 were negative for *Giardia.* The results from the study are shown in the following table.

		Microscopy	
		+	-
Monocent	+	26	0
	-	0	64

Sensitivity: 100% (26/26)
Specificity: 100% (64/64)

Study 2:

A study was performed comparing the Monocent, Inc.'s *Giardia* ELISA Test System with another commercially available ELISA. The study was performed using fresh/frozen specimens and specimens preserved in 10% Formalin and SAF. There was a total of 86 specimens used in the study that were identified either positive or negative for *Giardia* by microscopy. Of the 86 specimens, 22 were identified positive for *Giardia* and 64 were negative for *Giardia.* The results from the study are shown in the following table.

		Monocent	
		+	-
Other Commercial ELISA	+	22	0
	-	0	64

Positive Agreement: 100% (22/22)
Negative Agreement: 100% (64/64)

Reproducibility

- The intra-assay (well to well) CV was calculated using 4 positive and 4 negative samples assayed 24 times in a single run. The mean CV was 3.67% with the highest being 6.18%.
- The inter-assay (run to run) CV was calculated using 4 positive and 4 negative samples assayed on three separate days. The mean CV was 4.08% with the highest being 11.61%.

Cross Reactivity

No cross-reactions were seen with the following organisms:
Entamoeba hartmanni, Endolimax nana, Entamoeba histolytica/dispar, *Entamoeba coli, Blastocystis hominis, Dientamoeba fragilis*, *Chilomastix mesnili, Strongyloides stercoralis, Cryptosporidium, Ascaris lumbricoides, Enterobius vermicularis, Diphyllobothrium* species, *Hymenolepis nana, Clonorchis sinensis, Enteromonas hominis, Trichuris trichiura, Iodamoeba buetschlii,* Hookworm, *Schistosoma mansoni,* Rotavirus, *Taenia* eggs, *Fasciola* eggs, *Isospora belli, Entamoeba polecki*, Adenovirus, & 33 bacterial species (list available on request).

TROUBLESHOOTING

- **Problem:** Negative control has excessive color after development.
- **Reason:** Inadequate washings
- **Correction:** Wash more vigorously. Remove excessive liquid from the wells by tapping against an Absorbent towel. Do not allow test wells to dry out

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Revision Date: 2019-08

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H. pylori Ag
ELISA TEST SYSTEM

CE

REF EL2-1138 | Σ 96 TESTS | IVD

INTENDED USE

The Monocent, Inc.'s Helicobacter pylori Antigen ELISA Test System is a quantitative assay for the detection of *H. pylori* antigens in human stool specimen. The test results are intended to aid in the diagnosis of *H. pylori* infection, to monitor the effectiveness of therapng/mltic treatment and to confirm the eradication of *H. pylori* in peptic ulcer patients.

SUMMARY AND EXPLANATION

Helicobacter pylori is a spiral bacterium cultured from human gastric mucosa by Marshall in 19821. Studies have indicated that the presence of *H. pylori* is associated with a variety of gastrointestinal diseases including gastritis, duodenal and gastric ulcer, non-ulcer dyspepsia, gastric adenocarcinoma and lymphoma. The organism is present in 95-98% of patients with duodenal ulcer and 60-90% of patients with gastric ulcers. The studies have also demonstrated that removal of the organism by antimicrobial therapy is correlated with the resolution of symptoms and cure of diseases2.

Patients who present with clinical symptoms relating to the gastrointestinal tract can be diagnosed for *H. pylori* infection by two methods:

1) Invasive techniques include biopsy followed by culture or histological examination of biopsy specimen or direct detection of urease activity. The cost and discomfort to the patients are very high and biopsy samples are subject to errors related to sampling and interference of contaminated bacteria.

2) Non-invasive techniques include urea breath tests (UBT)3 and serological methods4. The UBT requires a high density and active bacteria and should not be performed until 4 weeks after therapy to allow residual bacteria to increase to the detection level. The main limitation of serology test is the inability to distinguish current and past infections.

H. pylori Antigen tests the presence of *H. pylori* antigens in stool specimens for an active infection.

PRINCIPLE OF THE TEST

Purified *H. pylori* antibody is coated on the surface of microwells. An aliquot of diluted stool sample is added to wells, and the *H. pylori* antigens, if present, bind to the antibody. All unbound materials are washed away. After adding enzyme conjugate, it binds to the antibody-antigen complex. Excess enzyme conjugate is washed off and TMB Chromogenic substrate is added. The enzyme conjugate catalytic reaction is stopped at a specific time. The intensity of the color generated is proportional to the amount of antigen in the sample. The results are read by a microwell reader compared in a parallel manner with calibrator and controls.

MATERIALS AND COMPONENTS PROVIDED

- Microwell Strips: Purified *H. pylori* antibody coated wells. (12 x 8 wells)
- Sample Treatment Solution: White Cap. 1 Bottle (100 ml)
- Washing Concentrate 20x 1 Bottle (50 ml)
- TMB Chromogenic Substrate: Amber bottle. 1 vial (12 ml)
- Enzyme Conjugate: Red color solution 1 vial (12 ml)
- Calibrator Set: 0, 6.3, 12.5, 25, 50, 100 ng/ml 1 ml/ vial
- Control Set: Negative and Positive Controls
  Ranges are indicated on labels 1 ml/vial
- Stop Solution: 1.25 M Acid Solution 1 vial (12 ml)

STORAGE AND STABILITY

- Store the kit at 2-8°C.
- Always keep microwells tightly sealed in pouch with desiccants. We recommend you use up all wells within 4 weeks after initial opening of the pouch.
- The reagents are stable until expiration of the kit.
- Do not expose test reagents to heat, sun or strong light during storage or usage.

PRECAUTIONS

1. Potential biohazardous materials:
   The calibrator and controls contain human source components, which have been tested and found nonreactive for hepatitis B surface antigen as well as HIV antibody with FDA licensed reagents. However, as there is no test method that can offer complete assurance that HIV, Hepatitis B virus or other infectious agents are absent, these reagents should be handled at the Biosafety Level 2, as recommended in the Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories." 1984
2. Do not pipette by mouth. Do not smoke, eat, or drink in the areas in which specimens or kit reagents are handled.
3. The components in this kit are intended for use as an integral unit. The components of different lots should not be mixed.
4. This product contains components preserved with sodium azide. Sodium azide may react with lead and copper plumbing to form explosive metal azide. On disposal, flush with a large volume of water.

