Digitally signed by Dolgopol Iulian
Date: 2026.06.11 09:24:05 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

CERTIFICATE

bioeksen

BİOEKSEN AR GE TEKNOLOJİLERİ ANONİM ŞİRKETİ

HQ: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34475 Sarıyer - İstanbul - Türkiye
Production: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/10, 34475 Sarıyer - İstanbul - Türkiye
R&D / Project: Maslak Mh. Büyükdere Cad. Noramin İş Merkezi No: 237/1, Maslak Sarıyer - İstanbul - Türkiye

Design, Production, Storage, Distribution, Installation and Technical Services of Molecular Based Analysis Kits and Devices

with a scope of

ISO 9001:2015

Has established a quality management system in accordance with international standard.

" Following elements of the standard are excluded "
"None"

Certificate No	: M 11839
Initial Certification Date	: 25 October 2019
Certification Date	: 10 October 2025
Expiration Date	: 09 October 2028

General Manager

Kiwa Belgelendirme Hizmetleri A.Ş.
ITOSB 9. Cadde No. 15 Tepeören Tuzla
Istanbul / Turkey

Tel: + 90 216 593 25 75
Faks: + 90 216 593 25 74
info@kiwa.com.tr
www.kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

TÜRKAK BDS NO YS-73A6-62EC

Last Modified : 10 October 2025 - R 01

CERTIFICATE

kiwa

bioeksen

BİOEKSEN AR GE TEKNOLOJİLERİ ANONİM ŞİRKETİ

HQ: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34475 Sarıyer - İstanbul - Türkiye
Production: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/10, 34475 Sarıyer - İstanbul - Türkiye
R&D / Project: Maslak Mh. Büyükdere Cad. Noramin İş Merkezi No: 237/1, Maslak Sarıyer - İstanbul - Türkiye

Design, Production, Storage, Distribution, Installation and Technical Services of Molecular Based Analysis Kits and Devices

with a scope of

EN ISO 13485:2016

Has established a management system in accordance
with international Medical Devices Quality Management System Standard

"Following elements of the standard are excluded"
"7.5.5" "7.5.7" " 7.5.9.2"

Certificate No	: M 11840
Initial Certification Date	: 25 October 2019
Certification Date	: 10 October 2025
Expiration Date	: 09 October 2028

General Manager

Kiwa Belgelendirme Hizmetleri A.Ş.
ITOSB 9. Cadde No. 15 Tepeören Tuzla
Istanbul / Turkey

Tel: + 90 216 593 25 75
Faks: + 90 216 593 25 74
info@kiwa.com.tr
www.kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

TÜRKAK
Medikal Cihazlar
TS EN ISO 13485: 2016+1
AB-0006-YS

TÜRKAK BDS NO
YS-4D64-4027

Last Modified : 10 October 2025 - R 01

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

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® 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
Mersis No: 0176 0932 8530 0001
info@bioeksen.com.tr - www.bioeksen.com.tr

Authorized Person: Canan Zöhre Ketre Kolukırık

Chairman of the Board

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® Carbapenem Resistance qPCR Kit
Description	: Bio-Speedy® Carbapenem Resistance qPCR Kit
	Ref No: BS-AR-CR-25
	Ref No: BS-AR-CR-100
Classification	: Other (Neither listed in the Annex II, Nor Self-testing device), GMDN code: 60673 - Multiple antimicrobial resistance 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
Mersis No: 0176 0932 8530 0001
info@bioeksen.com.tr - www.bioeksen.com.tr

Authorized Person: Canan Zöhre Ketre Kolukırık

Chairman of the Board

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

EU DECLARATION OF CONFORMITY

EU DECLARATION OF CONFORMITY

Pursuant to REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

Manufacturer	Bioeksen AR GE Teknolojileri A.Ş.
Manufacturer 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-mail:** info@bioeksen.com.tr
Manufacturer Individual Identification Number	TR-MF-000032826
Notified Body Name	N/A
Notified Body Address	N/A
Notified Body Identification Number	N/A
Conformity Assessment Route	EU Declaration of Conformity, under the responsibility of the manufacturer, according to ANNEX IV (Annex II and Annex III) of (EU) 2017/746 In Vitro Diagnostic Medical Device Regulation
Certificate Number	N/A
Product(s) Name	Bio-Speedy® Rapid Nucleic Acid Extraction Kit
Product Catalog Number(s)	ZFNAE01
Basic UDI-DI	868187745NAEXRK02NE
Intended Purpose	The Bio-Speedy® Rapid Nucleic Acid Extraction Kit is an in vitro diagnostic medical device intended for the extraction and purification of total nucleic acids (DNA and RNA) from clinical specimens. These include whole blood, positive blood culture, serum, plasma, urine, stool, rectal swab, nasopharyngeal swab, oropharyngeal swab, combined nasopharyngeal and oropharyngeal swab, nasopharyngeal aspirate (NPA), throat swab, oral/saliva swab, saliva, gargle, sputum, bronchoalveolar lavage (BAL), cerebrospinal fluid (CSF), bone tissue, synovial fluid, peri-prosthetic fluid, skin lesion swab, skin lesion crust, skin lesion fluid, vaginal swab, cervical swab, endocervical swab, penile swab, urethral swab, and urogenital swab. The kit utilizes magnetic bead-based purification technology and is suitable for use with robotic nucleic acid isolation systems operated in clinical laboratory environments. The extracted nucleic acids are of sufficient quality for direct use in downstream Real-Time PCR (qPCR)-based diagnostic applications.
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 a of (EU) 2017/746 In Vitro Diagnostic Medical Device Regulation
GMDN Code	52521- Nucleic acid extraction/isolation kit IVD
EMDN Code	W02060199 - ROBOTIC SAMPLE PROCESSING SYSTEMS - OTHER

EU DECLARATION OF CONFORMITY

Bioeksen AR GE Teknolojileri A.Ş. hereby declares that the above mentioned device complies with the general safety and performance requirements of Annex I of Regulation (EU) 2017/746 of the European Parliament and of the Council and under normal use it is safe and effective for its intended purpose. Bioeksen AR GE Teknolojileri A.Ş. has taken measures assuring compliance of all *in vitro* medical devices introduced into the market with their technical documentation and with the general safety and performance requirements.

EU declaration of conformity is issued under sole responsibility of Bioeksen AR GE Teknolojileri A.Ş.

Authorized Person:	Canan Zöhre Ketre	**Date of Issue:**	13-08-2025
Position:	Chair of the Board	**Place of Issue:**	İstanbul

On behalf of Bioeksen AR GE Teknolojileri A.Ş.

Seal/Signature:

BİOEKSEN AR GE TEKNOLOJİLERİ A.Ş.
Huzur Mah. Metin Oktay Cad. Rüzgar Ltd. Blok
No: 3/31 Sarıyer/İSTANBUL
Mastak V.D. 176 093 [illegible] Ticaret No: 904277-0
Mersis No: 0176 0932 8530 0001
info@bioeksen.com.tr - www.bioeksen.com.tr

EU DECLARATION OF CONFORMITY

ATTACHMENT
List of Applied Regulations and Standards

	Title	Content	Scope	Excluded Items
QMS	ISO 9001:2015	Quality management systems — Requirements	Covered	-
Harmonised Standard [(EU) 2017/746] 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 [(EU) 2017/746] 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	-
Harmonised Standard (98/79/EC) 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	-
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	-
Labelling	EN ISO 18113-2:2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use	Covered	-
Harmonised Standard [(EU) 2017/746] 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	-
Stability	CLSI EP25-A	Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline, CLSI, Wayne, PA, 2009	Covered	-
Documentation	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)

EU DECLARATION OF CONFORMITY

EU DECLARATION OF CONFORMITY

Pursuant to REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

Manufacturer	Bioeksen AR GE Teknolojileri A.Ş.
Manufacturer 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-mail:** info@bioeksen.com.tr
Manufacturer Individual Identification Number	TR-MF-000032826
Notified Body Name	N/A
Notified Body Address	N/A
Notified Body Identification Number	N/A
Conformity Assessment Route	EU Declaration of Conformity, under the responsibility of the manufacturer, according to ANNEX IV (Annex II and Annex III) of (EU) 2017/746 In Vitro Diagnostic Medical Device Regulation
Certificate Number	N/A
Product(s) Name	**νNAT®** Transfer Tube
Product Catalog Number(s)	BS-NA-513m-100
Basic UDI-DI	868187745NAEXT0672
Intended Purpose	The **νNAT®** Transfer Tube is a single-use *in vitro* diagnostic (IVD) medical device designed for the storage and stabilization of nucleic acids from nasopharyngeal, oropharyngeal, throat, rectal, vaginal, cervical, urethral, urogenital, endocervical, penile, and conjunctival swab samples. Each tube contains 2 mL of **νNAT®** reagent, which efficiently lyses cells, releases nucleic acids, and preserves them for downstream molecular diagnostic applications. The reagent also rapidly inactivates pathogens within 1 minute, reducing the risk of transmission and ensuring biosafety. Clinical specimens can be directly transferred into the **νNAT®** Transfer Tube, where nucleic acids remain stabilized for molecular testing. The preserved sample is compatible with Real-Time PCR (qPCR) assays without the need for separate nucleic acid extraction, enabling rapid and efficient molecular diagnostics. The **νNAT®** Transfer Tube is intended for professional use in sampling and sample storage environments of the healthcare providers.
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 (EU) 2017/746 In Vitro Diagnostic Medical Device Regulation
GMDN Code	63232 - General specimen container IVD, additive/medium
EMDN Code	W050301020101 - Samples Analyses, Plastic Tubes with Additives

EU DECLARATION OF CONFORMITY

Bioeksen AR GE Teknolojileri A.Ş. hereby declares that the above mentioned device complies with the general safety and performance requirements of Annex I of Regulation (EU) 2017/746 of the European Parliament and of the Council and under normal use it is safe and effective for its intended purpose. Bioeksen AR GE Teknolojileri A.Ş. has taken measures assuring compliance of all *in vitro* medical devices introduced into the market with their technical documentation and with the general safety and performance requirements.

EU declaration of conformity is issued under sole responsibility of Bioeksen AR GE Teknolojileri A.Ş.

Authorized Person:	Canan Zöhre Ketre	**Date of Issue:**	14-03-2025
Position:	Chair of the Board	**Place of Issue:**	İstanbul

On behalf of Bioeksen AR GE Teknolojileri A.Ş.

Seal/Signature:

EU DECLARATION OF CONFORMITY

ATTACHMENT
List of Applied Regulations and Standards

	Title	Content	Scope	Excluded Items
QMS	ISO 9001:2015	Quality management systems — Requirements	Covered	-
Harmonised Standard [(EU) 2017/746] 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 [(EU) 2017/746] 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	-
Harmonised Standard (98/79/EC) 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	-
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	-
Labelling	EN ISO 18113-2:2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use	Covered	-
Harmonised Standard [(EU) 2017/746] 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	-
Stability	CLSI EP25-A	Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline, CLSI, Wayne, PA, 2009	Covered	-
Documentation	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)

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® Respiratory Tract Virus RT-qPCR Panel
Description	: Bio-Speedy® Respiratory Tract Virus RT-qPCR Panel Ref No: BS-RTV-S-25 Ref No: BS-RTV-S-100 Ref No: BS-RTV-T-25 Ref No: BS-RTV-T-100 Ref No: BS-RTV-L-25 Ref No: BS-RTV-L-100
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.

BİOEKSEN AR GE TEKNOLOJİLERİ A.Ş.
Huzur Mah. Metin Oktay Cad. Nurol Life D Blok
No: 3/31 Sarıyer/İSTANBUL
Maslak V.D. 476 098 2650 Tic. Sicil No: 904277-0
Mersis No: 0176 0932 8530 0001
info@bioeksen.com.tr - www.bioeksen.com.tr

Place of Issue: İstanbul

Signature:

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 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® Respiratory ID-1 Kit
Description	: Bio-Speedy® Respiratory ID-1 Kit
	Ref No: BS-RIDK-1-25
	Ref No: BS-RIDK-1-100
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
	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 [illegible] Sicil No: 904277-0
Mersis No: 0176 0932 8530 0001
info@bioeksen.com.tr - www.bioeksen.com.tr

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-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 PCR Mix	Optimized ready-to-use mix for qPCR assay	1 x 500 µL	2 x 1000 µL
Bor 1 Oligo Mix	Specific nucleic acid amplification and detection: **FAM**: *IS481* gene **HEX:** Human (IC-Internal Control)	1 x 125 µL	1 x 500 µL
Bor 2 Oligo Mix	**FAM:** h*IS1001* gene **ROX:** *IS1001* gene **CY5:** *ptxP* gene	1 x 125 µL	1 x 500 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. Transport Condition, Storage Condition, and Shelf Life of the Components

Component	Transport Condition*	Storage Condition**	Shelf Life
2X PCR Mix	(-22) °C – (+8) °C	(-22) °C – (-18) °C	12 Months
Oligo Mix		(-22) °C – (-18) °C	
NTC		(-22) °C – (-18) °C before opening, (+2) °C – (+8) °C after first thaw	
PC		(-22) °C – (-18) °C before opening, (+2) °C – (+8) °C after first thaw	

* The kit was recommended to be shipped within 6 days at (-22) °C to (+8) °C and stored at (-22) °C to (-18) °C and used for 1 year.
**Following the first opening, each reagent stored at storage temperature can be used until the expiration date indicated on the tube. The kit's expiration date is determined by the expiration date of the reagents.

