

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

Holds Certificate Number:

MD 69326

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2002-10-25

Latest Revision Date: 2021-04-13

Effective Date: 2021-04-14

Expiry Date: 2024-04-13



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Page: 1 of 2

...making excellence a habit.™

Certificate No: **MD 69326**

Location

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Sunderland Enterprise Park
Colima Avenue
Sunderland
SR5 3XB
United Kingdom

Registered Activities

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.



Original Registration Date: 2002-10-25

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Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.



CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT UNITED KINGDOM

UL LLC®(UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

ISO 13485:2016

EN ISO 13485:2016

The manufacture of in vitro diagnostic blood grouping reagents. The purchase for resale of in vitro diagnostic serology test kit.

Authorized by



Michael J. Windler, P.E.

Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
Life and Health Sciences, UL LLC



Check Certificate
Status: [here](#)

File Number	A12241	Cycle Start	May 23, 2020
Certificate Number	1458.200523	Effective Date	May 23, 2020
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2023

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC.



UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA



Certificate

No. Q6 003096 0003 Rev. 01

Holder of Certificate: **Guangzhou iCare
Medical Technology Co., Ltd.**
First floor A No.8
Lianhua Port Industrial Zone
Lotus Mountain Bonded Area, Shilou Town
Panyu District
511440 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Production and Distribution of
Insulin pen needles, Safety Lancets,
Disposable Insulin Syringes (with Needle),
Alcohol Pads**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q6 003096 0003 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q6_003096_0003_Rev_01)

Report No.: SH21124101

Valid from: 2021-08-27

Valid until: 2024-06-28

Date, 2021-08-27



Christoph Dicks
Head of Certification/Notified Body



Product Service

Certificate

No. Q6 003096 0003 Rev. 01

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

Facility(ies): Guangzhou iCare Medical Technology Co., Ltd.
First floor A No.8, Lianhua Port Industrial Zone, Lotus Mountain
Bonded Area, Shilou Town, Panyu District, 511440 Guangzhou,
PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate



Certificate

No. Q6 003096 0003 Rev. 01

Holder of Certificate: **Guangzhou iCare
Medical Technology Co., Ltd.**
First floor A No.8
Lianhua Port Industrial Zone
Lotus Mountain Bonded Area, Shilou Town
Panyu District
511440 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

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Facility(ies): Guangzhou iCare Medical Technology Co., Ltd.
First floor A No.8, Lianhua Port Industrial Zone, Lotus Mountain
Bonded Area, Shilou Town, Panyu District, 511440 Guangzhou,
PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate



CERTIFICATE

EC No 1434-IVDD-134/2019
Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Lorne Laboratories Ltd

**Unit 1 Cutbush Park Industrial Estate, Danehill,
Lower Earley, Berkshire RG6 4UT, United Kingdom**

for the design, manufacture and final inspection of in vitro diagnostic medical devices
List A

Products list in attachments: 1

complies with requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended)
implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 10.04.2019 to 23.05.2023

The date of issue of the Certificate: 10.04.2019

The date of the first issue of the Certificate: 10.04.2019



Application No: 649/2019
Module: H7


mgr Anna Wyroba
Vice-President



Certificate No **1434-IVDD-134/2019**
Issued under the Contract No **MD-59/2019**
Bears the PCBC hologram.
Warsaw, 10.04.2019



ANNEX 1 TO CERTIFICATE
VALID ONLY WITH CERTIFICATE
No 1434-IVDD-134/2019

The products detailed below are covered under the scope of this certificate:

Name:	GMDN code:
Anti-A Monoclonal, 600010	52532
Anti-B Monoclonal, 610010	52538
Anti-A,B Monoclonal, 620010	46442
Anti-D Clone 1 Monoclonal, 730010	52647
Anti-D Clone 2 Monoclonal, 710010	52647
Anti-D Duoclone Monoclonal, 740010	52647
Anti-C Monoclonal, 690005	52546
Anti-E Monoclonal, 691005	52562
Anti-c Monoclonal, 692005	52547
Anti-e Monoclonal, 693005	52563
Anti-C+D+E Monoclonal, 700010	52550
Anti-K Monoclonal, 760010	52593




mgr Anna Wyroba
Vice-President



Annex 1 to certificate No. **1434-IVDD-134/2019**
Issued under the Contract No. **MD-59/2019**
Bears the PCBC hologram.
Warsaw, 10.04.2019



МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ БЕЛАРУСЬ
РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ

№ **ИМ-7.100258/1808**

Настоящее удостоверение выдано

ООО МиниМед, РОССИЙСКАЯ ФЕДЕРАЦИЯ

и является подтверждением того, что Министерством здравоохранения Республики Беларусь зарегистрированы

Масло иммерсионное: набор реагентов "Масло иммерсионное", ТУ 9398-011-29508133-2009

Тип: изделия медицинского назначения

Изготовитель: **ООО МиниМед, РОССИЙСКАЯ ФЕДЕРАЦИЯ**

и разрешены к производству, реализации и медицинскому применению на территории Республики Беларусь

В соответствии с инструкцией по использованию

Регистрационный номер: **Мн-7.117015/7.002-1803**


Регистрационное удостоверение не является обязательством к закупке данных изделий медицинского назначения.

Дата государственной регистрации:
30.08.2018 г.

Действительно до:
30.08.2023 г.

Заместитель Министра




В.Д. Шило

Ходас ОС

№ 0026050

EC Certificate

**Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)**

Registration No.: HL 1038121-1

Manufacturer: MACHEREY-NAGEL GmbH & Co. KG
Valenciener Str. 11
52355 Düren
Germany

Products: Products for self-testing
- Single and multi-parameter disposable test strips for urine analysis
- Indicator test strips and papers for measurement of pH in urine

Replaces Certificate, Registration No.: HL 60119814 0001

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 1106581-20

Effective date: 2022-02-16

Expiry date: 2025-05-26

Issue date: 2022-02-16



Dipl.-Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

EC Certificate

**Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)**

Registration No.: HL 1038121-1

Manufacturer: MACHEREY-NAGEL GmbH & Co. KG
Valenciener Str. 11
52355 Düren
Germany

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	MACHEREY-NAGEL GmbH & Co. KG Valenciener Str. 11 52355 Düren Germany	Design and development, manufacture and quality control
/02	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 1106581-20

Effective date: 2022-02-16

Expiry date: 2025-05-26

Issue date: 2022-02-16



TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Dipl.-Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

Product List – CE Marked

Certified by

ISO 13485:2016

EC – Directive 98 / 79 EC
For In-Vitro-Diagnostics

2020-02-1

NovaLisa®

Virology

Prod. No.

Name

ADVA0010	Adenovirus IgA
ADVG0010	Adenovirus IgG
ADVM0010	Adenovirus IgM
CHIG0590	Chikungunya Virus IgG capture
CHIM0590	Chikungunya Virus IgM μ -capture
CMVG0110	Cytomegalovirus (CMV) IgG
ACMV7110	Avidity Cytomegalovirus (CMV) IgG
CMVM0110	Cytomegalovirus (CMV) IgM
DENG0120	Dengue Virus IgG
DENM0120	Dengue Virus IgM
DVM0640	Dengue Virus IgM μ -capture
NS1D4020	Dengue Virus NS1 Antigen
EBVA0150	Epstein-Barr Virus (VCA) IgA
EBVG0150	Epstein-Barr Virus (VCA) IgG
AEBV7150	Avidity Epstein-Barr Virus (VCA) IgG
EBVM0150	Epstein-Barr Virus (VCA) IgM
EBVG0580	Epstein-Barr Virus (EBNA) IgG
HANG0670	Hantavirus IgG
HANM0670	Hantavirus IgM
HEVG0780	Hepatitis E Virus (HEV) IgG
HEVM0780	Hepatitis E Virus (HEV) IgM
HSVG0250	Herpes simplex Virus 1+2 (HSV) IgG
HSVM0250	Herpes simplex Virus 1+2 (HSV) IgM
HSV1G0500	Herpes simplex Virus 1 (HSV 1) IgG
HSV1M0500	Herpes simplex Virus 1 (HSV 1) IgM
HSV2G0540	Herpes simplex Virus 2 (HSV 2) IgG
HSV2M0540	Herpes simplex Virus 2 (HSV 2) IgM
INFA0290	Influenza Virus A IgA
INFG0290	Influenza Virus A IgG
INFM0290	Influenza Virus A IgM
INFA0300	Influenza Virus B IgA
INFG0300	Influenza Virus B IgG
INFM0300	Influenza Virus B IgM
MEAG0330	Measles Virus IgG
AMEA7330	Avidity Measles Virus IgG
MEAM0330	Measles Virus IgM
MUMG0340	Mumps Virus IgG
MUMM0340	Mumps Virus IgM
PAIA0360	Parainfluenza Virus 1,2,3 IgA
PAIG0360	Parainfluenza Virus 1,2,3 IgG
PARG0370	Parvovirus B 19 IgG
PARM0370	Parvovirus B 19 IgM
RSVA0380	Respiratory syncytial Virus IgA
RSVG0380	Respiratory syncytial Virus IgG
RSVM0380	Respiratory syncytial Virus IgM
RUBG0400	Rubella Virus IgG