SPECIMEN COLLECTION AND HANDLING

1. Transfer small piece of stool (~5mm in diameter; ~150mg) into 1ml of Sample Treatment Solution in a test tube, mix thoroughly.
2. If liquid samples such as from culture medium or others are available for test, dilute it 1:1 with Sample Treatment Solution.

ASSAY PREPARATION

1. Prepare 1x washing buffer.
   Prepare washing buffer by adding distilled or deionized water to 20x wash concentrate to a final volume of 1 liter.
2. Bring all specimens and kit reagents to room temperature (20-25°C) and gently mix.

TEST PROCEDURE

1. Place the desired number of coated strips into the holder.
2. Dispense 100µl of treated sample, calibrators, and controls into the appropriate wells. Tap the holder to remove air bubbles from the liquid and mix well. Incubate for 30 minutes at room temperature.
3. Remove liquid from all wells and repeat washing three times with washing buffer.
4. Dispense 100µl of enzyme conjugate to each well and incubate for 30 minutes at room temperature.
5. Remove enzyme conjugate from all wells. Repeat washing three times with washing buffer.
6. Dispense 100µl of TMB Chromogenic Substrate to each well and incubate for 15 minutes at room temperature.
7. Add 100µl of stop solution to stop reaction.

Make sure there are no air bubbles in each well before reading

8. Read O.D. at 450 nm with a microwell reader.

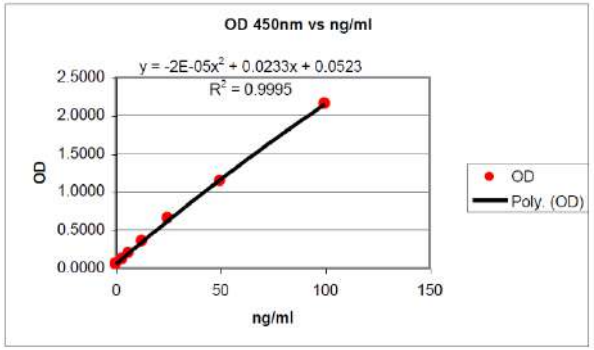
CALCULATION OF RESULTS

1. Construct a standard curve by plotting O.D. 450 nm on the y-axis against the concentration of calibrator ng/ml values on the x-axis with an order 2 Polynomial trendlines.
2. Using the O.D. value of each specimen, determine the concentration from the standard curve. If sample results are greater than 100 ng/ml (over the range of standard curve), they can be reported as " high positive and greater than 100 ng/ml". To assess accurate results, samples can be further diluted and retested again.

3. A typical example (for demonstration only):

Calibrator Set	H. Pylori Antigen (ng/ml)	O.D. 450 nm		O.D. 450 nm Mean	SD	CV %
Calibrator 1	0.0	0.019	0.022	0.021	0.0021	10.3%
Calibrator 2	6.3	0.153	0.161	0.157	0.0057	3.6%
Calibrator 3	12.5	0.300	0.299	0.300	0.0007	0.2%
Calibrator 4	25	0.555	0.536	0.546	0.0134	2.5%
Calibrator 5	50	1.096	1.042	1.069	0.0382	3.6%
Calibrator 6	100	1.942	1.891	1.917	0.0361	1.9%

4. A typical illustration of standard curve:



LIMITATIONS OF THE PROCEDURE

- The assay should be used only to evaluate patients with clinical signs and symptoms suggestive of gastrointestinal disease.
- A positive test result indicates an active infection and colonization by *H. pylori*. It does not necessarily indicate that gastrointestinal disease is present.
- For professional use only.

QUALITY CONTROL

1. The negative control and positive control should be run with every batch of samples tested and the concentration must be within the range stated on its label.
2. The O.D. value of calibrator 0 ng/ml must be lower than 0.15 and the O.D. value of calibrator 100 ng/ml must be greater than 1.0.

INTERPRETATION

Minimum detectable concentration:	0.5 ng/ml
Negative:	< 15 ng/ml
Positive:	> 20 ng/ml

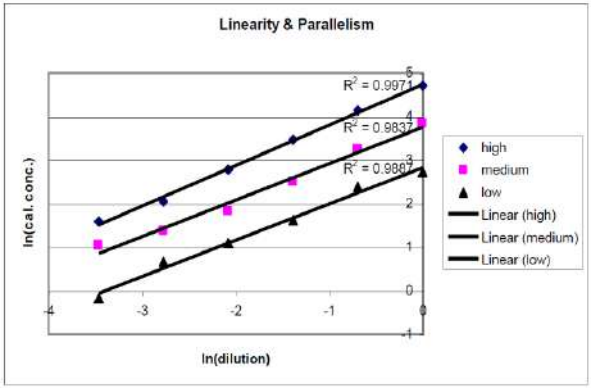
PERFORMANCE CHARACTERISTICS

LINEARITY and PARALLELISM:

A study was conducted to demonstrate linearity of the assay. Three positive patient samples were serially diluted. Ng/ml values were calculated for individual OD readings of the diluted samples. The linearity of R squared values are listed in the following table:

Serum #	Neat	1:2	1:4	1:8	1:16	1:32	R2
1	110.9	62.8	32.1	16.1	7.8	4.9	0.9971
2	46.6	25.7	12.1	6.2	3.9	2.8	0.9837
3	15.2	10.8	5.0	3.0	1.9	0.8	0.9887

The linear regression graph of above three positive samples:



PRECISION:

The precision of the assay was evaluated by testing three different sera and eight replicate readings in 3 days. The intra-assay and inter-assay %CV are summarized below:

N = 8	Low Positive	Middle Positive	High Positive
Intra-assay	6.7%	4.7%	3.3%
Inter-assay	7.4%	2.7%	16.7%

CROSS-REACTIVITY:

A study was performed to determine the cross-reactivity with the following bacterial and viral strains: Camplylobactor coli, Camplylobactor fetus, Camplylobactor jejuni, Camplylobactor lari, Candida albicans, Enterobacter cloacae, Helicobacter cinaedi.

All above positive samples were tested negative for Helicobacter pylori Antigen test.

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Mumps IgG ELISA TEST SYSTEM

CE

REF EL1-1179 Σ 96 TESTS IVD

INTENDED USE

The Monocent, Inc.'s Mumps IgG Elisa test system is an Enzyme-Linked Immunosorbent Assay kit providing material for the detection of IgG-class antibodies to the antigen of Mumps virus in human serum or plasma. This assay is intended for in vitro use only.