Table 3. Required Components Not Included in the Package

Required Components Not Included in the Package
1. Real-Time PCR Instrument
2. ***v*NAT® Transfer Tube** (Cat. No: BS-NA-513m-100) or nucleic acid preparation instruments and nucleic acid preparation consumables
3. Micropipettes and compatible filtered pipette tips (nuclease-free) suitable for transferring 1-10 µL, 10-100 µL, and 100-1000 µL of liquid
4. A centrifuge or Mini-spin
5. Vortex
6. Reaction tubes,PCR strips, PCR plates 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(s)	**Table 1**	**Nucleic Acid Extraction Method(s)**	***v*NAT® Transfer Tube** Zybio EXM3000 Nucleic Acid Isolation System Adaltis EXTRAlab and MDXlab
Qualitative/Quantitative	Qualitative	**Validated qPCR Instrument(s)**	Bio Molecular Systems: Magnetic Induction Cycler (Mic) / Mic IVD Bio-Rad: CFX96 Touch, CFX Opus 96, CFX96 Dx Qiagen: Rotor-Gene Q Roche: LightCycler 96 Applied Biosystems - Thermo Fisher Scientific: QuantStudio 5/5 Dx Adaltis: AmpliLab, MDXlab HiMedia: InstaQ 96
Test Principle	Real-Time PCR (qPCR)	**Inclusivity and Exclusivity**	Validated on the reference strains and the field isolates
Automated/Manual	Manual		
Intended Users	Laboratory professionals trained in the techniques of qPCR and in vitro diagnostic procedures	**Limit of Detection (LoD)**	**Table 5**
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	98.8% and 100.00%

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

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-100)	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 (-20) °C	**Nucleic acid preparation instruments:** 1) Zybio EXM3000, 2) Adaltis EXTRAlab, 3) Adaltis MDXlab **Nucleic acid preparation consumables:** Bio-Speedy® Rapid Nucleic Acid Extraction Kit (Cat. No: ZFNAE01)	125
Bronchoalveolar lavage, nasopharyngeal aspirate, and sputum	Preservative-free sterile containers	3 days at (+2) °C – (+8) °C 1 year at (-20) °C		500

*** Clinical specimens should be collected by a healthcare provider in accordance with national/international clinical specimen collection regulations.
**** If dry swab samples are received, put them into the ***v*NAT® Transfer Tube** for nucleic acid isolation.

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

1. APPLICATION PROTOCOL

1. Program the qPCR device using the QR Code/Link as indicated in **Table 6**.
2. Take the PCR kit out of the -20°C freezer.
3. Pipette (Sample Count + 3) *5 µL of Bor Oligo Mix 1 into an empty eppendorf tube. (i.e Sample Count = 3, pipette 5*(3+3) = 30 µL of Bor Oligo Mix 1)
4. Add (Sample Count + 3) *10 µL of 2X PCR Mix into the tube prepared in Step 3. (i.e Sample Count = 3, pipette 10*(3+3) = 60 µL of 2X PCR Mix)
5. Vortex the master mix to homogenize.
6. Repeat steps 3,4 and 5 for all master mixes. (Total 2 master mixes).
7. Pipette 15 µL of master mix into all PCR tubes, or wells to be used (including all samples, NTC and PC).
8. Pipette 5 µL of each isolated/ extracted sample into the relative PCR tube, or well.
9. Pipette 5 µL of NTC into the Negative Control PCR tube, or well.
10. Pipette 5 µL of PC-Bor 1 into the Positive Control tubes, or wells. Repeat for all PC.
11. Close the cap of the strips, or PCR tubes or seal PCR plate. Label to avoid confusion during spin -centrifuge.
12. Spin-centrifuge the strips, or PCR tubes or PCR plate.
13. Open the lid of the instrument. Place the strips, or PCR tubes or PCR plate.
14. Close the lid and start the instrument.

Table 6. Real Time qPCR Program Details

<table>
<tr><th colspan="2" rowspan="2">Reaction Setup</th><th colspan="7">RT-qPCR Program</th></tr>
<tr><th colspan="4">Protocol 1:

Bio Molecular Systems: Magnetic Induction Cycler (Mic) / Mic IVD, Bio-Rad: CFX96 Touch, CFX Opus 96, CFX96 Dx, Roche: LightCycler 96</th><th colspan="3">Protocol 2:

Qiagen: Rotor-Gene Q, Applied Biosystem - Thermo Fisher Scientific: QuantStudio 5/5 Dx, Adaltis: AmpliLab, MDXlab, HiMedia: InstaQ 96</th></tr>
<tr><th>Reagent</th><th>Volume/ Rxn</th><th>Step</th><th>Cycle No.</th><th>Temperature</th><th>Duration</th><th>Step</th><th>Cycle No.</th><th>Temperature</th><th>Duration</th></tr>
<tr><td>2X PCR Mix</td><td>10 µL</td><td>Enzyme Activation</td><td>1 Cycle</td><td>52 °C</td><td>3 min</td><td>Enzyme Activation</td><td>1 Cycle</td><td>52 °C</td><td>3 min</td></tr>
<tr><td rowspan="2"></td><td rowspan="2"></td><td>Pre-Incubation</td><td>1 Cycle</td><td>95 °C</td><td>10 sec</td><td>Pre-Incubation</td><td>1 Cycle</td><td>95 °C</td><td>10 sec</td></tr>
<tr><td>Denaturation</td><td rowspan="2">12 Touchdown Cycles:
1 °C decrement in annealing temperature per cycle</td><td>95 °C</td><td>1 sec</td><td>Denaturation</td><td rowspan="3">40 Cycles</td><td rowspan="2">95 °C</td><td rowspan="2">1 sec</td></tr>
<tr><td>Oligo Mix</td><td>5 µL</td><td>Annealing and Extension</td><td>67 °C to 56 °C</td><td>15 sec</td><td>Annealing and Extension</td></tr>
<tr><td>Template Nucleic Acid/NTC/PC</td><td>5 µL</td><td>Denaturation</td><td rowspan="3">30 Cycles</td><td>95 °C</td><td>1 sec</td><td rowspan="3">Detection (Reading)</td><td>55 °C</td><td>15 sec</td></tr>
<tr><td rowspan="2"></td><td rowspan="2"></td><td>Annealing and Extension</td><td>55 °C</td><td>15 sec</td><td colspan="2">(FAM -Green)/(HEX -Yellow)/ (ROX -Orange)/(CY5-Red)</td></tr>
<tr><td>Total Reaction Volume</td><td>20 µL</td><td>Detection (Reading)</td><td colspan="2">(FAM -Green)/(HEX -Yellow)/ (ROX -Orange)/(CY5-Red)</td></tr>
</table>

WARNING: The qPCR program file should be downloaded from the QR code on the left or from the link below.

https://www.bioeksen.com.tr/files/L_TD_43B

2. INTERPRETATION OF THE ASSAY RESULTS

- Once the run is complete, the instruments' software automatically calculates the threshold based on the background, and assigns a Cq value for the amplification curves over the threshold.
- Record all curves, including sigmoidal ones, under the threshold as negative for amplification. When the fluorescence level is too low (under the threshold RFU), the shape of the curves can be misleading.
- Record all non-sigmoidal curves above the threshold as negative for amplification.
- Record all sigmoidal curves over the threshold as positive for amplification, even if the amplification is weak, with a high Cq value and low RFU.
- **Negative Amplification of Analyte**:
  - The "**Positive Control**" must be **positive** for a **valid** negative result for the analyte.
  - If the "**Positive Control**" amplification is **negative**, the test is **invalid** due to the reactive stability problem. Contact the manufacturer for further assistance.
  - The "**Internal Control**" must be **positive** for a **valid** negative result for the analyte.
  - If the "**Internal Control**" amplification is **negative**, the test is **invalid** due to either sampling or inhibition problem. The sample must be retested. If the problem persists, a new sample from the same patient should be collected and tested again.
- **Positive Amplification of Analyte**:
  - The **negative control template** must be **negative** for the analyte for a **valid** positive result.

Contamination: If the analyte amplification is positive and the negative control template is positive for the analyte, the test is invalid for the analyte. Repeat the analysis, paying attention to the "Warnings and Limitations" section.

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

Table 7. Threshold Levels for Calculating Cq Values

Analyte	Real Time PCR Instrument									
	Bio-Rad CFX		LightCycler 96		Mic/Mic IVD		Rotor-Gene Q*****		QuantStudio 5/5 Dx	
	RFU	Cq Cut-off	RFU	Cq Cut-off	RFU	Cq Cut-off	RFU	Cq Cut-off	RFU	Cq Cut-off
***IS481* gene**	200	30	0.05	30	0.2	30	0.02	40	20000	30
Human (IC-Internal Control)	200	30	0.05	30	0.2	30	0.02	40	20000	30
***hIS1001* gene**	200	30	0.05	30	0.2	30	0.02	40	20000	30
***IS1001* gene**	200	30	0.05	30	0.2	30	0.02	40	20000	30
***ptxP* gene**	200	30	0.05	30	0.2	30	0.02	40	20000	30

***** Defined threshold with specific settings of "Outlier Removal = 0", "Dynamic Tube = On", and "Slope Correct = Off"

Table 8. Interpretation of Patient Results

Target	Internal Control (IC)	Result Interpretation		
Positive (+)	**Positive (+)** or **Negative (-)**	Results are valid Target is detected	**Protocol 1**	If 26<Cq ≤30 "Low Positive" If 16<Cq≤26 "Positive" If Cq≤16 "High Positive"
			Protocol 2	If 34<Cq ≤40 "Low Positive" If 22<Cq≤34 "Positive" If Cq≤22 "High Positive"
Negative (-)	**Positive (+)**	Results are valid Target is not detected		
Target	**Results Interpretation**	**Action**		
Bordetella pertussis	*IS481* and *ptxP* should be positive	Report as *Bordetella pertussis* **POSITIVE**		
Bordetella parapertussis	*IS1001* should be positive	Report as *Bordetella parapertussis* **POSITIVE**		
Bordetella holmesii	*IS481* and h*IS1001* should be positive	Report as *Bordetella pholmesi* **POSITIVE**		
Bordetella branchiseptica	*IS1001* and *IS481* should be positive******	Report *as Bordetella bronchiseptica* **POSITIVE**		

******Cq values should be examined. If the condition for the Cq values "IS481<IS1001" is met, the result should be reported as Bordetella bronchiseptica. Otherwise, it should be reported as Bordetella parapertussis.

Table 9. Expected Performance of Kit Controls

Control Type	Purpose	Expected Results and Cq Values			
		Protocol 1		Protocol 2	
		IC (HEX)	Target	IC (HEX)	Target
Negative Control	Contamination control during qPCR	**Not Detected**	**Not Detected**	**Not Detected**	**Not Detected**
Positive Control	Reagent stability control	**Detected** (Cq≤30)	**Detected** (Cq≤30)	**Detected** (Cq≤40)	**Detected** (Cq≤40)
Internal Control	Nucleic acid extraction and sampling control	**Detected**	Detection insignificant	**Detected**	Detection insignificant
		If "**Not Detected**" check the target Cq	If "**Detected"** IC is valid	If "**Not Detected**" check the target Cq	If "**Detected"** IC is valid

If a control does not work as expected (**Table 9**), apply the procedures described below.

1. **Contamination Problem:** If a target in the Negative Control reaction is "**Detected**".
   Recommended action: Repeat the run, paying attention to the "Warnings and Limitations" section.

2. **Invalid Internal Control Problem:** If the Internal Control (IC) and all other targets of a sample are "**Not Detected**".
   Recommended action: Sampling was not successfully done, or there was a problem during the sample transportation or extraction. Re-test the sample. If the problem repeats, a new sample from the same patient should be collected and tested again.

3. **Reagent Problem**: If all Internal Controls, Positive Controls and targets in the run are "**Not Detected**".
   Recommended action: The run is considered invalid. Re-test the PC. If the problem repeats, please reach out to the manufacturer for further assistance.

3. WARNINGS AND LIMITATIONS

1. False-negative results may occur if inadequate number (below 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 swabs with wooden sticks, cotton or calcium alginate swabs can lead to false negative results since they may contain substances that inactivate some pathogens and inhibit PCR.
4. False-negative results 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 national/international specimen collection guidelines.
6. Test procedures should be performed by personnel trained in the use of the kit.
7. Sample tubes should always be kept closed except for liquid transfers.
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. Waste disposal must be carried out in accordance with local, state, and federal regulations. These reagents and their container must be disposed of safely. The requirements of environmental protection and waste disposal legislation, as well as regional local authority requirements, must always be adhered to. If possible, it should be recycled. The reagents must not enter water pipes, sewers, or soil.
13. Proper personal protective equipment including lab coats, gowns, gloves, eye protection, and a biological safety cabinet are recommended for manipulation of clinical specimens.
14. 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.
15. The micropipettes used for pipetting PCR mixes and template nucleic acids should be separate. Filtered and nuclease-free pipette tips should be used.
16. Maintenance/ calibration interval should be determined for all instruments and equipment used with the kit.
17. For optimal signal accuracy and instrument performance, white strips must be used with top-reading systems.

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

Precaution Related REACH Regulation (EC 1907/2006)

This statement applies only to countries within the European Union (EU) regarding the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC 1907/2006). It is recommended that all material associated with the test, including materials used to clean up spills, contaminated packaging, and unused or expired IVD tests, be incinerated. Please ensure that you follow local regulations regarding disposal.

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	Catalog number		Do not use if package is damaged and consult *Instructions for Use*
	Manufacturer	NON STERILE	Non-sterile		Keep dry
	Expiration Date YYYY-MM		Consult *Instructions for Use* or consult electronic *Instructions for Use*		Keep upright
	Temperature limit (Storage Temperature)		Caution	Σ	Contains sufficient for <*n*> tests
CONTROL +	Positive Control	CONTROL -	Negative Control	CONTROL	Control
	Fragile, handle with care				

This Package Insert (PIS) document has been prepared as a single-page leaflet in accordance with the current packaging size and printing techniques. It provides essential information for the safe and correct use of the product. A comprehensive and detailed most updated Instructions for Use (IFU), prepared in accordance with applicable regulatory requirements, is available upon request at ifu@bioeksen.com.tr.