ARUB7400	Avidity Rubella Virus IgG
RUBM0400	Rubella Virus IgM μ -capture
TICG0440	TBE / FSME IgG
TICM0440	TBE / FSME IgM
PTICG044	TBE / FSME IgG plus
VZVA0490	Varicella-Zoster Virus (VZV) IgA
VZVG0490	Varicella-Zoster Virus (VZV) IgG
VZVM0490	Varicella-Zoster Virus (VZV) IgM
ZVG0790	Zika Virus IgG capture
ZVM0790	Zika Virus IgM μ -capture

NovaLisa[®] **Bacteriology**

Prod. No.	Name
BAR0900	Bartonella
BOPA0030	Bordetella pertussis IgA
BOPG0030	Bordetella pertussis IgG
BOPM0030	Bordetella pertussis IgM
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM
BRUG0050	Brucella IgG
BRUM0050	Brucella IgM
CHLA0070	Chlamydia trachomatis IgA
CHLG0070	Chlamydia trachomatis IgG
CHLM0070	Chlamydia trachomatis IgM
CHLA0510	Chlamydia pneumoniae IgA
CHLG0510	Chlamydia pneumoniae IgG
CHLM0510	Chlamydia pneumoniae IgM
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebacterium diphtheriae toxin 5S IgG plus
COX1G0600	Coxiella burnetii (Q-Fever) Phase 1 IgG
COX2G0600	Coxiella burnetii (Q-Fever) Phase 2 IgG
COX2M0600	Coxiella burnetii (Q-Fever) Phase 2 IgM
HELA0220	Helicobacter pylori IgA
HELG0220	Helicobacter pylori IgG
PHELA022	Helicobacter pylori IgA plus
PHELG022	Helicobacter pylori IgG plus
LEGG0650	Legionella Pneumophila IgG
LEGM0650	Legionella Pneumophila IgM
LEPG0660	Leptospira IgG
LEPM0660	Leptospira IgM

MYCA0350	Mycoplasma pneumoniae IgA
MYCG0350	Mycoplasma pneumoniae IgG
MYCM0350	Mycoplasma pneumoniae IgM
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani toxin 5S IgG
PTETG043	Clostridium tetani toxin 5S IgG plus

NovaLisa® Parasites

Prod. No.	Name
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
ENTG0140	Entamoeba histolytica IgG
LEIG0310	Leishmania infantum IgG
MAL0620	Malaria
TOXA0460	Toxoplasma gondii IgA
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TOXM0460	Toxoplasma gondii IgM μ -capture

NovaLisa® Worms

Prod. No.	Name
ASCG0020	Ascaris lumbricoides IgG
ECHG0130	Echinococcus IgG
FIL0760	Filariasis
SCHG0410	Schistosoma mansoni IgG
SCHM0410	Schistosoma mansoni IgM
STRO0690	Strongyloides
TAEG0420	Taenia solium IgG
TOCG0450	Toxocara canis IgG
TRIG0480	Trichinella spiralis IgG

NovaLisa® Fungi

Prod. No.	Name
ASPG0680	Aspergillus fumigatus IgG
ASPM0680	Aspergillus fumigatus IgM
CANA0060	Candida albicans IgA
CANG0060	Candida albicans IgG
CANM0060	Candida albicans IgM

NovaLisa® Hormones

THYROID HORMONES

(ELISAs for the determination of thyroid hormones and antibodies)

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO
FT41050	Free T4
TSH1030	TSH

Hormones

STEROID HORMONES

(ELISAs for the determination of steroid hormones in plasma and serum)