SUMMARY AND EXPLANATION

Mumps is a frequent childhood disease that is normally diagnosed on the basis of the parotitis that constitutes the presenting symptom. However, patients presenting the most common complications, i.e., orchitis, meningitis, meningoencephalitis, without inflammation of the salivary gland may require confirmation of the infection by serological methods.

PRINCIPLE OF THE TEST

The Monocent, Inc.'s Mumps IgG kit is based on the ELISA technique. In the assay, controls and unknowns are incubated in microtitration wells coated with purified and inactivated Mumps Virus antigen. After incubation and washing, the wells are treated with the conjugate, composed of anti-human IgG antibodies labeled with peroxidase. After a second incubation and washing step, the wells are incubated with the substrate tetramethylbenzidine (TMB). An acidic stopping solution is then added and the degree of enzymatic turnover of the substrate is determined by wavelength absorbance measurement at 450 nm. The absorbance measured is directly proportional to the concentration of anti-Mumps virus IgG antibodies present.

MATERIALS PROVIDED

Antigen-Coated Microtitration Strips: One strip holder containing 12x8 (96) microtitration wells coated with Mumps virus antigen. Store at 2-8°C until expiration date. Remove the support and strips to be used from the foil package and place the unused strips in the polythene bag with the silica gel, expel the air and seal by pressing the closure. Once opened, the product is stable for 4 weeks at 2-8°C.

Wash Concentrate: One bottle, 100 mL, containing a phosphate buffered saline, concentrated 10-fold containing 0.5% Brij weight by volume (w/v). Dilute with deionized/distilled water prior to use. Store at 2-8°C until expiration date.

Sample Diluent: One bottle, 100 ml, containing a protein solution with 0.09% sodium azide as a preservative. Store at 2-8°C until expiration date.

Mumps IgG Controls: Three vials, negative, cut off and positive, each 2 mL of human serum in a 0.01 M phosphate buffer with 0.09% sodium azide as a preservative. Store at 2-8°C until expiration date.

2nd Antibody Conjugate: One bottle, 12 mL, containing anti-human IgG monoclonal antibodies labelled with peroxidase, in a phosphate buffer solution with 0.02% Proclin. Store at 2-8°C until expiration date.

TMB-Substrate: One bottle, 12 mL, containing tetramethylbenzidine (TMB) and hydrogen peroxide stabilized in citrate buffer, pH 3.8. Store at 2-8°C until expiration date.

MATERIALS PROVIDED	96 Tests
Mumps Virus Antigen-Coated Microtitration Strip	One Plate
Wash Concentrate	One Bottle
Sample Diluent	One Bottle
TMB-Substrate	One Bottle
Negative control	One Vial
Cut off control	One Vial
Positive control	One Vial
2nd Antibody Conjugate	One Bottle
Stopping Solution	One Bottle

Stopping Solution: One bottle, 15 mL, containing 0.3 M H_2SO_4 in solution. Store at 2-8°C until expiration date.

MATERIALS REQUIRED BUT NOT PROVIDED

- Microtitration plate reader capable of absorbance measurement at 450 nm
- Deionized/Distilled water
- Precision pipette to deliver 10 µL, 100 µL and 1 mL
- Semi-automatic pipette to deliver 100 µL
- Automatic microtitration plate washer
- Absorbent materials for blotting the strips
- Incubator

PRECAUTIONS

For in vitro use. The following universal Good Laboratory Practices should be observed:

Do not eat, drink, smoke or apply cosmetics where immunodiagnostic material is being handled. Do not pipet by mouth. Wear lab coats and disposable gloves when handling immunodiagnostic material. Wash hands thoroughly afterwards. Cover working area with disposable absorbent paper. Wipe up spills immediately and decontaminate affected surfaces. Avoid generation of aerosols. Provide adequate ventilation. Handle and dispose all reagents and materials in compliance with applicable regulations

WARNING: POTENTIAL BIOHAZARDOUS MATERIAL

This kit may contain some reagents made with human source material (e.g. serum or plasma) or used in conjunction with human source materials. The material in this kit has been tested by CE marked methods and found to be non-reactive for HIV-1/2 Antibodies, HCV and HBsAg. No available test method can offer complete assurance of eliminating potential biohazardous risk. Handle all reagents and patient samples at a Biosafety Level 2, as recommended for any potentially infectious human material in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories," 4th Edition, April 1999.

WARNING AND PRECAUTION:

Some of the reagents in this kit contain sodium azide as a preservative at concentrations below the regulatory limit of < 0.1%. Although significantly diluted, concentrated sodium azide is an irritant to skin and mucous membranes and may react with lead and copper plumbing to form explosive metal azides, especially if accumulated. Additionally, TMB and Sulfuric Acid, in concentrated amounts are also irritants to skin and mucous membranes. These substances are in diluted form and therefore may minimize exposure risks significantly but not completely. Provide adequate ventilation. Avoid contact with skin, eyes and clothing. In case of contact with any of these reagents, wash thoroughly with water and seek medical advice. Dispose all nonhazardous reagents by flushing with large volumes of water to prevent buildup of chemical hazards in the plumbing system.

For further information regarding hazardous substances in the kit, please refer to the component specific MSDS by request.

SPECIMEN COLLECTION

Serum should be used, and the usual precautions for venepuncture should be observed. Specimens may be stored at 2-8°C for 2 days. For longer periods, store at –20°C. Do not use haemolyzed or lipemic specimens. Avoid repeated freezing and thawing of samples.

PREPARATION FOR ASSAY

A thorough understanding of this package insert is necessary for successful use of the product. Reliable results will only be obtained by using precise laboratory techniques and accurately following the package insert. Bring all kit reagents and specimens to room temperature (~25°C) before use. Thoroughly mix the reagents and samples before use by gentle inversion. Do not mix various lots of any kit component within an individual assay. Do not use any component beyond the expiration date shown on its label. Incomplete washing will adversely affected the outcome and assay precision. To minimize potential assay drift due to variation in the substrate incubation time, care should be taken to add the stopping solution into the wells in the same order and speed to add the TMB Chromogen Solution. Avoid microbial contamination of reagents, especially of the conjugate, wash buffer and diluent. Avoid contamination of the TMB Chromogen Solution with the Conjugate. Use a clean disposable pipette tip for each reagent. Avoid pipettes with metal parts. Containers and semi-automatic pipette tips used for the Conjugate and TMB can be reused provided they are thoroughly rinsed with deionized/distilled water and dried prior to and after each usage. The enzyme used as the label is inactivated by oxygen, and is highly sensitive to microbial contamination, sodium azide, hypochlorous acid and aromatic chlorohydrocarbons often found in laboratory water supplies. Use high quality water. Avoid exposure of the reagents to excessive heat or sunlight during storage and incubation.