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, 34475 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 promptly report any serious incidents to us (via vigilance@bioeksen.com.tr), distributor or the relevant competent authority in the respective Member State.

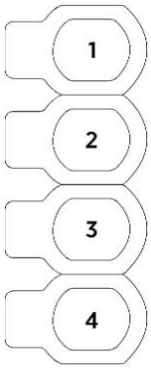
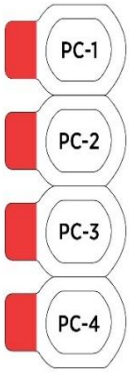
ALL RIGHTS RESERVED

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		Component	Intended Use		48 Reactions	96 Reactions
WNV Rxn* 	**1:**	Specific nucleic acid amplification and detection: **FAM:** West Nile Virus **HEX:** Human (IC-Internal Control)	**PC-WNV Rxn *** 	**1:**	**FAM:** West Nile Virus + **Template** **HEX:** Human (IC-Internal Control) + **Template**	12 Strips/48 WNV Rxn Tubes + 2 Strips/8 PC-WNV Rxn Tubes	24 Strips/96 WNV Rxn Tubes + 4 Strips/16 PC-WNV Rxn Tubes
	2:	**FAM:** West Nile Virus **HEX:** Human (IC-Internal Control)		**2:**	**FAM:** West Nile Virus + **Template** **HEX:** Human (IC-Internal Control) + **Template**		
	3:	**FAM:** West Nile Virus **HEX:** Human (IC-Internal Control)		**3:**	**FAM:** West Nile Virus + **Template** **HEX:** Human (IC-Internal Control) + **Template**		
	4:	**FAM:** West Nile Virus **HEX:** Human (IC-Internal Control)		**4:**	**FAM:** West Nile Virus + **Template** **HEX:** Human (IC-Internal Control) + **Template**		
Control Template	Nuclease-free Water (CT)					1 x 1250 µL	2 x 1250 µL

***1 WNV Rxn Strips equals to 4 reactions, (1=2=3=4) and 1 PC-WNV Rxn Strips equals to 4 PC reactions (PC-1 = PC-2 = PC-3 = PC-4). Cut the WNV Rxn and PC-WNV Rxn Strips into tubes according to the required reaction number.**

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

Component	Transport Condition**	Storage Condition***	Shelf Life
WNV Rxn Strips	(-22) °C – (+8) °C	(-22) °C – (-18) °C	12 months
PC-WNV Rxn Strips		(-22) °C – (-18) °C	
Control Template		(-22) °C – (-18) °C before opening, (+2) °C – (+8) °C after first thaw	

** The kit was recommended to be shipped within 6 days at (-22) °C to (+8) °C and stored at (-22) °C to (-18) °C and used for 1 year.
***Following the first opening, each reagent stored at storage temperature can be used until the expiration date indicated on the tube. The kit's expiration date is determined by the expiration date of the reagents.

Table 3. Required Components Not Included in the Package

Required Components Not Included in the Package
1. BMS Magnetic Induction Cycler (Mic)/Mic IVD Real-Time PCR instruments
2. Micropipettes and filtered pipette tips (nuclease-free) suitable for transferring 1-10 µL of liquid
3. Nucleic acid preparation instruments and nucleic acid preparation consumables
4. Vortex
5. vCAP rack (Catalog No: VCAP-R48)

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)**	Zybio EXM3000 Nucleic Acid Extraction System Adaltis EXTRAlab
Qualitative/Quantitative	Qualitative	**Validated PCR Instrument(s)**	Bio Molecular Systems (BMS) Magnetic Induction Cycler (Mic)/Mic IVD
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	Laboratory professionals trained in the techniques of qPCR and in vitro diagnostic procedures.	**Limit of Detection (LoD)**	**Table 5**
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	100.0% and 100.0%

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

Sample Type****	Sample Transfer	Sample Storage	Nucleic Acid Preparation Method	LoD (cp/mL)
Whole Blood	EDTA-treated blood tube	3 days at (+2) °C – (+8) °C 1 year at (-20) °C	**Nucleic acid preparation instruments:** 1) Zybio EXM3000, 2) Adaltis EXTRAlab **Nucleic acid preparation consumables:** Bio-Speedy® Rapid Nucleic Acid Extraction Kit (Cat. No: ZFNAE01)	250
Serum				
Plasma	Anti-coagulant free blood tube			

****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. APPLICATION PROTOCOL

1. Program the qPCR instrument using the QR code/ hyperlink as indicated in **Table 6.**
2. An Internal Control (IC) is included in each reaction and processed with every specimen to monitor amplification, detection, and, where applicable, nucleic acid extraction and PCR inhibition. A valid IC result is required for each sample. Failure of the IC may indicate inhibition, reagent failure, or instrument malfunction; in such cases, the sample result shall be considered invalid and testing should be repeated according to laboratory procedures.
3. Positive Control Usage: Positive Control (PC) is recommended to verify reagent integrity and assay performance and should be tested at least once per week during routine use, when no amplification is observed in any reaction within a run, with each new reagent lot or shipment, after instrument maintenance or service, and during training or troubleshooting. The PC must yield a positive result for the intended target(s).
4. A Negative Control (NC) is recommended to monitor contamination and should be tested at least once per day of testing or with each PCR run, with each new reagent lot or shipment, after instrument maintenance or service, and during training or troubleshooting. The NC must yield a negative result for all targets. If any control fails to produce the expected result, the associated run shall be considered invalid, the cause of failure should be investigated, and testing should be repeated according to laboratory procedures.
5. Place the "WMV Rxn Strips" into the vCAP rack immediately. If required by the positive control usage rule (i.e., at first use of a kit box or when troubleshooting), also place the "PC-WMV Rxn Strips."
6. Add **10 ul of Template Nucleic Acid (sample)** to the wall on the notched side of the vCAP tube in each well of the "WMV Rxn Strips". **(Figure 1)**
7. **Positive Control Test (at first use of a kit box or when troubleshooting):** Add **10 µL of "Control Template"** to the wall on the notched side of the vCAP tube in each well of the "PC-WMV Rxn Strips". **(Figure 1)**
8. **Negative Control Test:** In each run, add **10 µL of "Control Template"** to the wall on the notched side of the vCAP tube in each well of a new "WNV Rxn Strips". **(Figure 1)**
9. Open the lid and remove the magnetic tube clamp.
10. Place the strips starting from well number 1 of the rotor with the notch facing inward. Fill all remaining empty positions in the instrument with "**Balance Strips**".
11. Place the magnetic tube clamp, close the lid and start the instrument.

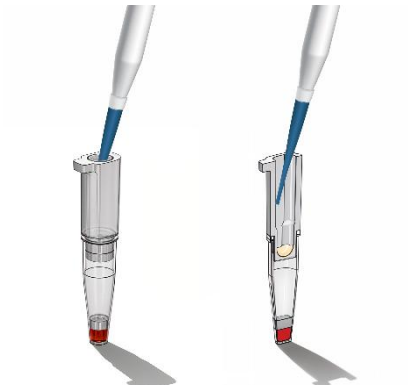


Figure 1: Representation of notched side of vCAP

Table 6. Reaction Set-up and Real-Time PCR Program

Step	Cycle No.	Temperature	Duration
Reverse Transcription	1 Cycle	52 °C	3 min
Pre-Incubation	1 Cycle	95 °C	10 sec
Denaturation	12 Touchdown Cycles:	95 °C	1 sec
Annealing and Extension	1 °C decrement in annealing temperature per cycle	67 °C – 56 °C	15 sec
Denaturation	30 Cycles	95 °C	1 sec
Annealing and Extension		55 °C	15 sec
Detection (Reading)		(**FAM** -Green)/(**HEX** -Yellow)	

WARNING: The RT-qPCR program file should be downloaded from the QR code on the left or from the link below.
https://bioeksen.com.tr/files/Protocols/vCAP_Format/index.html

2. INTERPRETATION OF THE ASSAY RESULTS

- Once the run is complete, the instruments' software automatically calculates the threshold based on the background, and assigns a Cq value for the amplification curves over the threshold.
- Record all curves, including sigmoidal ones, under the threshold as negative for amplification. When the fluorescence level is too low (under the threshold RFU), the shape of the curves can be misleading.
- Record all non-sigmoidal curves above the threshold as negative for amplification.
- Record all sigmoidal curves over the threshold as positive for amplification, even if the amplification is weak, with a high Cq value and low RFU.
- **Negative Amplification of Analyte**:
  - For a valid negative analyte result:
    - The Positive Control must be tested at the first use of each test kit box and when troubleshooting (as defined in the positive control usage rule).
    - In routine runs where a Positive Control is not included, the Internal Control of at least one sample in the same qPCR run acts as the positive control.
    - If all Internal Controls in a run are negative, the kit must be retested with a Positive Control to determine whether the issue is due to reagent stability or the samples.
    - If the required Positive Control (when used) is negative, the test is invalid due to a reagent stability problem. Contact the manufacturer for further assistance.
    - If a sample's Internal Control is negative, the result for that sample is invalid due to possible sampling or inhibition issues. The sample must be retested, and if the problem persists, a new sample from the same patient should be collected and tested.
- **Positive Amplification of Analyte**:
  - The **negative control template** must be **negative** for the analyte for a **valid** positive result.

Contamination: If the analyte amplification is positive and the negative control template is positive for the analyte, the test is invalid for the analyte. Repeat the analysis, paying attention to the "Warnings and Limitations" section.

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

Table 7. Threshold Levels for Calculating Cq Values

Analyte	RFU Threshold Level	Cq Cut-off
	Mic/Mic IVD	Mic/Mic IVD
West Nile Virus	0.2	30
Human (IC-Internal Control)	0.2	30

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**	

Table 9. 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**	**Not Detected**
Positive Control	Reagent stability control	**Detected** (Cq≤30)	**Detected** (Cq≤30)
Human (IC-Internal Control)	Nucleic acid extraction and sampling control	**Detected**	Detection insignificant
		If "**Not Detected**" check the target Cq	If "**Detected"** IC is valid

If a control does not work as expected (**Table 9**), apply the procedures described below.

1. **Contamination Problem:** If a target in the Negative Control reaction is "**Detected**".
   Recommended action: Repeat the run, paying attention to the "Warnings and Limitations" section.

2. **Invalid Internal Control Problem:** If the Internal Control (IC) and all other targets of a sample are "**Not Detected**".
   Recommended action: Sampling was not successfully done, or there was a problem during the sample transportation or extraction. Re-test the sample. If the problem repeats, a new sample from the same patient should be collected and tested again.

3. **Reagent Problem**: If all Internal Controls, Positive Controls and targets in the run are "**Not Detected**".
   Recommended action: The run is considered invalid. Re-test the PC. If the problem repeats, please reach out to the manufacturer for further assistance.

3. WARNINGS AND LIMITATIONS

1. False-negative results may occur if inadequate number (below 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. False-negative results 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 national/international specimen collection guidelines.
5. Test procedures should be performed by personnel trained in the use of the kit.
6. Sample tubes should always be kept closed except for liquid transfers.
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. Waste disposal must be carried out in accordance with local, state, and federal regulations. These reagents and their container must be disposed of safely. The requirements of environmental protection and waste disposal legislation, as well as regional local authority requirements, must always be adhered to. If possible, it should be recycled. The reagents must not enter water pipes, sewers, or soil.
12. Proper personal protective equipment including lab coats, gowns, gloves, eye protection, and a biological safety cabinet are recommended for manipulation of clinical specimens.
13. 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.
14. The micropipettes used for pipetting PCR mixes and template nucleic acids should be separate. Filtered and nuclease-free pipette tips should be used.
15. Maintenance/ calibration interval should be determined for all instruments and equipment used with the kit.
16. After removal from the storage conditions stated on the product label, the kit remains stable for no longer than 60 minutes at 25 °C under direct light. Load the strips into the instrument immediately. Do not use strips if more than 60 minutes have elapsed since removal.

4. PRECAUTION RELATED REACH REGULATION (EC 1907/2006)

This statement applies only to countries within the European Union (EU) regarding the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC 1907/2006). It is recommended that all material associated with the test, including materials used to clean up spills, contaminated packaging, and unused or expired IVD tests, be incinerated. Please ensure that you follow local regulations regarding disposal.

5. EXPLANATION OF SYMBOLS

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		Do not use if package is damaged and consult *Instructions for Use*
	Manufacturer	NON STERILE	Non-*sterile*		Keep dry

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

	Expiration Date YYYY-MM		Consult *Instructions for Use* or consult electronic *Instructions for Use*		Keep upright
	Temperature limit (Storage Temperature)		Caution		Contains sufficient for *<n>* tests
	Positive control		Negative control		Control
	Fragile, handle with care		Single use/Do not reuse		

 This Package Insert (PIS) contains all information required for the safe and correct use of the product. A more detailed Instructions for Use (IFU), providing supplementary information beyond the essential user instructions, is available upon request at ifu@bioeksen.com.tr.

6. MANUFACTURER AND TECHNICAL SUPPORT

Bioeksen AR GE Teknolojileri A.Ş
Address: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34475 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 promptly report any serious incidents to us (via vigilance@bioeksen.com.tr), distributor or the relevant competent authority in the respective Member State.