Prod. No.	Name
DNOV001	Cortisol
DNOV002	Testosterone
DNOV003	17 beta-Estradiol
DNOV004	17-OH Progesterone
DNOV005	DHEA-S
DNOV006	Progesterone
DNOV008	Androstenedione
DNOV009	Free Testosterone
DNOV011	Total Estriol
DNOV012	Aldosterone

STEROID HORMONES IN URINE

(ELISAs for the determination of steroid hormones in urine)

Prod. No.	Name
DNOV010	Urinary Cortisol

STEROID HORMONES IN SALIVA

(ELISAs for the determination of steroid hormones in saliva)

Prod. No.	Name
DSNOV20	Cortisol Saliva
DSNOV21	Testosterone Saliva
DSNOV24	DHEA-S Saliva
DSNOV27	Androstenedione Saliva

PROTEIN HORMONES

(ELISAs for the determination of proteins in plasma and serum)

Prod. No.	Name
DNOV030	LH
DNOV031	FSH
DNOV032	Prolactin
DNOV033	AFP
DNOV034	beta HCG

THYROID HORMONES

(ELISAs for the determination of thyroid hormones and antibodies)

Prod. No.	Name
DNOV051	Free T3
DNOV053	Total T3
DNOV054	Total T4
DNOV057	Thyroglobulin

DIABETES MONITORING

(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV111	Insulin
DNOV112	C-Peptide

CIRCULATING IMMUNO COMPLEXES

(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV093	CIC-C1q
DNOV094	CIC-C3d
DNOV096	CH-50

TUMOR MARKERS

(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV 060	CEA
DNOV061	CA 125
DNOV062	CA 15-3
DNOV063	CA 19-9

MISCELLANEOUS

(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
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DNOV100	Ferritin
DNOV101	HGH
DNOV102	IgE

NovoLisa[®] Autoimmune

Autoimmune

(ELISAs for the determination of specific autoimmune antibodies)

Prod. No.	Name
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ATG1010	Anti-TG
ATPO1020	Anti-TPO

Rheumatology

(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
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RFM3010	Rheumatoid Factor IgM
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NovoLisa[®] Recombinant Antigens

Prod. No.	Name
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BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
HANG0670	Hantavirus IgG
HANM0670	Hantavirus IgM
HELA0220	Helicobacter pylori IgA
PHELA022	Helicobacter pylori IgA plus
HEVG0780	Hepatitis E Virus (HEV) IgG
HEVM0780	Hepatitis E Virus (HEV) IgM
HSV1G0500	Herpes simplex Virus 1 (HSV 1) IgG
HSV1M0500	Herpes simplex Virus 1 (HSV 1) IgM
HSV2G0540	Herpes simplex Virus 2 (HSV 2) IgG
HSV2M0540	Herpes simplex Virus 2 (HSV 2) IgM
MAL0620	Malaria
STRO0690	Strongyloides
ZVG0790	Zika Virus IgG capture
ZVM0790	Zika Virus IgM μ -capture

NovaLisa[®] Quantitative Assays (WHO standardized)

Prod. No.	Name
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebacterium diphtheriae toxin 5S IgG plus
RFM3010	Rheumatoid Factor IgM
RUBG0400	Rubella Virus IgG
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani toxin 5S IgG
PTETG043	Clostridium tetani toxin 5S IgG plus
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TSH1030	TSH

NovaLisa[®] Quantitative Assays

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebacterium diphtheriae toxin 5S IgG plus
FT41050	Free T4
HELA0220	Helicobacter pylori IgA
HELG0220	Helicobacter pylori IgG
PHELA022	Helicobacter pylori IgA plus
PHELG022	Helicobacter pylori IgG plus
RFM3010	Rheumatoid Factor IgM
RUBG0400	Rubella Virus IgG
ARUB7400	Avidity Rubella Virus IgG
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani 5S toxin IgG
PTETG043	Clostridium tetani toxin 5S IgG plus
TICG0440	TBE / FSME IgG
PTICG044	TBE / FSME IgG plus
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TSH1030	TSH

Antigen Assays

Prod. No.	Name
NS1D4020	Dengue Virus NS1 Antigen

NovaLisa® IgM μ -capture Assays

Prod. No.	Name
CHIM0590	Chikungunya Virus IgM μ -capture
DVM0640	Dengue Virus IgM μ -capture
RUBM0400	Rubella Virus IgM μ -capture
TOXM0460	Toxoplasma gondii IgM μ -capture
ZVM0790	Zika Virus IgM μ -capture