REAGENT PREPARATION

Wash Solution:

Dilute 1:10 with deionized/distilled water prior to use. If crystals are present, they should be dissolved at 37°C before dilution. Pour 100 mL of the Wash Concentrate into a clean container and dilute by adding 900 mL of deionized/distilled water. Mix thoroughly by inversion. The wash solution is stable for 5 days at room temperature and 2 weeks at 2-8°C when stored in a tightly sealed bottle.

Microtitration Strips:

Select the number of coated strips required for the assay. The remaining unused wells should be placed in the resealable pouch with a desiccant pack. The pouch must be resealed to protect from moisture.

TEST PROCEDURE

All specimens and reagents to reach room temperature (~25°C) before use. Serum Samples and Controls should be assayed in duplicate.

1. Mark the microtitration strips to be used.
2. Dilute serum samples 1:101 distributing 10 µL of serum into 1 mL of Sample Diluent.
3. Pipette 100 µL of each diluted serum sample and ready to use controls to the appropriate wells. Add 30 µL Sorbent M only in to the wells of diluted samples.
4. Incubate for 45 minutes at 37°C.
5. Aspirate and wash each well four (4) times for 30 seconds with Washing Solution using an automatic microplate washer or manually using a dispenser. Blot and dry by inverting plate on absorbent material.
   NOTE: Use of an automatic microplate washer is strongly recommended. Incomplete washing will adversely affect assay precision. If a microplate washer is not available, (a) completely aspirate the liquid from each well, (b) dispense 300 uL of the Wash Solution into each well and (c) repeat step (a) and (b) four times.
6. Add 100 µL of Enzyme-Labelled 2nd Antibody- Conjugate into each well.
7. Incubate for 45 minutes at 37°C.
8. Aspirate and wash each well four times for 30 seconds with Washing Solution using an automatic microplate washer or manually using a dispenser. Blot and dry by inverting plate on absorbent material.
9. Add 100 µL of TMB Chromogen Solution to each well using a dispenser.
10. Incubate for 15 minutes at room temperature. Avoid exposure to direct sunlight.
11. Add 100 µL of Stopping Solution to each well using a dispenser.
12. Read the absorbance of the solution in the wells within 30 minutes, using a microplate reader set to 450 nm. If wavelength correction is available, set the instrument to dual wavelength measurement at 450 nm with background wavelength correction set at 600 or 620 nm.

CALCULATION OF RESULTS

Calculate the mean absorbance for each control and unknown.

Qualitative results:
If the absorbance of the sample is higher than that of the Cut-Off, the sample is positive for the presence of specific IgG.
Calculate the ratio between the average OD value of the sample and that of the Cut-Off. The sample is considered:
Positive: if the ratio is > 1.1.
Doubtful: if +/- 10% of the Cut-Off.
Negative: if the ratio is < 0.9.
If the result is doubtful, repeat the test. If it remains doubtful, collect a new serum sample.

LIMITATIONS OF THE PROCEDURE

- A serum sample obtained during the early phase of infection, when only IgM antibodies are present, may be negative by this procedure.
- The test result should be used in conjunction with information available from the evaluation of other clinical and diagnostic procedures.
- Avoid repeated freezing and thawing of reagents and specimens.
- Grossly haemolyzed, icteric or lipemic specimens should be avoided.
- Heat inactivated sera should be avoided.

QUALITY CONTROL

The OD values of Cut-Off control must be at least 0.2. Positive control must have an OD at least 1.5 times that of Cut-Off.

PERFOMANCE CHARACTERISTICS

1. Sensitivity and Specificity:
130 human sera were analyzed by this Mumps IgG Elisa and an Elisa reference method. Out of 130 samples, 92 were positive for the presence of IgG antibodies to Mumps virus by Monocent, Inc Elisa and reference Elisa also showed 92 of them as positive. The results are summarized below.

Monocent	Positive	Negative	FN (false negative)	FP (false positive)
	92	38	0	0
Test A	92	38	0	0

2. Precision

Inter-Assay

Serum	No. of Replicates	Mean	SD	CV (%)
1	16	0.123	0.00	3.4
2	16	0.457	0.01	1.7
3	16	1.036	006	5.7

Intra-Assay

Serum	No. of Replicates	Mean	SD	CV (%)
1	16	0.022	0.003	14.45
2	16	0.88	0.067	7.6
3	16	0.86	0.069	8.08

3. Interference Study

Interferences with lipemic, hemolytic or icteric sera are not observed up to a concentration of 10 mg/ml hemoglobin, 5 mg/ml triglycerides and 0.2 mg/ml bilirubin.

REFERENCES

1. E.H. Wasmuth and w. Miller. J. Med. Virology 32:189 (1990)
2. M.L.Landry, S.D. Cohen, D. Mayo, C. Fong, W. Andiman: J Clin. Microbiology 25:832 (1987)
3. P.Larussa, S.Steinberg,,et.al. J. Clin. Microbiology 25:2059 (1987)
4. G. Berbers, et. al. Blocking ELISA for detection of mumps virus antibodies in human sera. J. Virol. Methods 42, 155 (1993).

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Revision Date: 2012/08

MONOCENT
Innovation & Excellence

ENGLISH

Mumps IgM ELISA TEST SYSTEM

CE

REF EL1-1180 | Σ 96 TESTS | IVD

INTENDED USE

The Monocent, Inc.'s Mumps IgM Elisa is an Enzyme-Linked Immunosorbent Assay kit providing material for the detection of IgM-class antibodies to Mumps virus in human serum or plasma. This assay is intended for in vitro use only.

SUMMARY AND EXPLANATION

Mumps is a frequent childhood disease that is normally diagnosed on the basis of the parotitis that constitutes the presenting symptom. However, patients presenting the most common complications, i.e., orchitis, meningitis, meningoencephalitis, without inflammation of the salivary gland may require confirmation of the infection by serological methods.

PRINCIPLE OF THE TEST

The Monocent, Inc.'s Mumps IgM kit is based on the ELISA technique. In the assay, controls and unknowns are incubated in microtitration wells coated with purified and inactivated Mumps virus antigen. After incubation and washing, the wells are treated with the conjugate, composed of anti-human IgM antibodies labeled with peroxidase. After a second incubation and washing step, the wells are incubated with the substrate tetramethylbenzidine (TMB). An acidic stopping solution is then added and the degree of enzymatic turnover of the substrate is determined by wavelength absorbance measurement at 450 nm. The absorbance measured is directly proportional to the concentration of anti-Mumps virus IgM antibodies present.