ALL RIGHTS RESERVED

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

Carbapenem Resistance qPCR Kit

Package Insert

Table 1. Kit Content

Component	Intended Use	25 Reactions	100 Reactions
2X PCR Mix	Optimized ready-to-use mix for qPCR assay	1 x 500 µL	2 x 1000 µL
CRE Oligo Mix	Specific nucleic acid amplification and detection: **FAM:** *KPC* **HEX:** *NDM* **ROX:** *VIM* **CY5:** *IMP*	1 x 125 µL	1 x 500 µL
OXA Oligo Mix	**FAM:** *CTX-M* **HEX:** Human (Internal Control) **CY5 :** *OXA-48*	1 x 125 µL	1 x 500 µL
NTC	Negative Control	1 x 1000 µL	1 x 1000 µL
PC-CRE / PC-OXA	Positive Control (PC)	1 x 100 µL	1 x 100 µL

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

Component	Transport Condition*	Storage Condition**	Shelf Life
2X PCR Mix	(-22) °C – (+8) °C	(-22) °C – (-18) °C	12 months
Oligo Mix		(-22) °C – (-18) °C	
NTC		(-22) °C – (-18) °C before opening, (+2) °C – (+8) °C after first thaw	
PC		(-22) °C – (-18) °C before opening, (+2) °C – (+8) °C after first thaw	

* The kit was recommended to be shipped within 6 days at (-22) °C to (+8) °C and stored at (-22) °C to (-18) °C and used for 1 year
**Following the first opening, each reagent stored at storage temperature can be used until the expiration date indicated on the tube. The kit's expiration date is determined by the expiration date of the reagents.

Table 3. Required Components Not Included in the Package

Required Components Not Included in the Package
1. Real-Time PCR Instrument
2. ***v*NAT® Transfer Tube** (Cat. No: BS-NA-513m-100) or nucleic acid preparation instruments and nucleic acid preparation consumables
3. Micropipettes and compatible filtered pipette tips (nuclease-free) suitable for transferring 1-10 µL, 10-100 µL, and 100-1000 µL of liquid
4. A centrifuge or Mini-spin
5. Vortex
6. Reaction tubes,PCR strips, PCR plates 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(s)	**Table 1**	**Nucleic Acid Preparation Method(s)**	***v*NAT® Transfer Tube** Zybio EXM3000 Nucleic Acid Isolation System Adaltis EXTRAlab and MDXlab
Qualitative/Quantitative	Qualitative	**Validated qPCR Instrument(s)**	Bio Molecular Systems: Magnetic Induction Cycler (Mic) / Mic IVD Bio-Rad: CFX96 Touch, CFX Opus 96, CFX96 Dx Qiagen: Rotor-Gene Q Roche: LightCycler 96 Applied Biosystems - Thermo Fisher Scientific: QuantStudio 5/5 Dx Adaltis: AmpliLab, MDXlab HiMedia: InstaQ 96
Test Principle	Real-Time PCR (qPCR)	**Inclusivity and Exclusivity**	Validated on the reference strains and the field isolates
Automated/Manual	Manual		
Intended Users	Laboratory professionals trained in the techniques of qPCR and in vitro diagnostic procedures	**Limit of Detection (LoD)**	**Table 5**
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	%94.3 and %95.1

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

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) °C – (+8) °C 1 year at (-20) °C	**Nucleic acid preparation instruments:** 1) Zybio EXM3000, 2) Adaltis EXTRAlab, 3) Adaltis MDXlab **Nucleic acid preparation consumables:** Bio-Speedy® Rapid Nucleic Acid Extraction Kit (Cat. No: ZFNAE01)	50
Bronchoalveolar Lavage (BAL) samples	Preservative-free sterile containers/tubes	3 days at (+2) °C – (+8) °C 1 year at (-20) °C		
Positive blood culture samples	Blood culture bottle	Room temperature		
Whole blood samples	Anti-coagulant treated tube	3 days at (+2) °C – (+8) °C 1 year at (-20) °C		

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

Urine samples	Preservative-free sterile containers/tubes	3 days at (+2) °C – (+8) °C 1 year at (-20) °C		
Rectal Swab samples****	***v*NAT® Transfer Tube** (Cat. No: BS-NA-513m-100)	3 months at (+2) °C – (+8) °C 1 year at (-20) °C	Nucleic acid preparation is not required. Samples can be used directly in qPCR.	200

*** Clinical specimens should be collected by a healthcare provider in accordance with national/international clinical specimen collection regulations.
**** If dry swab samples are received, put them into the ***v*NAT® Transfer Tube** for nucleic acid isolation

1. APPLICATION PROTOCOL

1. Program the qPCR device using the QR Code/Link as indicated in **Table 6**.
2. Take the PCR kit out of the -20°C freezer.
3. Pipette (Sample Count + 3) *5 µL of CRE Oligo Mix into an empty eppendorf tube. (i.e Sample Count = 3, pipette 5*(3+3) = 30 µL of CRE Oligo Mix)
4. Add (Sample Count + 3) *10 µL of 2X PCR Mix into the tube prepared in Step 3. (i.e Sample Count = 3, pipette 10*(3+3) = 60 µL of 2X PCR Mix)
5. Vortex the master mix to homogenize.
6. Repeat steps 3,4 and 5 for all master mixes. (Total 2 master mixes).
7. Pipette 15 µL of master mix into all PCR tubes, or wells to be used (including all samples, NTC and PC).
8. Pipette 5 µL of each isolated/ extracted sample into the relative PCR tube, or well.
9. Pipette 5 µL of NTC into the Negative Control PCR tube, or well.
10. Pipette 5 µL of PC-CRE into the Positive Control tubes, or wells. Repeat for all PC.
11. Close the cap of the strips, or PCR tubes or seal PCR plate. Label to avoid confusion during spin -centrifuge.
12. Spin-centrifuge the strips, or PCR tubes or PCR plate.
13. Open the lid of the instrument. Place the strips, or PCR tubes or PCR plate.
14. Close the lid and start the instrument.

Table 6. Real Time qPCR Program Details

<table>
<tr><th rowspan="2">Reaction Setup</th><th colspan="9">RT-qPCR Program</th></tr>
<tr><th colspan="5">Protocol 1:
Bio Molecular Systems: Magnetic Induction Cycler (Mic) / Mic IVD, Bio-Rad: CFX96 Touch, CFX Opus 96, CFX96 Dx, Roche: LightCycler 96</th><th colspan="4">Protocol 2:
Qiagen: Rotor-Gene Q, Applied Biosystem - Thermo Fisher Scientific: QuantStudio 5/5 Dx, Adaltis: AmpliLab, MDXlab, HiMedia: InstaQ 96</th></tr>
<tr><th>Reagent</th><th>Volume/ Rxn</th><th>Step</th><th>Cycle No.</th><th>Temperature</th><th>Duration</th><th>Step</th><th>Cycle No.</th><th>Temperature</th><th>Duration</th></tr>
<tr><td rowspan="2">2X PCR Mix</td><td rowspan="2">10 µL</td><td>Enzyme Activation</td><td>1 Cycle</td><td>52 °C</td><td>3 min</td><td>Enzyme Actvation</td><td>1 Cycle</td><td>52 °C</td><td>3 min</td></tr>
<tr><td>Pre-Incubation</td><td>1 Cycle</td><td>95 °C</td><td>10 sec</td><td>Pre-Incubation</td><td>1 Cycle</td><td>95 °C</td><td>10 sec</td></tr>
<tr><td rowspan="3">Oligo Mix</td><td rowspan="3">5 µL</td><td>Denaturation</td><td rowspan="2">12 Touchdown Cycles:
1 °C decrement in annealing temperature per cycle</td><td>95 °C</td><td>1 sec</td><td>Denaturation</td><td rowspan="3">40 Cycles</td><td>95 °C</td><td>1 sec</td></tr>
<tr><td>Annealing and Extension</td><td>67 °C to 56 °C</td><td>15 sec</td><td>Annealing and Extension</td><td>55 °C</td><td>15 sec</td></tr>
<tr><td rowspan="2">Template Nucleic Acid/NTC/PC</td><td rowspan="2">5 µL</td><td>Denaturation</td><td rowspan="3">30 Cycles</td><td>95 °C</td><td>1 sec</td><td rowspan="3">Detection (Reading)</td><td rowspan="3">(FAM -Green)/(HEX -Yellow)/ (ROX -Orange)/(CY5-Red)</td></tr>
<tr><td>Annealing and Extension</td><td>55 °C</td><td>15 sec</td></tr>
<tr><td>Total Reaction Volume</td><td>20 µL</td><td>Detection (Reading)</td><td>(FAM -Green)/(HEX -Yellow)/ (ROX -Orange)/(CY5-Red)</td></tr>
</table>

WARNING: The qPCR program file should be downloaded from the QR code on the left or from the link below.

https://www.bioeksen.com.tr/files/L_TD_43B

2. INTERPRETATION OF THE ASSAY RESULTS

- Once the run is complete, the instruments' software automatically calculates the threshold based on the background, and assigns a Cq value for the amplification curves over the threshold.
- Record all curves, including sigmoidal ones, under the threshold as negative for amplification. When the fluorescence level is too low (under the threshold RFU), the shape of the curves can be misleading.
- Record all non-sigmoidal curves above the threshold as negative for amplification.
- Record all sigmoidal curves over the threshold as positive for amplification, even if the amplification is weak, with a high Cq value and low RFU.
- **Negative Amplification of Analyte**:
  - The "**Positive Control**" must be **positive** for a **valid** negative result for the analyte.
  - If the "**Positive Control**" amplification is **negative**, the test is **invalid** due to the reactive stability problem. Contact the manufacturer for further assistance.
  - The "**Internal Control**" must be **positive** for a **valid** negative result for the analyte.
  - If the "**Internal Control**" amplification is **negative**, the test is **invalid** due to either sampling or inhibition problem. The sample must be retested. If the problem persists, a new sample from the same patient should be collected and tested again.
- **Positive Amplification of Analyte**:

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

- The **negative control template** must be **negative** for the analyte for a **valid** positive result.

Contamination: If the analyte amplification is positive and the negative control template is positive for the analyte, the test is invalid for the analyte. Repeat the analysis, paying attention to the "Warnings and Limitations" section.

Table 7. Threshold Levels for Calculating Cq Values

Analyte	Real Time PCR Instrument									
	Bio-Rad CFX		LightCycler 96		Mic/Mic IVD		Rotor-Gene Q****		QuantStudio 5/5 Dx	
	RFU	Cq Cut-off	RFU	Cq Cut-off	RFU	Cq Cut-off	RFU	Cq Cut-off	RFU	Cq Cut-off
KPC	750	30	0.1	30	0.5	30	0.05	40	20000	30
NDM	750	30	0.1	30	0.5	30	0.05	40	20000	30
VIM	750	30	0.1	30	0.5	30	0.05	40	20000	30
IMP	750	30	0.1	30	0.5	30	0.05	40	20000	30
CTX-M	750	30	0.1	30	0.5	30	0.05	40	20000	30
Human (Internal Control)	200	30	0.05	30	0.2	30	0.02	40	20000	30
OXA-48	750	30	0.1	30	0.5	30	0.05	40	20000	30

**** Defined threshold with specific settings of "Outlier Removal = 0", "Dynamic Tube = On", and "Slope Correct = Off"

Table 8. Interpretation of Patient Results

Target	Internal Control (IC)	Result Interpretation		
Positive (+)	Positive (+) or Negative (-)	Results are valid Target is detected	Protocol 1	If 26<Cq ≤30 "Low Positive" If 16<Cq≤26 "Positive" If Cq≤16 "High Positive"
			Protocol 2	If 34<Cq ≤40 "Low Positive" If 22<Cq≤34 "Positive" If Cq≤22 "High Positive"
Negative (-)	Positive (+)	Results are valid Target is not detected		

Table 9. Expected Performance of Kit Controls

Control Type	Purpose	Expected Results and Cq Values			
		Protocol 1		Protocol 2	
		IC (HEX)	Target	IC (HEX)	Target
Negative Control	Contamination control during qPCR	**Not Detected**	**Not Detected**	**Not Detected**	**Not Detected**
Positive Control	Reagent stability control	**Detected** (Cq≤30)	**Detected** (Cq≤30)	**Detected** (Cq≤40)	**Detected** (Cq≤40)
Internal Control	Nucleic acid extraction and sampling control	**Detected**	Detection insignificant	**Detected**	Detection insignificant
		If "**Not Detected**" check the target Cq	If "**Detected"** IC is valid	If "**Not Detected**" check the target Cq	If "**Detected"** IC is valid

If a control does not work as expected (**Table 9**), apply the procedures described below.

1. **Contamination Problem:** If a target in the Negative Control reaction is "**Detected**".
   Recommended action: Repeat the run, paying attention to the "Warnings and Limitations" section.

2. **Invalid Internal Control Problem:** If the Internal Control (IC) and all other targets of a sample are "**Not Detected**".
   Recommended action: Sampling was not successfully done, or there was a problem during the sample transportation or extraction. Re-test the sample. If the problem repeats, a new sample from the same patient should be collected and tested again.

3. **Reagent Problem**: If all Internal Controls, Positive Controls and targets in the run are "**Not Detected**".
   Recommended action: The run is considered invalid. Re-test the PC. If the problem repeats, please reach out to the manufacturer for further assistance.

3. WARNINGS AND LIMITATIONS

1. False-negative results may occur if inadequate number (below 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.
1. The use of swabs with wooden sticks, cotton or calcium alginate swabs can lead to false negative results since they may contain substances that inactivate some pathogens and inhibit PCR.
2. False-negative results may occur if a specimen is improperly collected, transported, or handled.
3. The clinical specimens shall be collected by a healthcare provider in accordance with the national/international specimen collection guidelines.
4. Test procedures should be performed by personnel trained in the use of the kit.
5. Sample tubes should always be kept closed except for liquid transfers.
6. Filtered and nuclease-free pipette tips should be used for sample transfer.
7. The components in the kit should not be used together with different LOT numbers or chemicals of the same name but from different manufacturers.
8. ***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.
9. The surfaces of the workbenches should be wiped with freshly diluted 10% bleach (0.5% NaClO) at the beginning and end of each day.
10. Waste disposal must be carried out in accordance with local, state, and federal regulations. These reagents and their container must be disposed of safely. The requirements of environmental protection and waste disposal legislation, as well as regional local authority requirements, must always be adhered to. If possible, it should be recycled. The reagents must not enter water pipes, sewers, or soil.
11. Proper personal protective equipment including lab coats, gowns, gloves, eye protection, and a biological safety cabinet are recommended for manipulation of clinical specimens.
12. 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.
13. The micropipettes used for pipetting PCR mixes and template nucleic acids should be separate. Filtered and nuclease-free pipette tips should be used.
14. Maintenance/ calibration interval should be determined for all instruments and equipment used with the kit.
15. For optimal signal accuracy and instrument performance, white strips must be used with top-reading systems.