NovaLisa® Antibody Assays

Prod. No.	Name
ASCG0020	Ascaris lumbricoides IgG
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
ENTG0140	Entamoeba histolytica IgG
LEIG0310	Leishmania infantum IgG
MAL0620	Malaria
STRO0690	Strongyloides
TAEG0420	Taenia solium IgG
TOCG0450	Toxocara canis IgG
TRIG0480	Trichinella spiralis IgG

NovaLisa® Avidity Assays

Prod. No.	Name
ACMV7110	Avidity Cytomegalovirus (CMV) IgG
AEBV7150	Avidity Epstein-Barr Virus (VCA) IgG
AMEA7330	Avidity Measles Virus IgG
ARUB7400	Avidity Rubella Virus IgG
ATOX7460	Avidity Toxoplasma gondii IgG

NovaLisa[®] Liquor Diagnostic

Prod. No.	Name
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM

EG Konformitätserklärung**EC Declaration of Conformity**

ORGENTEC Diagnostika GmbH
Carl-Zeiss-Straße 49-51, 55129 Mainz, GERMANY

Wir erklären in eigener Verantwortung, dass das ORGENTEC Produkt
We declare in our sole responsibility that the ORGENTEC product

ORG 516 AMA-M2

zur quantitativen in-vitro-Bestimmung bestimmt ist und entsprechend Art. 9 Abs. Satz 1 der Europäischen Richtlinie 98/79/EG als „Sonstige Produkte“ (non-A, non-B, keine Selbstanwendung) klassifiziert ist.

as intended for use in quantitative in vitro determination is classified as "Other Devices" (non-A, non-B, no self-testing device) according to article 9 paragraph 1 sentence 1 of the European directive 98/79/EC.

Das Produkt stimmt mit den Grundlegenden Anforderungen und allen zutreffenden Bestimmungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über in-vitro-Diagnostika überein. Die Konformität zur Richtlinie wurde durch ein Konformitätsbewertungsverfahren nach Anhang III der Richtlinie festgestellt.

This product is conform with the essential requirements and meet the appropriate provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Conformity was proved by a conformity assessment procedure referred to in annex III of the directive.

Liste angewandeter Normen:

List of standards applied for CE marking:

EN ISO 13485, EN ISO 14971, EN ISO 18113, EN ISO 15223, EN ISO 23640, EN 13612.

Mainz, 2021-02-05

René Betz
Head of Regulatory Affairs



Gültig ab / Valid from 2021-02-05 bis / until 2024-02-28

Notification pursuant to §25 Abs. 3 Nr. 3 Medical Devices Act, MPG

Type: Reagent

EDMS 12-10-90-02-00

GMDN 43106

ORG 516_CE declaration of conformity_QM120330_2021-02-05_8

F4.01B Declaration of conformity

ORGENTEC Diagnostika GmbH

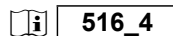
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ORG 516 AMA-M2

INTENDED PURPOSE

AMA-M2 is an ELISA test system for the quantitative measurement of IgG class autoantibodies against mitochondrial M2 subtype antigen in human serum or plasma. This product is intended for professional in vitro diagnostic use only.

The test is used as an aid in the differential diagnosis of primary biliary cirrhosis (PBC). In patients with other autoimmune diseases occurrence of AMA antibodies may be related to the development or association of PBC. Evaluation of a test result should always take into account all clinical and laboratory diagnostic findings.

SYMBOLS USED ON LABELS

	In vitro diagnostic medical device		Microplate
	Manufacturer		Calibrator
	Catalogue number		Calibrator
	Sufficient for 96 determinations		Calibrator
	Batch code		Calibrator
	Use by		Calibrator
	Temperature limitation		Calibrator
	Keep away from sunlight		Control positive
	Do not reuse		Control negative
	Date of manufacture		Sample Buffer P
	CE marked according to 98/79/EC		Enzyme Conjugate
	Consult instructions for use		TMB Substrate
	Electronic Instruction For Use: version		Stop solution
			Wash Buffer
			Ready to use