MATERIALS REQUIRED BUT NOT PROVIDED

- Microtitration plate reader capable of absorbance measurement at 450 nm
- Deionized/Distilled water
- Precision pipette to deliver 10 µL, 100 µL and 1 mL
- Semi-automatic pipette to deliver 100 µL
- Automatic microtitration plate washer
- Absorbent materials for blotting the strips
- Incubator

MATERIALS PROVIDED

MATERIALS PROVIDED	96 Tests
Mumps Antigen-Coated Microtitration Strip	One Plate
Wash Concentrate	One Bottle
Sample Diluent	One Bottle
TMB-Substrate	One Bottle
Negative control	One Vial
Cut off control	One Vial
Positive control	One Vial
2nd Antibody Conjugate	One Bottle
Stopping Solution	One Bottle
Sorbent M	One Bottle

Mumps-Antigen-Coated Microtitration Strips: One strip holder containing 12x8 (96) microtitration wells coated with purified inactivated Mumps virus antigen. Store at 2-8°C until expiration date. Remove the support and strips to be used from the foil package and place the unused strips in the polythene bag with the silica gel, expel the air and seal by pressing the closure. Once opened, the product is stable for 4 weeks at 2-8°C.

Wash Concentrate: One bottle, 100 mL, containing a phosphate buffered saline, concentrated 10-fold containing 0.5% Brij weight by volume (w/v). Dilute with deionized/distilled water prior to use. Store at 2-8°C until expiration date.

Sample Diluent: One bottle, 100 ml, containing a BSA solution with 0.09% sodium azide as a preservative. Store at 2-8°C until expiration date.

Mumps IgM Controls: Three vials, negative, cut off and positive, each 2 mL of human serum in a 0.01 M phosphate buffer containing BSA with 0.09% sodium azide as a preservative. Store at 2-8°C until expiration date.

2nd Antibody Conjugate: One bottle, 12 mL, containing anti-human IgM monoclonal antibodies labelled with peroxidase, in a phosphate buffer solution with 0.02% Proclin™. Store at 2-8°C until expiration date.

Sorbent M: One Bottle, 4 ml containing protein solution in a phosphate buffer solution with 0.02% proclin™. Store at 2°-8° C.

TMB-Substrate: One bottle, 12 mL, containing tetramethylbenzidine (TMB) and hydrogen peroxide stabilized in citrate buffer, pH 3.8. Store at 2-8°C until expiration date.

Stopping Solution: One bottle, 15 mL, containing 0.3 M H_2SO_4 in solution. Store at 2-8°C until expiration date.

PRECAUTIONS

For in vitro use. The following universal Good Laboratory Practices should be observed:

Do not eat, drink, smoke or apply cosmetics where immunodiagnostic material is being handled. Do not pipet by mouth. Wear lab coats and disposable gloves when handling immunodiagnostic material. Wash hands thoroughly afterwards. Cover working area with disposable absorbent paper. Wipe up spills immediately and decontaminate affected surfaces. Avoid generation of aerosols. Provide adequate ventilation. Handle and dispose all reagents and materials in compliance with applicable regulations.

WARNING: POTENTIAL BIOHAZARDOUS MATERIAL

This kit may contain some reagents made with human source material (e.g. serum or plasma) or used in conjunction with human source materials. The material in this kit has been tested by CE marked methods and found to be non-reactive for HIV-1/2 Antibodies, HCV and HBsAg. No available test method can offer complete assurance of eliminating potential biohazardous risk. Handle all reagents and patient samples at a Biosafety Level 2, as recommended for any potentially infectious human material in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories," 4th Edition, April 1999.

WARNING AND PRECAUTION:

Some of the reagents in this kit contain sodium azide as a preservative at concentrations below the regulatory limit of < 0.1%. Although significantly diluted, concentrated sodium azide is an irritant to skin and mucous membranes and may react with lead and copper plumbing to form explosive metal azides, especially if accumulated. Additionally, TMB and Sulfuric Acid, in concentrated amounts are also irritants to skin and mucous membranes. These substances are in diluted form and therefore may minimize exposure risks significantly but not completely. Provide adequate ventilation. Avoid contact with skin, eyes and clothing. In case of contact with any of these reagents, wash thoroughly with water and seek medical advice. Dispose all nonhazardous reagents by flushing with large volumes of water to prevent buildup of chemical hazards in the plumbing system.

For further information regarding hazardous substances in the kit, please refer to the component specific MSDS by request.

SPECIMEN COLLECTION

Serum should be used, and the usual precautions for venepuncture should be observed. Specimens may be stored at 2-8°C for 2 days. For longer periods, store at –20°C. Do not use haemolyzed or lipemic specimens. Avoid repeated freezing and thawing of samples.

PREPARATION FOR ASSAY

A thorough understanding of this package insert is necessary for successful use of the product. Reliable results will only be obtained by using precise laboratory techniques and accurately following the package insert. Bring all kit reagents and specimens to room temperature (~25°C) before use. Thoroughly mix the reagents and samples before use by gentle inversion. Do not mix various lots of any kit component within an individual assay. Do not use any component beyond the expiration date shown on its label. Incomplete washing will adversely affected the outcome and assay precision. To minimize potential assay drift due to variation in the substrate incubation time, care should be taken to add the stopping solution into the wells in the same order and speed to add the TMB Chromogen Solution. Avoid microbial contamination of reagents, especially of the conjugate, wash buffer and diluent. Avoid contamination of the TMB Chromogen Solution with the Conjugate. Use a clean disposable pipette tip for each reagent. Avoid pipettes with metal parts. Containers and semi-automatic pipette tips used for the Conjugate and TMB can be reused provided they are thoroughly rinsed with deionized/distilled water and dried prior to and after each usage. The enzyme used as the label is inactivated by oxygen, and is highly sensitive to microbial contamination, sodium azide, hypochlorous acid and aromatic chlorohydrocarbons often found in laboratory water supplies. Use high quality water. Avoid exposure of the reagents to excessive heat or sunlight during storage and incubation.