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

Precaution Related REACH Regulation (EC 1907/2006)

This statement applies only to countries within the European Union (EU) regarding the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC 1907/2006). It is recommended that all material associated with the test, including materials used to clean up spills, contaminated packaging, and unused or expired IVD tests, be incinerated. Please ensure that you follow local regulations regarding disposal.

1. 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	Catalog number		Do not use if package is damaged and consult *Instructions for Use*
	Manufacturer	NON STERILE	Non-sterile		Keep dry
	Expiration Date YYYY-MM		Consult *Instructions for Use* or consult electronic *Instructions for Use*		Keep upright
	Temperature limit (Storage Condition)		Caution	Σ	Contains sufficient for *<n>* tests
CONTROL +	Positive Control	CONTROL -	Negative Control	CONTROL	Control
	Fragile, handle with care				

This Package Insert (PIS) document has been prepared as a single-page leaflet in accordance with the current packaging size and printing techniques. It provides essential information for the safe and correct use of the product. A comprehensive and detailed most updated Instructions for Use (IFU), prepared in accordance with applicable regulatory requirements, is available upon request at ifu@bioeksen.com.tr.

2. MANUFACTURER AND TECHNICAL SUPPORT

Bioeksen AR GE Teknolojileri A.Ş
Address: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34475 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 promptly report any serious incidents to us (via vigilance@bioeksen.com.tr), distributor or the relevant competent authority in the respective Member State.

ALL RIGHTS RESERVED

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

Cat No: ZFNAE01

Rapid Nucleic Acid Extraction Kit

Package Insert

1. KIT CONTENT and SHELF LIFE

Shelf Life: 12 months; Check the expiration date on the box. Each reagent stored at storage temperature can be used until the expiration date indicated on the tube. The expiry date of the kit is determined by the expiry date of the reagents. Cartridges are stored at (+2) – (+8) °C for 12 months, away from direct sunlight and moisture. After opening the kit box, it can be stored in a dry and cool environment for 60 days at room temperature.

Table 1. Kit Content

Kit Content and Intended Use	Storage Temperature	Transport Temperature	20 Reactions	Reaction Consumption per Sample
Nucleic Acid Extraction Cartridge (B200-20)	(+2) – (+8) °C	(+2) – (+30) °C	1 x 20 pieces	1 piece
Magnetic Rod Sleeve	(+2) – (+30) °C	(+2) – (+30) °C	5 x 2 pieces	1 piece
Proteinase K (Lysis)	(+2) – (+8) °C	(+2) – (+30) °C	1 x 300 µL	15 µL
STL-B	(+2) – (+30) °C	(+2) – (+30) °C	1 x 8 mL	Variable according to the sample type

2. MATERIALS REQUIRED BUT NOT PROVIDED

Table 2. Components Required but Not Included with The Test

Components Required but Not Included with The Test		
General	**Stool, sputum, tissue, and solid samples**	**Blood samples**
10-100 µL and 100-1000 µL micropipette and filtered pipette tip (Nuclease-free)	Heat Block (Compatible with 2 mL tubes)	Bio-Speedy® Condenser Tube (Cat. No: BS-NA-R1) (1 Tube/Sample)
A centrifuge compatible with 2 mL tubes: 14000 g	***v*NAT® Transfer Tube** (Cat. No: BS-NA-513m-100) (Swab included) (1 Tube/Sample)	Bio-Speedy® Magnetic Bead (Cat. No: BS-NA-R2) (25 µL/Sample)
Vortex	5min NA (Cat. No: BS-NA-516) (20 µL/Sample)	Bio-Speedy® Magnetic Stand (Cat. No: BS-NA-R4)
1.5 mL microcentrifuge tube (nuclease-free) for nucleic acid isolate storage	Lancet/Scalpel (Tissue and solid samples)	5min NA (Cat. No: BS-NA-514) (50 µL/Sample)
Nucleic Acid Isolation Systems Compatible with The Kit: Zybio EXM3000 Nucleic Acid Isolation System (Robot Model No: EXM3000) Zybio EXM6000 Nucleic Acid Isolation System (Robot Model No: EXM6000)	2.5 mL Injector/Syringe (Sputum homogenization)	Nuclease-free water (200 µL/Sample)

3. INTENDED USE AND TEST PRINCIPLE

The Bio-Speedy® Rapid Nucleic Acid Extraction Kit is an in vitro diagnostic medical device intended for the extraction and purification of total nucleic acids (DNA and RNA) from clinical specimens. These include whole blood, positive blood culture, serum, plasma, urine, stool, rectal swab, nasopharyngeal swab, oropharyngeal swab, combined nasopharyngeal and oropharyngeal swab, nasopharyngeal aspirate (NPA), throat swab, oral/saliva swab, saliva, gargle, sputum, bronchoalveolar lavage (BAL), cerebrospinal fluid (CSF), bone tissue, synovial fluid, peri-prosthetic fluid, skin lesion swab, skin lesion crust, skin lesion fluid, vaginal swab, cervical swab, endocervical swab, penile swab, urethral swab, and urogenital swab. The kit utilizes magnetic bead-based purification technology and is suitable for use with robotic nucleic acid isolation systems operated in clinical laboratory environments. The extracted nucleic acids are of sufficient quality for direct use in downstream Real-Time PCR (qPCR)-based diagnostic applications.

4. SAMPLE TRASNPORT AND STORAGE PROOCOLS

Sample transport and storage protocols vary by sample type. Transport and storage conditions should be determined according to national and/or international standards specific to the sample type.

5. ANALYTICAL SPECIFICATIONS

The kit is validated with all "Bio-Speedy®" PCR detection kits manufactured by Bioeksen AR GE Teknolojileri A.Ş. The kit is also validated with the systems such as Zybio EXM3000 Nucleic Acid Isolation System, and Zybio EXM6000 Nucleic Acid Isolation System. The amount of nucleic acid obtained varies according to the sample type. Reproducible results are obtained with samples containing nucleic acid analytes at concentrations of 50 copies/mL or more. The nucleic acid quality obtained is between OD (Optical Density) 260/A280 = 1.65-1.90.

6. PRE-TREATMENT PROTOCOLS

Sample Types Not Requiring Pre-treatment

All swab samples collected in a transport medium, nasopharyngeal aspirate, tracheal aspirate, saliva, gargle, Cerebrospinal fluid (CSF), plasma, blood serum, urine, intraocular fluid, whole blood, culture etc.

Dry Swab Samples

The dry swab is placed in the "***v*NAT® Transfer Tube**", and vortexed for 10 seconds at maximum speed, and the sample is ready for robotic extraction.

Stool

- The heating block is set to 95 °C.
- Add 400 µL of Bio-Speedy® STL-B into a 2 mL centrifuge tube.
- Take a substantial amount of swab sample using a nylon-flocked swab to represent the entire stool sample.
- Transfer the collected swab sample into the "STL-B Tube".
- After adding 20 µL of "5min NA" to the STL-B Tube, vortex at maximum speed for 10 seconds, incubate at 95 °C for 3 minutes, and then centrifuge at maximum speed for 1 minute.
- The upper phase of the sample is now ready for use in robotic extraction process.

Liquid stool

- The heating block is set to 95 °C.
- Add 200 µL of Bio-Speedy® STL-B into a 2 mL centrifuge tube.
- Take 200 µL from the stool sample and combine with the 2 mL centrifuge tube that contains 200 µL of Bio-Speedy® STL-B.

Revision Date: 2026-01-12/Rev.20
Published Date: 2021-11-11

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

- After adding 20 µL of "5min NA" to the centrifuge tube, vortex at maximum speed for 10 seconds, incubate at 95 °C for 3 minutes, and then centrifuge at maximum speed for 1 minute.
- The upper phase of the sample is now ready for use in robotic extraction process.

Sputum, bronchoalveolar lavage, and dense body fluids

- The heating block is set to 95 °C.
- Add 200 µL of Bio-Speedy® STL-B to a 2 mL centrifuge tube.
- Transfer 200 µL of samples with pipetteable density to the "STL-B Tube".
- Convert samples with non-pipetteable density into a fluid state using a 2.5 mL syringe, then transfer 200 µL of the sample to the "STL-B Tube".
- After adding 20 µL of "5min NA" to the "STL-B Tube," vortex at maximum speed for 10 seconds, incubate at 95 °C for 3 minutes, and vortex again at maximum speed for 10 seconds.
- The sample is ready for robotic extraction process.

Tissue and other solid samples

- The heating block is set to 95 °C.
- Add 200 µL of Bio-Speedy® STL-B to a 2 mL centrifuge tube.
- A pea-sized solid sample is taken into a sterile container and cut into as small pieces as possible using a scalpel.
- The fragmented sample and 20 µL “5min NA” are transferred to the “STL-B Tube”, vortexed for 10 seconds at maximum speed, incubated for 3 minutes at 95 °C and vortexed again for 10 seconds at maximum speed.
- The sample is ready for robotic extraction.

⚠ **WARNING**: In case a tissue sample absorbs a large amount of the solution after being transferred to the “STL-B Tube” resulting in no solution left in the tube, 200 µL of Bio-Speedy® STL-B is transferred to the tube containing the tissue sample, and the relevant pre-processing protocol is continued after vortexing at the highest speed for 10 seconds. (Some tissue types absorb a large amount of liquid. Therefore, an additional 10% of "STL-B" is provided along with the specimen.)

Culture Samples

- Add 200 µL of Bio-Speedy® STL-B to a 2 mL centrifuge tube.
- Transfer 25 µL of liquid culture sample into a STL-B Tube and vortexed at maximum speed for 10 seconds.
- From the culture in solid medium, 1-3 colonies are transferred to the “STL-B Tube” depending on the colony size and vortexed at maximum speed for 10 seconds
- The sample is ready for robotic extraction.

7. ROBOTIC EXTRACTION PROTOCOL

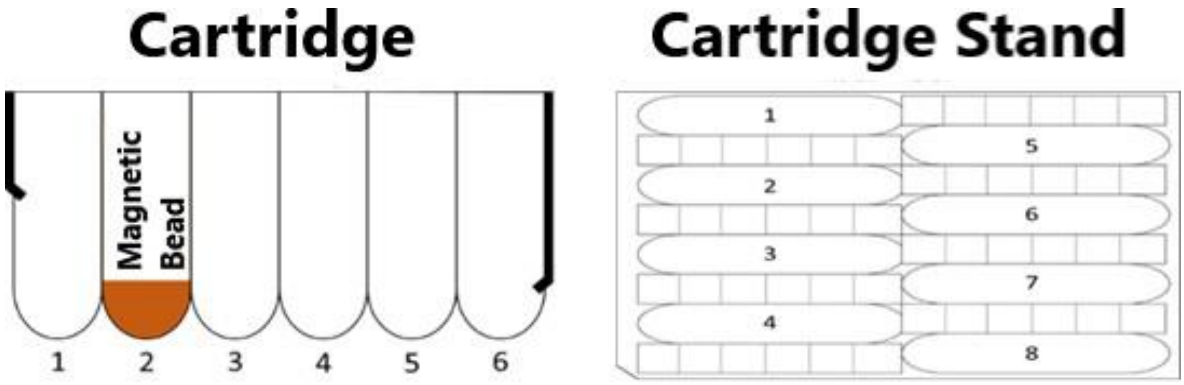


Figure 1. Extraction Cartridge Diagram: The protrusions on the edges of the cartridges are indicated by thick black lines for proper positioning on the cartridge stand. The cartridge wells are numbered. The magnetic bead is located in the second well of the cartridge.

1. The Zybio EXM3000 device is plugged in and the button on the back right of the device is turned on.
2. The light of the device is turned on by touching the light symbol in the lower-left corner of the main screen. Ventilation is activated with the fan symbol.
3. The plastic cartridge stand is placed on a flat surface with the cut corner at the bottom left. (Figure 1)
4. The cartridge is shaken vigorously to collect the cartridge contents from the foil covering the cartridge to the bottom of the well.
5. The first well of the cartridge (Figure 1) is placed on the “cartridge stand” firmly on the left side. 8 positions where cartridges can be placed on the cartridge stand are shown in Figure-1. Samples should be placed on the stand in the order indicated in the figure.
6. The cartridge foil is carefully opened paying attention not to splash liquid.
7. Pipette 15 µL of Proteinase K into the first well of the cartridge
8. Pipette 200 µL of clinical specimens into well number 1.
9. The cartridge stand is placed in the device with the cut corner at the bottom left (Figure 1) and make sure that the stand is fixed.
10. The cartridge stand is attached to the device, one for position 1-4 and one for position 5-8. The magnetic rod sleeve is placed on the device by pushing it to the end of its slot, making sure that it is fixed. Otherwise, the magnetic rods may be broken during operation.
11. The lid of the device is closed. The “ZYBIO-CS-B-200” symbol is touched for the whole blood samples and “ZYBIO-B-200” symbol is touched for other sample types on the “Run” menu. Touch the "Confirm" symbol on the "Prompt" screen that appears.
12. Once the run is completed; The UV sterilization screen appears, the lid is opened without pressing any button, and the magnetic rod sleeves are removed first and thrown away. Then the cartridge stand is removed and placed on a flat surface.
13. Transfer 80-100 µL of an isolate from well number 6 of the cartridge with a micropipette into a nuclease-free 1.5 mL centrifuge tube.
14. By selecting the UV tab, the desired time is determined, and the UV sterilization process is started. UV sterilization is performed for 10 minutes after each operation and 20 minutes at the end of the day.

Revision Date: 2026-01-12/Rev.20
Published Date: 2021-11-11

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

The components need to be mixed well before use. In case of precipitation in Extraction Reagent, it can be used after sufficient dissolution at room temperature. Extraction Reagent contains guanidine thiocyanate. Please take care to protect yourself from skin or eye damage when using. Extraction Reagent contains isopropyl alcohol. Please keep away from fire sources or other risk factors.

8. 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		Do not use if package is damaged and consult *instructions for use*
	Manufacturer	NON STERILE	Non-*sterile*		Keep dry
	Use-by date		Caution		Keep it upright
Σ	Contains sufficient for *<n>* tests		Consult *instructions for use* or consult electronic *instructions for use*		Temperature limit (Storage Temperature)
	Fragile, handle with care		Hazard (GHS07)		Do-not reuse

This Package Insert (PIS) document has been prepared as a single-page leaflet in accordance with the current packaging size and printing techniques. It provides essential information for the safe and correct use of the product. A comprehensive and detailed most updated Instructions for Use (IFU), prepared in accordance with applicable regulatory requirements, is available upon request at ifu@bioeksen.com.tr.

9. MANUFACTURER AND TECHNICAL SUPPORT

Bioeksen AR GE Teknolojileri A.Ş
Address: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34475 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 promptly report any serious incidents to us (via vigilance@bioeksen.com.tr), distributor or the relevant competent authority in the respective Member State.

ALL RIGHTS RESERVED

Revision Date: 2026-01-12/Rev.20
Published Date: 2021-11-11

For in vitro diagnostic use only.
For professional use only.
Cat No: BS-RTV-T-25/ BS-RTV-T-100
Ordering Ref No: RTI-P3-T-25/ RTI-P3-T-100

Respiratory Tract Virus 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	1 x 1000 µL	4 x 1000 µL
RTV Oligo Mix 1	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
RTV Oligo Mix 2	**FAM**: Human Coronavirus 229E/ OC43 **HEX:** Human Parainfluenza 1/2 **ROX:** Human Coronavirus NL63/ HKU1 **CY5:** Human Parainfluenza 3/4	1 x 125 µL	1 x 500 µL
RTV Oligo Mix 3	**FAM**: Respiratory Syncytial Virus A/B **HEX:** Human Metapneumovirus **ROX:** Human Enterovirus **CY5:** Human Adenovirus	1 x 125 µL	1 x 500 µL
RTV Oligo Mix 4	**FAM**: Human Bocavirus **CY5:** Human Rhinovirus	1 x 125 µL	1 x 500 µL
NTC	Negative Control	1 x 1000 µL	1 x 1000 µL
PC-RTV 1 / PC-RTV 2 PC-RTV 3 / PC-RTV 4	Positive Control (PC)	1 x 100 µL	1 x 100 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		(-22) °C – (-18) °C before opening, (+2) °C – (+8) °C after first thaw	
PC		(-22) °C – (-18) °C before opening, (+2) °C – (+8) °C after first thaw	

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

Table 3. Required Components Not Included in the Package

Required Components Not Included in the Package
1. Real-Time PCR Instrument
2. Bioeksen **vNAT® Transfer Tube** (Cat. No: BS-NA-513m) or nucleic acid preparation instruments and nucleic acid preparation consumables
3. Micropipettes and compatible filtered pipette tips (nuclease-free) suitable for transferring 1-10 µL, 10-100 µL, and 100-1000 µL of liquid
4. A centrifuge or Mini-spin
5. Vortex
6. Reaction tubes,PCR strips, PCR plates 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(s)	**Table 1**	**Nucleic Acid Preparation Method(s)**	Bioeksen **vNAT® Transfer Tube** Zybio EXM3000 Nucleic Acid Isolation System Adaltis EXTRAlab and MDXlab
Qualitative/Quantitative	Qualitative	**Validated qPCR Instrument(s)**	Bio Molecular Systems: Magnetic Induction Cycler (Mic)/Mic IVD Bio-Rad: CFX96 Touch/Dx, CFX Opus 96/Dx, CFX384 Touch, CFX Opus 384 Qiagen: Rotor-Gene Q 5-Plex/MDx Roche: LightCycler 96 Thermo Fisher Scientific: QuantStudio 5/5 Dx/6/7/12k Flex/Pro, StepOne Plus, Applied Biosystems 7500/7500 Fast Adaltis: AmpliLab, MDXlab HiMedia: InstaQ 96 Bioer: Linegene 9600 Plus Atila Biosystems: Fujirebio Co-Dx: Co-Dx Box Tianlong: Gentier 96E Sansure: SLAN-96P Azure: Cielo
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	Laboratory professionals trained in the techniques of qPCR and in vitro diagnostic procedures	**Limit of Detection (LoD)**	**Table 5**

Revision Date: 2024-11-20/Rev.04
Published Date: 2023-10-04

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

Target Population	Individuals with the suspected infection	Sensitivity and Specificity	99.93% and 99.14%

Table 5. Collection, Storage, Transfer and Nucleic Acid Preparation Method of Clinical Specimens

Sample Type**	Sample Transfer	Sample Storage	Nucleic Acid Preparation Method	LoD (cp/mL)
Combined nasopharyngeal and oropharyngeal swab samples ***	**vNAT® Transfer Tube** (Cat. No: BS-NA-513m)	3 months at (+2) °C – (+8) °C 1 year at (-20) °C	Nucleic acid preparation is not needed, samples can be used directly in RT-qPCR	250
	Transport Medium (without antibiotics)	3 days at (+2) °C – (+8) °C 1 year at (-20) °C	**Nucleic acid preparation instruments:** 1) Zybio EXM3000, 2) Adaltis EXTRAlab, 3) Adaltis MDXlab	125
Bronchoalveolar lavage (BAL), sputum, and nasopharyngeal aspirate (NAP) samples	Preservative-free sterile containers/tubes	3 days at (+2) °C – (+8) °C 1 year at (-20) °C	**Nucleic acid preparation consumables:** Bioeksen Bio-Speedy® Rapid Nucleic Acid Extraction Kit (Cat. No: ZFNAE01)	500

** Clinical specimens should be collected by a healthcare provider in accordance with national/international clinical specimen collection regulations.
*** If dry swab samples are received, put them into the **vNAT® Transfer Tube** for nucleic acid isolation.

1. APPLICATION PROTOCOL

1. Program the qPCR device using the QR Code/Link as indicated in Table 6.
2. Take the PCR kit out of the -20°C freezer.
3. Pipette (Sample Count + 3) *5 µL of RTV Oligo Mix 1 into an empty eppendorf tube. (i.e Sample Count = 3, pipette 5*(3+3) = 30 µL of RTV Oligo Mix)
4. Add (Sample Count + 3) *10 µL of 2X Prime Script Mix into RTV Oligo Mix 1. (i.e Sample Count = 3, pipette 10*(3+3) = 60 µL of 2X Prime Script Mix)
5. Vortex the master mix to homogenize.
6. Repeat Steps 3, 4 and 5 for all master mixes (4 master mixes in total).
7. Pipette 15 µL of each master mix into relative PCR tube, or wells to be used (including all samples, NTC and PC).
8. Pipette 5 µL of extracted/isolated sample into relative PCR tube, or wells.
9. Pipette 5 µL of NTC into the Negative Control PCR tube, or wells.
10. Pipette 5 µL of PC-RTV 1 into the relative PC tube, or wells. Repeat for all PC.
11. Close the cap of the strips, or PCR tubes or seal PCR plate. Label to avoid confusion during spin-centrifuge.
12. Spin-centrifuge the strips, or PCR tubes and PCR plate.
13. Open the lid of the instrument. Place the strips, or PCR tubes and PCR plate.
14. Close the lid and start the instrument.

Table 6. Real-Time qPCR Program Details

Reaction Setup		RT-qPCR Program							
		Protocol 1: Bio Molecular Systems: Magnetic Induction Cycler (Mic)/Mic IVD, Bio-Rad: CFX96 Touch/Dx, CFX Opus 96/Dx, CFX384 Touch, CFX Opus 384, Roche: LightCycler 96, Co-Dx: Co-Dx Box, Azure: Cielo				**Protocol 2:** Qiagen: Rotor-Gene Q 5-Plex/MDx, Thermo Fisher Scientific: QuantStudio 5/5 Dx/6/7/12k Flex/Pro, StepOne Plus, Applied Biosystems 7500/7500 Fast, Adaltis: AmpliLab, MDXlab, HiMedia: InstaQ 96, Bioer: Linegene 9600 Plus, Atila Biosystems: FujirebioTianlong: Gentier 96E, Sansure: SLAN-96P			
Reagent	**Volume/Rxn**	**Step**	**Cycle No.**	**Temperature**	**Duration**	**Step**	**Cycle No.**	**Temperature**	**Duration**
2X Prime Script Mix	10 µL	**Reverse Transcription**	1 Cycle	52 °C	3 min	**Reverse Transcription**	1 Cycle	52 °C	3 min
		Pre-Incubation	1 Cycle	95 °C	10 sec	**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	**Denaturation**	40 Cycles	95 °C	1 sec
		Annealing and Extension		67 °C to 56 °C	15 sec	**Annealing and Extension**		55 °C	15 sec
Template Nucleic Acid/NTC/PC	5 µL	**Denaturation**	30 Cycles	95 °C	1 sec	**Detection (Reading)**		FAM/HEX/ROX/CY5	
		Annealing and Extension		55 °C	15 sec				
Total Reaction Volume	**20 µL**	**Detection (Reading)**		FAM/HEX/ROX/CY5					

WARNING: The qPCR program file should be downloaded from the QR code on the left or from the link below.

https://www.bioeksen.com.tr/files/L_TD_43B

2. INTERPRETATION OF THE ASSAY RESULTS

Cq values of the results obtained from PCR instruments indicated in **Table 7** are calculated referring to the relative RFU threshold levels and Cq cut-offs. Auto-threshold and default options are used for devices not included in **Table 7**. For all targets that do not exceed the Cq cut-off, the shape of the amplification curve must be analyzed, and Cq values of the sigmoidal curves must be determined. Non-sigmoidal curves must be reported as "negative". The PCR results can be reported manually, as indicated in **Table 8**, or using the "**Sigmoida**" software for BMS Magnetic Induction Cycler (Mic)/Mic IVD and Bio-Rad CFX instruments. Sigmoida software sorts each target as positive or negative. To obtain the "**Sigmoida**" software installer, please send an e-mail to support@bioeksen.com.tr.

Table 7. Threshold Levels for Calculating Cq Values

Analyte	Real Time PCR Instrument											
	Bio-Rad CFX		Cielo		LightCycler 96		Mic/Mic IVD and Co-Dx Box		Rotor-Gene Q****		QuantStudio 5/5 Dx/6/7/12k Flex/Pro	
	RFU	Cq Cut-off	RFU	Cq Cut-off	RFU	Cq Cut-off	RFU	Cq Cut-off	RFU	Cq Cut-off	RFU	Cq Cut-off
SARS-CoV-2	200	30	20000	30	0.05	30	0.5	30	0.02	40	20000	30

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

Human (IC-Internal Control)	200	30	20000	30	0.05	30	0.5	30	0.02	40	20000	30
Influenza B	750	30	75000	30	0.1	30	0.5	30	0.05	40	75000	30
Influenza A	200	30	20000	30	0.05	30	0.5	30	0.02	40	20000	30
Human Coronavirus 229E/ OC43	750	30	75000	30	0.1	30	0.5	30	0.05	40	20000	30
Human Parainfluenza 1/2	750	30	75000	30	0.1	30	0.5	30	0.05	40	20000	30
Human Coronavirus NL63/ HKU1	750	30	75000	30	0.1	30	0.5	30	0.05	40	20000	30
Human Parainfluenza 3/4	750	30	75000	30	0.1	30	0.5	30	0.05	40	20000	30
Respiratory Syncytial Virus A/B	750	30	75000	30	0.1	30	0.5	30	0.05	40	20000	30
Human Metapneumovirus	750	30	75000	30	0.1	30	0.5	30	0.05	40	20000	30
Human Enterovirus	750	30	75000	30	0.1	30	0.5	30	0.05	40	20000	30
Human Adenovirus	200	30	20000	30	0.05	30	0.5	30	0.02	40	20000	30
Human Bocavirus	750	30	75000	30	0.1	30	0.5	30	0.05	40	20000	30
Human Rhinovirus	200	30	20000	30	0.05	30	0.5	30	0.02	40	20000	30

**** Defined threshold with specific settings of "Outlier Removal = 0", "Dynamic Tube = On", and "Slope Correct = Off"

Table 8. Interpretation of Patient Results

Target	Internal Control (IC)	Result Interpretation		
Positive (+)	**Positive (+)** or **Negative (-)**	Results are valid Target is detected	**Protocol 1**	If 26<Cq ≤30 "Low Positive" If 16<Cq≤26 "Positive" If Cq≤16 "High Positive"
			Protocol 2	If 34<Cq ≤40 "Low Positive" If 22<Cq≤34 "Positive" If Cq≤22 "High Positive"
Negative (-)	**Positive (+)**	Results are valid Target is not detected		

Table 9. Expected Performance of Kit Controls

Control Type	Purpose	Expected Results and Cq Values			
		Protocol 1		Protocol 2	
		IC (HEX)	Target	IC (HEX)	Target
Negative Control	Contamination control during RT-qPCR	**Not Detected**	**Not Detected**	**Not Detected**	**Not Detected**
Positive Control	Reagent stability control	**Detected** (Cq≤30)	**Detected** (Cq≤30)	**Detected** (Cq≤40)	**Detected** (Cq≤40)
Internal Control	Nucleic acid extraction and sampling control	**Detected**	Detection insignificant	**Detected**	Detection insignificant
		If "**Not Detected**" check the target Cq	If "**Detected"** IC is valid	If "**Not Detected**" check the target Cq	If "**Detected"** IC is valid

If a control does not work as expected (**Table 9**), apply the procedures described below.