REAGENT PREPARATION

Wash Solution:

Dilute 1:10 with deionized/distilled water prior to use. If crystals are present, they should be dissolved at 37°C before dilution. Pour 100 mL of the Wash Concentrate into a clean container and dilute by adding 900 mL of deionized/distilled water. Mix thoroughly by inversion. The wash solution is stable for 5 days at room temperature and 2 weeks at 2-8°C when stored in a tightly sealed bottle.

Microtitration Strips:

Select the number of coated strips required for the assay. The remaining unused wells should be placed in the resealable pouch with a desiccant pack. The pouch must be resealed to protect from moisture.

ASSAY PROCEDURE

All specimens and reagents to reach room temperature (~25°C) before use. Serum Samples and Controls should be assayed in duplicate.

1. Mark the microtitration strips to be used.
2. Dilute serum samples 1:101 distributing 10 µL of serum into 1 mL of Sample Diluent.
3. Pipette 100 µL of each diluted serum sample and ready to use controls to the appropriate wells. Add 30 µL Sorbent M only in to the wells of diluted samples.
4. Incubate for 45 minutes at 37°C.
5. Aspirate and wash each well four (4) times for 30 seconds with Washing Solution using an automatic microplate washer or manually using a dispenser. Blot and dry by inverting plate on absorbent material.
   NOTE: Use of an automatic microplate washer is strongly recommended. Incomplete washing will adversely affect assay precision. If a microplate washer is not available, (a) completely aspirate the liquid from each well, (b) dispense 300 uL of the Wash Solution into each well and (c) repeat step (a) and (b) four times.
6. Add 100 µL of Enzyme-Labelled 2nd Antibody- Conjugate into each well.
7. Incubate for 45 minutes at 37°C.
8. Aspirate and wash each well four times for 30 seconds with Washing Solution using an automatic microplate washer or manually using a dispenser. Blot and dry by inverting plate on absorbent material.
9. Add 100 µL of TMB Chromogen Solution to each well using a dispenser.
10. Incubate for 15 minutes at room temperature. Avoid exposure to direct sunlight.
11. Add 100 µL of Stopping Solution to each well using a dispenser.
12. Read the absorbance of the solution in the wells within 30 minutes, using a microplate reader set to 450 nm. If wavelength correction is available, set the instrument to dual wavelength measurement at 450 nm with background wavelength correction set at 600 or 620 nm.

CALCULATION OF RESULTS

Calculate the mean absorbance for each control and unknown.

Qualitative results:
If the absorbance of the sample is higher than that of the Cut-Off, the sample is positive for the presence of specific IgM.
Calculate the ratio between the average OD value of the sample and that of the Cut-Off. The sample is considered:
Positive: if the ratio is > 1.1.
Doubtful: if +/- 10% of the Cut-Off.
Negative: if the ratio is < 0.9.
If the result is doubtful, repeat the test. If it remains doubtful, collect a new serum sample.

LIMITATIONS OF THE PROCEDURE

- A serum sample obtained during the late phase of infection, when only IgG antibodies are present, may be negative by this procedure.
- The test result should be used in conjunction with information available from the evaluation of other clinical and diagnostic procedures.
- Avoid repeated freezing and thawing of reagents and specimens.
- Grossly haemolyzed, icteric or lipemic specimens should be avoided.
- Heat inactivated sera should be avoided.

QUALITY CONTROL

The OD values of Cut off control must be at least 0.2. Positive control must have an OD at least 1.5 times that of Cut off control.

PERFOMANCE CHARACTERISTICS

1. Sensitivity and Specificity:
108 human sera were analyzed by this Mumps IgM Elisa and a commercial Elisa (Test A) as reference method. Out of 108 samples, 12 were positive for the presence of IgM antibodies to Mumps virus by Monocent, Inc. Elisa and commercial Elisa showed 13 of them as positive. The results are summarized below.

Monocent	Positive	Negative	FN (false negative)	FP (false positive)
	12 (1)	96	0	0
Test A	13	95	0	0

2. Precision

Inter-Assay

Serum	No. of Replicates	Mean	SD	CV (%)
1	16	0.539	0.061	11.3
2	16	1.69	0.10	6.1
3	16	0.057	0.007	12,3

Intra-Assay

Serum	No. of Replicates	Mean	SD	CV (%)
1	16	0,469	0,061	11,4
2	16	0,078	0,007	12,3
3	16	1,69	0.1	6,1

3. Interference Study

Interferences with lipemic, hemolytic or icteric sera are not observed up to a concentration of 5 mg/ml hemoglobin, 5 mg/ml triglycerides and 0.2 mg/ml bilirubin.

REFERENCES

1. E.H. Wasmuth and w. Miller. J. Med. Virology 32:189 (1990)
2. M.L.Landry, S.D. Cohen, D. Mayo, C. Fong, W. Andiman: J Clin. Microbiology 25:832 (1987)
3. P.Larussa, S.Steinberg,,et.al. J. Clin. Microbiology 25:2059 (1987)

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ENGLISH

Rubella IgG
ELISA TEST SYSTEM

REF **EL46-1190** **96 TESTS** RUO

INTENDED USE

The Monocent, Inc.'s Rubella IgG ELISA Test System is an Enzyme-Linked Immunosorbent Assay kit providing material for the detection of IgG-class antibodies to Rubella virus in human serum or plasma in order to determine the immune-status of the patient and/or latent Rubella infection. This assay is intended for *in vitro* use only.

SUMMARY AND EXPLANATION

The Rubella virus, most commonly known as the German or 3-day measles is an RNA virus that belongs to the family Togaviridae and contains three major structural proteins, E1, E2 and C. It is spread through direct or droplet contact from nasopharyngeal secretions. The infection is highly contagious and affects children, 5-14 years as well as young adults. Rubella infection, however, is largely benign with symptoms ranging from subclinical to a disease characterized by an erythematous rash, low-grade fever, headache, lymphadenopathy, arthralgia, and conjunctivitis. Immunizations and natural infection both confer lifelong immunity and reinfection is extremely rare. Congenital Rubella infection, unlike acquired infection, may cause disastrous clinical effects to the unborn child. A fetus may be stillborn or have such abnormalities as bone and cardiovascular defects, mental retardation, encephalitis, hepatomegaly, splenomegaly, thrombocytopenic purpura, cataracts and microcephaly. Because of severity of the complication from infection, detection in pregnant women is paramount. Therefore, it is important that the level of immunity be determined in women of child-bearing age, pregnant women, neonates who were exposed in utero, and others who may have been in close contact. The clinical recognition of Rubella infection is highly unreliable, and subclinical cases are frequent. Serological testing has been shown to be an effective method of detecting infection.