1. **Contamination Problem:** If a target in the Negative Control reaction is "**Detected**".
   Recommended action: Repeat the run, paying attention to the "Warnings and Limitations" section.

2. **Invalid Internal Control Problem:** If the Internal Control (IC) and all other targets of a sample are "**Not Detected**".
   Recommended action: Sampling was not successfully done, or there was a problem during the sample transportation or extraction. Re-test the sample. If the problem repeats, a new sample from the same patient should be collected and tested again.

3. **Reagent Problem**: If all Internal Controls, Positive Controls and targets in the run are "**Not Detected**".
   Recommended action: The run is considered invalid. Re-test the PC. If the problem repeats, please reach out to the manufacturer for further assistance.

3. WARNINGS AND LIMITATIONS

1. False-negative results may occur if inadequate number (below 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. False-negative results 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 national/international specimen collection guidelines.
6. Test procedures should be performed by personnel trained in the use of the kit.
7. Sample tubes should always be kept closed except for liquid transfers.
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. Waste disposal must be carried out in accordance with local, state, and federal regulations.
13. Proper personal protective equipment including lab coats, gowns, gloves, eye protection, and a biological safety cabinet are recommended for manipulation of clinical specimens.
14. 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.
15. The micropipettes used for pipetting PCR mixes and template nucleic acids should be separate. Filtered and nuclease-free pipette tips should be used.
16. Maintenance/ calibration interval should be determined for all instruments and equipment used with the kit.

4. EXPLANATIONS OF SYMBOLS

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	Catalog number		Protect from heat and radioactive sources

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

	Manufacturer		Non-sterile		Do not use if package is damaged and consult *Instructions for Use*
	Expiration Date YYYY-MM		Consult *Instructions for Use* or consult electronic *Instructions for Use*		Keep dry
	Negative Control		Caution		Keep upright
	Positive Control		Temperature limit		Contains sufficient for <*n*> tests
	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 send an e-mail to **vigilance@bioeksen.com.tr** about product-related incidents, within 24 hours.

ALL RIGHTS RESERVED

For in vitro diagnostic use only.
For professional use only.
Cat No: BS-RIDK-1-25/BS-RIDK-1-100

Respiratory ID-1 Kit

Package Insert

Table 1. Kit Content

Component	Intended Use	25 Reactions	100 Reactions
2X PCR Mix	Optimized ready-to-use mix for RT-qPCR assay	1 x 500 µL	2 x 1000 µL
RIDK-1 Oligo Mix 1	Specific nucleic acid amplification and detection: **FAM**: Respiratory Syncytial Virus A/B **HEX:** Human (IC-Internal Control) **ROX:** Influenza B **CY5:** Influenza A	1 x 125 µL	1 x 500 µL
RIDK-1 Oligo Mix 2	**FAM**: SARS-CoV-2 **HEX:** *Streptococcus pyogenes* **ROX:** Human Adenovirus **CY5:** Human Rhinovirus	1 x 125 µL	1 x 500 µL
NTC	Negative Control	1 x 1000 µL	1 x 1000 µL
PC-RIDK-1-1 / PC-RIDK-1-2	Positive Control	1 x 100 µL	1 x 100 µL

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

Component	Transport Condition*	Storage Condition**	Shelf Life
2X PCR Mix	(-22) °C – (+8) °C	(-22) °C – (-18) °C	12 Months
Oligo Mix		(-22) °C – (-18) °C	
NTC		(-22) °C – (-18) °C before opening, (+2) °C – (+8) °C after first thaw	
PC		(-22) °C – (-18) °C before opening, (+2) °C – (+8) °C after first thaw	

* The kit was recommended to be shipped within 6 days at (-22) °C to (+8) °C and stored at (-22) °C to (-18) °C and used for 1 year.
**Following the first opening, each reagent stored at storage temperature can be used until the expiration date indicated on the tube. The kit's expiration date is determined by the expiration date of the reagents.

Table 3. Required Components Not Included with The Test

Required Components Not Included with The Test
1. Real-Time PCR Instrument
2. ***v*NAT® Transfer Tube** (Cat. No: BS-NA-513m-100) or Nucleic acid preparation instruments and nucleic acid preparation consumables
3. Micropipettes and compatible filtered pipette tips (nuclease-free) suitable for transferring 1-10 µL, 10-100 µL, and 100-1000 µL of liquid
4. A centrifuge or Mini-spin
5. Vortex
6. Reaction tubes,PCR strips, PCR plates 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(s)	**Table 1**	**Nucleic Acid Extraction Method(s)**	***v*NAT® Transfer Tube** Zybio EXM3000 Nucleic Acid Isolation System Adaltis EXTRAlab and MDXlab
Qualitative/Quantitative	Qualitative	**Validated Real-Time PCR Instruments**	Bio Molecular Systems: Magnetic Induction Cycler (Mic) / Mic IVD Bio-Rad: CFX96 Touch, CFX Opus 96, CFX96 Dx Qiagen: Rotor-Gene Q Roche: LightCycler 96 Applied Biosystems - Thermo Fisher Scientific: QuantStudio 5/5 Dx Adaltis: AmpliLab, MDXlab HiMedia: InstaQ 96
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	Laboratory professionals trained in the techniques of qPCR and in vitro diagnostic procedures	**Limit of Detection (LoD)**	**Table 5**
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	%100.00 and %99.2

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

Sample Type***	Sample Transfer	Sample Storage	Nucleic Acid Preparation Method	LoD (cp/mL)
Combined nasopharyngeal and oropharyngeal swab samples****	***v*NAT® Transfer Tube** (Cat. No: BS-NA-513m-100)	3 months at (+2) °C – (+8) °C 1 year at (-20) °C	Nucleic acid preparation is not needed, samples can be used directly in RT-qPCR	250
	Transport Medium (without antibiotics)	3 days at (+2) °C – (+8) °C 1 year at (-20) °C	**Nucleic acid preparation instruments:** 1) Zybio EXM3000, 2) Adaltis EXTRAlab 3)Adaltis MDXlab **Nucleic acid preparation consumables:** Bio-Speedy® Rapid Nucleic Acid Extraction Kit (Cat. No: ZFNAE01)	125
Bronchoalveolar lavage (BAL), sputum, and nasopharyngeal aspirate (NAP) samples	Preservative-free sterile containers/tubes	3 days at (+2) °C – (+8) °C 1 year at (-20) °C		500

***Clinical specimens should be collected by a healthcare provider in accordance with national/international clinical specimen collection regulations.
****If dry swab samples are received, put them into the ***v*NAT® Transfer Tube** for nucleic acid isolation.

Revision Date: 2026-01-20/Rev.08
Published Date: 2023-10-31

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

1. APPLICATION PROTOCOL

1. Program the qPCR device using the QR Code/Link
2. Take the PCR kit out of the -20°C freezer.
3. Pipette (Sample Count + 3) *5 µL of RIDK-1 Oligo Mix 1 into an empty eppendorf tube. (i.e Sample Count = 3, pipette 5*(3+3) = 30 µL of RIDK-1 Oligo Mix 1)
4. Add (Sample Count + 3) *10 µL of 2X PCR Mix into RIDK-1 Oligo Mix 1. (i.e Sample Count = 3, pipette 10*(3+3) = 60 µL of 2X PCR Mix)
5. Vortex the master mix to homogenize.
6. Repeat Steps 3, 4 and 5 for all master mixes (2 master mixes in total).
7. Pipette 15 µL of each master mix into relative PCR tube, or wells to be used (including all samples, NTC and PC).
8. Pipette 5 µL of extracted/isolated sample into relative PCR tube, or wells.
9. Pipette 5 µL of NTC into the Negative Control PCR tube, or wells.
10. Pipette 5 µL of PC-RIDK-1 1 into the PC tube, or wells. Repeat for all PC.
11. Close the cap of the strips, or PCR tubes or seal PCR plate. Label to avoid confusion during spin-centrifuge.
12. Spin-centrifuge the strips, or PCR tubes and PCR plate.
13. Open the lid of the instrument. Place the strips, or PCR tubes and PCR plate.
14. Close the lid and start the instrument.

Table 6. Real-Time qPCR Program Details

<table>
<tr><th colspan="2" rowspan="2">Reaction Setup</th><th colspan="7">RT-qPCR Program</th></tr>
<tr><th colspan="4">Protocol 1:
Bio Molecular Systems: Magnetic Induction Cycler (Mic) / Mic IVD, Bio-Rad: CFX96 Touch, CFX Opus 96, CFX96 Dx, Roche: LightCycler 96</th><th colspan="3">Protocol 2:
Qiagen: Rotor-Gene Q, Applied Biosystem - Thermo Fisher Scientific: QuantStudio 5/5 Dx, Adaltis: AmpliLab, MDXlab, HiMedia: InstaQ 96</th></tr>
<tr><th>Reagent</th><th>Volume/ Rxn</th><th>Step</th><th>Cycle No.</th><th>Temperature</th><th>Duration</th><th>Step</th><th>Cycle No.</th><th>Temperature</th><th>Duration</th></tr>
<tr><td rowspan="2">2X PCR Mix</td><td rowspan="2">10 µL</td><td>Reverse Transcription</td><td>1 Cycle</td><td>52 °C</td><td>3 min</td><td>Reverse Transcription</td><td>1 Cycle</td><td>52 °C</td><td>3 min</td></tr>
<tr><td>Pre-Incubation</td><td>1 Cycle</td><td>95 °C</td><td>10 sec</td><td>Pre-Incubation</td><td>1 Cycle</td><td>95 °C</td><td>10 sec</td></tr>
<tr><td rowspan="3">Oligo Mix</td><td rowspan="3">5 µL</td><td>Denaturation</td><td rowspan="2">12 Touchdown Cycles:
1 °C decrement in annealing temperature per cycle</td><td>95 °C</td><td>1 sec</td><td>Denaturation</td><td rowspan="3">40 Cycles</td><td>95 °C</td><td>1 sec</td></tr>
<tr><td>Annealing and Extension</td><td>67 °C to 56 °C</td><td>15 sec</td><td>Annealing and Extension</td><td>55 °C</td><td>15 sec</td></tr>
<tr><td rowspan="2">Template Nucleic Acid/NTC/PC</td><td rowspan="2">5 µL</td><td>Denaturation</td><td rowspan="3">30 Cycles</td><td>95 °C</td><td>1 sec</td><td rowspan="3">Detection (Reading)</td><td rowspan="3">(FAM -Green)/(HEX -Yellow)/ (ROX -Orange)/(CY5-Red)</td></tr>
<tr><td>Annealing and Extension</td><td>55 °C</td><td>15 sec</td></tr>
<tr><td>Total Reaction Volume</td><td>20 µL</td><td>Detection (Reading)</td><td>(FAM -Green)/(HEX -Yellow)/ (ROX -Orange)/(CY5-Red)</td></tr>
</table>

WARNING: The qPCR program file should be downloaded from the QR code on the left or from the link below.

https://www.bioeksen.com.tr/files/L_TD_43B

2. INTERPRETATION OF THE ASSAY RESULTS

- Once the run is complete, the instruments' software automatically calculates the threshold based on the background, and assigns a Cq value for the amplification curves over the threshold.
- Record all curves, including sigmoidal ones, under the threshold as negative for amplification. When the fluorescence level is too low (under the threshold RFU), the shape of the curves can be misleading.
- Record all non-sigmoidal curves above the threshold as negative for amplification.
- Record all sigmoidal curves over the threshold as positive for amplification, even if the amplification is weak, with a high Cq value and low RFU.
- **Negative Amplification of Analyte**:
  - The "**Positive Control**" must be **positive** for a **valid** negative result for the analyte.
  - If the "**Positive Control**" amplification is **negative**, the test is **invalid** due to the reactive stability problem. Contact the manufacturer for further assistance.
  - The "**Internal Control**" must be **positive** for a **valid** negative result for the analyte.
  - If the "**Internal Control**" amplification is **negative**, the test is **invalid** due to either sampling or inhibition problem. The sample must be retested. If the problem persists, a new sample from the same patient should be collected and tested again.
- **Positive Amplification of Analyte**:
  - The **negative control template** must be **negative** for the analyte for a **valid** positive result.

Contamination: If the analyte amplification is positive and the negative control template is positive for the analyte, the test is invalid for the analyte. Repeat the analysis, paying attention to the "Warnings and Limitations" section.

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

Table 7. Threshold Levels for Calculating Cq Values

Analyte	Real Time PCR Instrument									
	CFX		LightCycler 96		Mic/Mic IVD		Rotor-Gene Q*****		QuantStudio 5/5 Dx	
	RFU	Cq Cut-off	RFU	Cq Cut-off	RFU	Cq Cut-off	RFU	Cq Cut-off	RFU	Cq Cut-off
Respiratory Syncytial Virus A/B	750	30	0.1	30	0.5	30	0.05	40	20000	30
Human (IC- Internal Control)	200	30	0.05	30	0.2	30	0.02	40	20000	30
Influenza B	750	30	0.1	30	0.5	30	0.05	40	75000	30
Influenza A	200	30	0.05	30	0.5	30	0.02	40	20000	30
SARS-CoV-2	200	30	0.05	30	0.5	30	0.02	40	20000	30
Streptococcus pyogenes	1000	30	0.12	30	0.75	30	0.08	40	75000	30
Human Adenovirus	200	30	0.05	30	0.5	30	0.02	40	20000	30
Human Rhinovirus	200	30	0.05	30	0.5	30	0.02	40	20000	30

***** Defined threshold with specific settings of "Outlier Removal = 0", "Dynamic Tube = On", and "Slope Correct = Off"

Table 8. Interpretation of Patient Results

Target	Internal Control (IC)	Result Interpretation		
Positive (+)	**Positive (+)** or **Negative (-)**	Results are valid Target is detected	**Protocol 1**	If 26<Cq ≤30 "Low Positive" If 16<Cq≤26 "Positive" If Cq≤16 "High Positive"
			Protocol 2	If 34<Cq ≤40 "Low Positive" If 22<Cq≤34 "Positive" If Cq≤22 "High Positive"
Negative (-)	**Positive (+)**	Results are valid Target is not detected		

Table 9. Expected Performance of Kit Controls

Control Type	Purpose	Expected Results and Cq Values			
		Protocol 1		Protocol 2	
		IC (HEX)	Target	IC (HEX)	Target
Negative Control	Contamination control during RT-qPCR	**Not Detected**	**Not Detected**	**Not Detected**	**Not Detected**
Positive Control	Reagent stability control	**Detected** (Cq≤30)	**Detected** (Cq≤30)	**Detected** (Cq≤40)	**Detected** (Cq≤40)
Internal Control	Nucleic acid extraction and sampling control	**Detected**	Detection insignificant	**Detected**	Detection insignificant
		If "**Not Detected**" check the target Cq	If "**Detected"** IC is valid	If "**Not Detected**" check the target Cq	If "**Detected"** IC is valid

If a control does not work as expected (**Table 9**), apply the procedures described below.