PRINCIPLE OF THE TEST

The Rubella IgG kit is based on the ELISA technique. In the assay, calibrators and unknowns are incubated in microtitration wells coated with purified and inactivated Rubella virus antigen. After incubation and washing, the wells are treated with the conjugate, composed of anti-human IgG antibodies labeled with peroxidase. After a second incubation and washing step, the wells are incubated with the substrate tetramethylbenzidine (TMB). An acidic stopping solution is then added and the degree of enzymatic turnover of the substrate is determined by wavelength absorbance measurement at 450 nm. The absorbance measured is directly proportional to the concentration of anti-Rubella virus IgG antibodies present.

MATERIALS AND COMPONENTS PROVIDED

• Rubella Antigen-Coated Microtitration Strip	One Plate
• Wash Concentrate	One Bottle
• Sample Diluent	One Bottle
• TMB-Substrate	One Bottle
• Calibrator 0	One Vial
• Calibrator 1	One Vial
• Calibrator 2	One Vial
• Calibrator 3	One Vial
• Calibrator 4	One Vial
• 2nd Antibody Conjugate	One Bottle
• Stopping Solution	One Bottle

MATERIALS REQUIRED BUT NOT PROVIDED

- Microtitration plate reader capable of absorbance measurement at 450 nm
- Deionized/Distilled water
- Precision pipette to deliver 10 µl, 100 µl and 1 ml
- Semi-automatic pipette to deliver 100 µl
- Automatic microtitration plate washer
- Absorbent material for blotting the strips
- Incubator

REAGENTS PROVIDED

- **Antigen-Coated Microtitration Strips:**

One stripholder containing 12x8 (96) microtitration wells coated with purified inactivated *Rubella virus* antigen. Store at 2-8°C until expiration date. Remove the support and strips to be used from the foil package and place the unused strips in the polythene bag with the silica gel, expel the air and seal by pressing the closure. Once opened, the product is stable for 4 weeks at 2-8°C.

- **Wash Concentrate:**

One bottle, 100 ml, containing a phosphate buffered saline, concentrated 10-fold containing 0.5% Brij weight by volume (w/v). Dilute with deionized/distilled water prior to use. Store at 2-8°C until expiration date.

- **Sample Diluent:**

One bottle, 100 ml, containing BSA solution with 0.09% sodium azide as a preservative. Store at 2-8°C until expiration date.

- ***Rubella* IgG Calibrators:**

Five vials, calibrated according to PEI reference standards Anti-Rubella IgG, source Paul-Ehrlich-Institute, Germany, each 2 ml of human serum in a 0.01 M phosphate buffer containg BSA with 0.09% sodium azide as a preservative. The value for Calibrator 1 represents the Cut-Off control, values are reported on the labels of the vials. Store at 2-8°C until expiration date.

- **2nd Antibody Conjugate:**

One bottle, 12 ml, containing anti-human IgG antibodies labeled with peroxidase, in a phosphate buffer solution with 0.02% Proclin™. Store at 2-8°C until expiration date.

- **TMB-Substrate:**

One bottle, 12 ml, containing tetramethylbenzidine (TMB) and hydrogen peroxide stabilized in citrate buffer, pH 3.8. Store at 2-8°C until expiration date.

- **Stopping Solution:**

One bottle, 15 ml, containing 0.3 M H_2SO_4 in solution. Store at 2-8°C until expiration date.

PRECAUTIONS

For *in vitro* use

The following universal Good Laboratory Practices should be observed:

Do not eat, drink, smoke or apply cosmetics where immunodiagnostic material is being handled. Do not pipet by mouth. Wear lab coats and disposable gloves when handling immunodiagnostic material. Wash hands thoroughly afterwards. Cover working area with disposable absorbent paper. Wipe up spills immediately and decontaminate affected surfaces. Avoid generation of aerosols. Provide adequate ventilation. Handle and dispose all reagents and material in compliance with applicable regulations.

WARNING: POTENTIAL BIOHAZARDOUS MATERIAL

This kit may contain some reagents made with human and animal sources material (e.g. serum, plasma or bovine albumin) or used in conjunction with human and animal source material. Human sera obtained from blood donors used in this kit have been tested by CE recommended methods and found to be non-reactive for HIV-1/2 Antibodies, HCV and HbsAg; the material of animal source is also free from infection. No available test method can offer complete assurance of eliminating potential biohazardous risk. Handle all reagents and patient samples at a Biosafety Level 2, as recommended for any potentially infectious human material in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories," 4th Edition, April 1999.

WARNING AND PRECAUTION:

Some of the reagents in this kit contain sodium azide as a preservative at concentrations below the regulatory limit of < 0.1%. Although significantly diluted, concentrated sodium azide is an irritant to skin and mucous membranes and may react with lead and copper plumbing to form explosive metal azides, especially if accumulated. Additionally, TMB and Sulfuric Acid, in concentrated amounts are also irritants to skin and mucous membranes. These substances are in diluted form and therefore may minimize exposure risks significantly but not completely. Provide adequate ventilation. Avoid contact with skin, eyes and clothing. In case of contact with any of these reagents, wash thoroughly with water and seek medical advice. Dispose all nonhazardous reagents by flushing with large volumes of water to prevent buildup of chemical hazards in the plumbing system.

For further information regarding hazardous substances in the kit, please refer to the component specific MSDS by request.

SPECIMEN COLLECTION AND HANDLING

Serum should be used, and the usual precautions for venepuncture should be observed. Specimens may be stored at 2-8°C for 2 days. For longer periods, store at –20°C. Do not use haemolyzed or lipemic specimens. Avoid repeated freezing and thawing of samples.

ASSAY PREPARATION

A thorough understanding of this package insert is necessary for successful use of the product. Reliable results will only be obtained by using precise laboratory techniques and accurately following the package insert. Bring all kit reagents and specimens to room temperature (~25°C) before use. Thoroughly mix the reagents and samples before use by gentle inversion. Do not mix various lots of any kit component within an individual assay. Do not use any component beyond the expiration date shown on its label. Incomplete washing will adversely affect the outcome and assay precision. To minimize potential assay drift due to variation in the substrate incubation time, care

should be taken to add the stopping solution into the wells in the same order and speed to add the TMB Chromogen Solution. Avoid microbial contamination of reagents, especially of the conjugate, wash buffer and diluent. Avoid contamination of the TMB Chromogen Solution with the Conjugate. Use a clean disposable pipette tip for each reagent. Avoid pipettes with metal parts. Containers and semi-automatic pipette tips used for the Conjugate and TMB can be reused provided they are thoroughly rinsed with deionized/distilled water and dried prior to and after each usage. The enzyme used as the label is inactivated by oxygen, and is highly sensitive to microbial contamination, sodium azide, hypochlorous acid and aromatic chlorohydrocarbons often found in laboratory water supplies. Use high quality water. Avoid exposure of the reagents to excessive heat or sunlight during storage and incubation.

REAGENT PREPARATION

- **Wash Solution:**
  Dilute 1:10 with deionized/distilled water prior to use. If crystals are present, they should be dissolved at 37°C before dilution. Pour 100 ml of the Wash Concentrate into a clean container and dilute by adding 900 ml of deionized/distilled water. Mix thoroughly by inversion. The wash solution is stable for 5 days at room temperature and 2 weeks at 2-8°C when stored in a tightly sealed bottle.
- **Microtitration Strips:**
  Select the number of coated strips required for the assay. The remaining unused wells should be placed in the resealable pouch with a desiccant pack. The pouch must be resealed to protect from moisture.

TEST PROCEDURE

All specimens and reagents to reach room temperature (~25°C) before use. Serum Samples and Ready-to-use-Calibrators should be assayed in duplicate. Cut-Off Serum (Calibrator 1) should be assayed in triplicate.

1. Mark the microtitration strips to be used.
2. Dilute serum samples 1:101 distributing 10 µl of serum into 1 ml of Sample Diluent.
3. Pipette 100 µl of each diluted serum sample Calibrators to the appropriate wells.
4. Incubate for 45 minutes at 37°C.
5. Aspirate and wash each well four (4) times for 30 seconds with Washing Solution using an automatic microplate washer or manually using a dispenser. Blot and dry by inverting plate on absorbent material.

NOTE: *Use of an automatic microplate washer is strongly recommended. Incomplete washing will adversely affect assay precision. If a microplate washer is not available, (a) completely aspirate the liquid from each well, (b) dispense 0.35 ml of the Wash Solution into each well. (c) repeat step (a) and (b) four times.*

6. Add 100 µl of Enzyme-Labeled 2nd Antibody into each well.
7. Incubate for 45 minutes at 37°C.
8. Aspirate and wash each well four times for 30 seconds with Washing Solution using an automatic microplate washer or manually using a dispenser. Blot and dry by inverting plate on absorbent material.
9. Add 100 µl of TMB Chromogen Solution to each well using a dispenser.
10. Incubate for 15 minutes at room temperature. Avoid exposure to direct sunlight.
11. Add 100 µl of Stopping Solution to each well using a dispenser.
12. Read the absorbance of the solution in the wells within 30 minutes, using a microplate reader set to 450 nm. If wavelength correction is available, set the instrument to dual wavelength measurement at 450 nm with background wavelength correction set at 600 or 620 nm.

CALCULATION OF RESULTS

Calculate the mean absorbance for each calibrator and unknown.

Qualitative results:

The Cut-off control corresponds to Calibrator 1.
If the absorbance of the sample is higher than that of the Cut-Off, the sample is positive for the presence of specific IgG.
Calculate the ratio between the average OD value of the sample and that of the Cut-Off. The sample is considered:

Positive: if the ratio is > 1.1.
Doubtful: if +/- 10% of the Cut-Off.
Negative: if the ratio is < 0.9.

If the result is doubtful, repeat the test. If it remains doubtful, collect a new serum sample.

Semi-Quantitative results:

The anti-*Rubella virus* IgG concentration of each sample can be expressed in International Units/ml (IU/mL) according to PEI, Germany. The International Unit values for the calibrators are printed on the labels of the vials.

A graph can be constructed by plotting the IU/mL against the average OD of the controls; when the OD of the sample is reported on the graph, the IU/mL contained in the serum sample can be calculated. A standard curve must be performed for each run.

Positive/Negative results can be expressed in IU as follows:

Positive: sample concentration > 11 IU/mL

Negative: sample concentration < 9 IU/mL

Equivocal: sample concentration ranges between 9 and 11 IU/mL.

LIMITATIONS OF THE PROCEDURE

- A serum sample obtained during the acute phase of infection, when only IgM antibodies are present, may be negative by this procedure.
- The test result should be used in conjunction with information available from the evaluation of other clinical and diagnostic procedures.
- Avoid repeated freezing and thawing of reagents and specimens.
- Grossly haemolyzed, icteric or lipemic specimens should be avoided.
- Heat inactivated sera should be avoided.
- Serological data of immunocompromised patients and new-born children have restricted value.

QUALITY CONTROL

The OD values of Calibrator 1 must be at least 0.2. Calibrator 4 must have an OD at least 3 times that of Calibrator 1.

PERFORMANCE CHARACTERISTICS

1. Sensitivity and Specificity

150 well selected human sera, collected from a clinical laboratory in Frankfurt/Germany, were analysed by this Rubella IgG Elisa and a reference Elisa method. Out of 150 samples, 103 were positive for the presence of IgG antibodies to Rubella virus by Monocent, Inc.'s ELISA Test System, and reference method also showed 103 of them as positive. The Monocent, Inc.'s Rubella IgG ELISA Test System has 100% sensitivity and 100% specificity. An analytical comparison between two assays showed R^2=0.86 which is acceptable considered a serological assay. The results are briefly summarized below (see Tab. 1).

Assay Comparison	Monocent		
TEST A	Positive	Negative	Brd Line
Positive	103	0	0
Negative	0	47	0
Brd Line	0	0	0

2. Precision

1. Inter-assay Study			
No of Replicates 32	Serum 1	Serum 2	Serum 3
Mean	0.03	0.6	0.98
SD	0.003	0.01	0.02
CV%	**9.9**	**2.1**	**2.1**

2. Intra-assay study			
No of Replicates 80	Serum 1	Serum 2	Serum 3
Mean	0.038	0.44	1.19
SD	0.004	0.02	0.037
CV%	**11.2**	**5.3**	**3.1**

3. Interferences Study

Interferences with lipemic, hemolytic or icteric sera are not observed up to a concentration of 5 mg/ml hemoglobin, 5 mg/ml triglycerides and 0.2 mg/ml bilirubin.

4. Analytical Sensitivity

The Monocent, Inc.'s Rubella IgG ELISA Test System has an analytical sensitivity up to 2.3 Units/mL.

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