1. **Contamination Problem:** If a target in the Negative Control reaction is "**Detected**".
   Recommended action: Repeat the run, paying attention to the "Warnings and Limitations" section.

2. **Invalid Internal Control Problem:** If the Internal Control (IC) and all other targets of a sample are "**Not Detected**".
   Recommended action: Sampling was not successfully done, or there was a problem during the sample transportation or extraction. Re-test the sample. If the problem repeats, a new sample from the same patient should be collected and tested again.

3. **Reagent Problem**: If all Internal Controls, Positive Controls and targets in the run are "**Not Detected**".
   Recommended action: The run is considered invalid. Re-test the PC. If the problem repeats, please reach out to the manufacturer for further assistance.

3. WARNINGS AND LIMITATIONS

1. False-negative results may occur if inadequate number (below 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 swabs with wooden sticks, cotton or calcium alginate swabs can lead to false negative results since they may contain substances that inactivate some pathogens and inhibit PCR.
4. False-negative results 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 national/international specimen collection guidelines.
6. Test procedures should be performed by personnel trained in the use of the kit.
7. Sample tubes should always be kept closed except for liquid transfers.
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. Waste disposal must be carried out in accordance with local, state, and federal regulations. These reagents and their container must be disposed of safely. The requirements of environmental protection and waste disposal legislation, as well as regional local authority requirements, must always be adhered to. If possible, it should be recycled. The reagents must not enter water pipes, sewers, or soil.
13. Proper personal protective equipment including lab coats, gowns, gloves, eye protection, and a biological safety cabinet are recommended for manipulation of clinical specimens.
14. 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.
15. The micropipettes used for pipetting PCR mixes and template nucleic acids should be separate. Filtered and nuclease-free pipette tips should be used.
16. Maintenance/ calibration interval should be determined for all instruments and equipment used with the kit.
17. For optimal signal accuracy and instrument performance, white strips must be used with top-reading systems.

Precaution Related REACH Regulation (EC 1907/2006)

This statement applies only to countries within the European Union (EU) regarding the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC 1907/2006). It is recommended that all material associated with the test, including materials used to clean up spills, contaminated packaging, and unused or expired IVD tests, be incinerated. Please ensure that you follow local regulations regarding disposal.

For in vitro diagnostic use only.
For 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	Catalog number		Do not use if package is damaged and consult *Instructions for Use*
	Manufacturer	NON STERILE	Non-sterile		Keep dry
	Expiration Date YYYY-MM		Consult *Instructions for Use* or consult electronic *Instructions for Use*		Keep upright
	Temperature limit (Storage Temperature)		Caution	Σ	Contains sufficient for <*n*> tests
CONTROL +	Positive Control	CONTROL −	Negative Control	CONTROL	Control
	Fragile, handle with care				

This Package Insert (PIS) document has been prepared as a single-page leaflet in accordance with the current packaging size and printing techniques. It provides essential information for the safe and correct use of the product. A comprehensive and detailed most updated Instructions for Use (IFU), prepared in accordance with applicable regulatory requirements, is available upon request at ifu@bioeksen.com.tr.

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, 34475 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 promptly report any serious incidents to us (via vigilance@bioeksen.com.tr), distributor or the relevant competent authority in the respective Member State.

ALL RIGHTS RESERVED

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

Cat No: BS–NA–513m–100

*v*NAT® Transfer Tube

Package Insert

CE IVD

1. Kit Content

Table 1. Kit Content

Component	Description	Amount
*v*NAT® Transfer Tube	Nucleic acid storage and stabilization	100 tubes

Table 2. Storage Requirements and Shelf Life

Component	Transport Conditions	Storage Conditions	Shelf Life
*v*NAT® Transfer Tube	+2 to +50 °C	+15 to +30 °C	60 months

2. Intended Use

The *v*NAT® Transfer Tube is a single-use in vitro diagnostic (IVD) medical device designed for the storage and stabilization of nucleic acids from nasopharyngeal, oropharyngeal, throat, rectal, vaginal, cervical, urethral, urogenital, endocervical, penile, and conjunctival swab samples.

Each tube contains 2 mL of *v*NAT® reagent, which efficiently lyses cells, releases nucleic acids, and preserves them for downstream molecular diagnostic applications. The reagent also rapidly inactivates pathogens within 1 minute, reducing the risk of transmission and ensuring biosafety.

Clinical specimens can be directly transferred into the *v*NAT® Transfer Tube, where nucleic acids remain stabilized for molecular testing. The preserved sample is compatible with Real-Time PCR (qPCR) assays without the need for separate nucleic acid extraction, enabling rapid and efficient molecular diagnostics.

The *v*NAT® Transfer Tube is intended for professional use in sampling and sample storage environments of the healthcare providers.

3. Analytical Specifications

*v*NAT® Transfer Tube is validated for RT-qPCR based test kits and panels produced by Bioeksen AR GE Teknolojileri A.Ş.

4. Sampling Protocol

Nasopharyngeal, oropharyngeal, throat, rectal, vaginal, cervical, urethral, urogenital, endocervical, penile, and conjunctival swab samples shall be collected by a healthcare provider in accordance with the specimen collection guidelines. The swab samples should be placed immediately into the *v*NAT® Transfer Tube.

5. Collection, Storage and Shipment of Clinical Specimens

The specimen should be stored at +2 °C to +8 °C and be shipped to the laboratory with the ice pack. If a specimen is frozen at -20 °C or lower temperature, it should be shipped to the laboratory with dry ice.

Specimens in the *v*NAT® Transfer Tube can be stored at +15°C to +30 °C for up to 72 hours and +2 °C to +8 °C for up to 3 months after collection. If a delay in the RT-qPCR test is expected, the specimen should be stored at -20 °C or lower in accordance with national/international clinical specimen collection regulations.

- One minute after the sampling, the samples 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.

6. Explanation of Symbol

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
CE	European Conformity CE Mark	IVD	*In vitro* diagnostic *medical device*		Keep away from sunlight
	Manufacturer	LOT	Batch code		Keep dry
	Use-by date	REF	Catalogue number		Caution
	Temperature limit	NON STERILE	Non-*sterile*	2	Do not re-use
	Keep it upright		Consult *instructions for use* or consult electronic *instructions for use*		

This Package Insert (PIS) document has been prepared as a single-page leaflet in accordance with the current packaging size and printing techniques. It provides essential information for the safe and correct use of the product. A comprehensive and detailed most updated Instructions for Use (IFU), prepared in accordance with applicable regulatory requirements, is available upon request at ifu@bioeksen.com.tr.

7. MANUFACTURER AND TECHNICAL SUPPORT

Bioeksen AR GE Teknolojileri A.Ş
Address: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34475 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 promptly report any serious incidents to us (via vigilance@bioeksen.com.tr), distributor or the relevant competent authority in the respective Member State.

ALL RIGHTS RESERVED

Sadece in vitro diagnostik kullanım içindir.
Sadece profesyonel kullanım içindir.

Kat No: BS–NA–513m–100

*v*NAT® Transfer Tüpü

Kullanım Talimatı

CE IVD

1. Kit İçeriği

Tablo 1. Kit İçeriği

İçerik	Kullanım Amacı	Miktar
*v*NAT® Transfer Tube	Nükleik asit saklama ve stabilizasyonu	100 Tüp

Tablo 2. Saklama Koşuları ve Raf Ömrü

İçerik	Transfer Koşulu	Saklama Koşulu	Raf Ömrü
*v*NAT® Transfer Tube	(+2) °C – (+50) °C	(+15) °C – (+30) °C	60 ay

2. Kullanım Amacı

*v*NAT® Transfer Tüpü nazofarengeal, orofarengeal, boğaz, rektal, vajinal, servikal, üretral, ürogenital, endoservikal, penil ve konjonktival sürüntü örneklerinden elde edilen nükleik asitlerin saklanması ve stabilizasyonu için tasarlanmış tek kullanımlık bir in vitro diagnostik (IVD) tıbbi cihazdır.

Her bir tüp, hücreleri etkili bir şekilde parçalayan, nükleik asitleri serbest bırakan ve bunları moleküler tanı uygulamaları için koruyan 2 mL *v*NAT® reaktifi içerir. Reaktif ayrıca patojenleri 1 dakika içinde hızla inaktive ederek bulaşma riskini azaltır ve biyogüvenliği sağlar.

Klinik numuneler doğrudan *v*NAT® Transfer Tüpü'ne aktarılabilir ve bu tüpte nükleik asitler moleküler testler için stabilize halde kalır. Korunan örnek, ayrı bir nükleik asit ekstraksiyonuna gerek kalmadan Gerçek Zamanlı PCR (qPCR) analizleriyle uyumludur ve hızlı ve verimli moleküler tanı sağlar.

*v*NAT® Transfer Tüpü, sağlık hizmeti sağlayıcılarının numune alma ve numune saklama ortamlarında profesyonel kullanım için tasarlanmıştır.

3. Analitik Özellikler

*v*NAT® Transfer Tüpü, Bioeksen Ar Ge Teknolojileri A.Ş. tarafından üretilen RT-qPCR tabanlı test kitleri ve panelleri için valide edilmiştir.

4. Örneklem Protokolü

Nazofaringeal sürüntü, orofaringeal sürüntü, nazal sürüntü ve oral/tükürük sürüntü, vajinal sürüntü, ürogenital sürüntü, penil sürüntü, endoservikal sürüntü, deri lezyonu sürüntü, konjonktival sürüntü örnekleri, numune toplama kurallarına uygun olarak bir sağlık uzmanı tarafından toplanacaktır. Sürüntü örnekleri hemen *v*NAT® Transfer Tüpü'ne yerleştirilmelidir.

5. Örnek Taşıma, Saklama ve Analiz Protokolü

Örnekler +2 ila +8°C'de saklanmalı ve buz paketi ile laboratuvara gönderilmelidir. Eğer örnek -20°C veya daha düşük sıcaklıkta dondurulmuşsa, laboratuvara kuru buz ile gönderilmelidir.

*v*NAT® Transfer Tüpü'ne alınan örnekler, toplandıktan sonra 72 saate kadar +15 ila +30 °C'de, 3 aya kadar +2 ila +8°C'de saklanabilir. Daha uzun süreler için, örnekler ulusal/uluslararası örnek toplama yönetmeliğine göre -20°C veya daha düşük sıcaklıkta saklanmalıdır.

- Sürüntünün tüpe yerleştirilmesinden 1 dakika sonra, *v*NAT® Transfer Tüpü ndeki örnekler doğrudan RT-qPCR reaksiyonunda kullanılabilir.
- Örneği RT-qPCR reaksiyonuna eklemeden önce tüp en yüksek hızda 3 saniye vortekslenmelidir.

6. Sembollerin Açıklaması

Sembol	Sembolün Başlığı	Sembol	Sembolün Başlığı	Sembol	Sembolün Başlığı
CE	Avrupa Uygunluğu CE işareti	IVD	*In vitro* tanı *tıbbi cihazı*		Güneş ışığından uzak tutun
	Üretici	LOT	Lot numarası		Kuru tutun
	Son kullanma tarihi AA-YYYY	REF	Katalog numarası		Dikkat
	Sıcaklık sınırı	NON STERILE	*Steril* değil	2	Tekrar kullanmayın
	Dik tutun		*Kullanım talimatına* bakın veya elektronik *kullanım talimatına* bakın		

Bu Paket Kullanım Talimatı (PIS) belgesi, mevcut ambalaj boyutu ve baskı tekniklerine uygun olarak tek sayfalık bir broşür şeklinde hazırlanmıştır. Ürünün güvenli ve doğru kullanımı için gerekli temel bilgileri sunar. İlgili düzenleyici gerekliliklere uygun olarak hazırlanmış, kapsamlı ve ayrıntılı en güncel Kullanım Talimatı (KK/IFU) talep üzerine ifu@bioeksen.com.tradresinden temin edilebilir.

7. ÜRETİCİ VE TEKNİK DESTEK

Bioeksen AR GE Teknolojileri A.Ş.
Adres: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34475 Sarıyer/İstanbul-TÜRKİYE
Tel: +90 (212) 285 10 17, **Faks:** +90 (212) 285 10 18
Web: www.bioeksen.com.tr, **E-posta:** info@bioeksen.com.tr,
Teknik Destek: support@bioeksen.com.tr

Kullanıcıya Bildirim: Lütfen herhangi bir ciddi olayı derhal bize (vigilance@bioeksen.com.tr aracılığıyla), distribütöre veya ilgili Üye Devletteki yetkili otoriteye bildiriniz.

TÜM HAKLARI SAKLIDIR