PRINCIPLE OF THE TEST

Highly purified mitochondrial M2 subtype (PDC-E2, BCOADC-E2, OGDC-E2) antigen is bound to microwells. The determination is based on an indirect enzyme linked immune reaction with the following steps: Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subsequently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stops the reaction generating a yellow end-product. The intensity of the yellow color correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
 - Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
 - Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
 - Avoid contact with the substrate TMB (3,3',5,5'-Tetramethyl-benzidine).
 - Stop solution contains acid, classification is non-hazardous. Avoid contact with skin.
 - Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
 - Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.
- During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:
- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
 - Personal precautions, protective equipment and emergency procedures:
Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.
 - Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
 - Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
 - For disposal of laboratory waste the national or regional legislation has to be observed.
- Observe the guidelines for performing quality control in medical laboratories by assaying control sera.

CONTENTS OF THE KIT

ORG 516		Sufficient for 96 determinations
MICROPLATE	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Product code on module: AMA
CALIBRATOR A	1x 1.5 ml	Calibrator A 0 IU/ml, containing serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR B	1x 1.5 ml	Calibrator B 12.5 IU/ml, containing AMA-M2 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR C	1x 1.5 ml	Calibrator C 25 IU/ml, containing AMA-M2 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR D	1x 1.5 ml	Calibrator D 50 IU/ml, containing AMA-M2 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR E	1x 1.5 ml	Calibrator E 100 IU/ml, containing AMA-M2 antibodies in a serum/buffer matrix (PBS, BSA, NaN3 0.09%), yellow. Ready to use.
CALIBRATOR F	1x 1.5 ml	Calibrator F 200 IU/ml, containing AMA-M2 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use.
CONTROL +	1x 1.5 ml	Control positive, containing AMA-M2 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
CONTROL -	1x 1.5 ml	Control negative, containing AMA-M2 antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN3 0.09%), yellow. Ready to use. The concentration is specified on the certificate of analysis.
DILUENT	20 ml	Sample Buffer P, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
CONJUGATE	15 ml	Enzyme Conjugate containing anti-human IgG antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
TMB	15 ml	TMB Substrate; containing 3,3', 5,5'- Tetramethylbenzidin, colorless. Ready to use.
STOP	15 ml	Stop solution; contains acid. Ready to use.
WASH	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.
	1	Certificate of Analysis

MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
 - Data reduction software
 - Multi-channel dispenser or repeatable pipette for 100 µl
 - Vortex mixer
 - Pipettes for 10 µl, 100 µl and 1000 µl
 - Laboratory timing device
 - Distilled or deionised water
 - Measuring cylinder for 1000 ml and 100 ml
 - Plastic container for storage of the wash solution
- This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store microplate sealed and dessicated in the clip bag provided.
- Shelf life of the unopened test kit is 18 months from day of production.
Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C.
We recommend consumption on the same day.

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.
- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, perform the test without interruption.
- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

PREPARATION OF REAGENTS

WASH
Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

DILUENT
Sample Buffer P: Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.

TEST PROCEDURE

Prepare enough microplate modules for all calibrators / controls and patient samples.

- Pipette **100 µl** of calibrators, controls and prediluted patient samples into the wells.
Incubate for **30 minutes** at room temperature (20-28 °C).
Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
- Dispense **100 µl** of enzyme conjugate into each well.
Incubate for **15 minutes** at room temperature.
Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
- Dispense **100 µl** of TMB substrate solution into each well.
Incubate for **15 minutes** at room temperature
- Add 100 µl** of stop solution to each well of the modules
Incubate for **5 minutes** at room temperature.
Read the optical density at 450 nm (reference 600-690nm) and calculate the results.
The developed colour is stable for at least 30 minutes. Read during this time.

Example for a pipetting scheme:

	1	2	3	4	5	6	7	8	9	10	11	12
A	A	P1										
B	B	P2										
C	C	P3										
D	D											
E	E											
F	F											
G	C+											
H	C-											

P1, ... patient sample A-F calibrators C+, C- controls

VALIDATION

Test results are valid if the optical densities at 450 nm for calibrators / controls and the results for controls comply with the reference ranges indicated on the Certificate of Analysis enclosed in each test kit.
If these quality control criteria are not met the assay run is invalid and should be repeated.

CALCULATION OF RESULTS

For quantitative results plot the optical density of each calibrator versus the calibrator concentration to create a calibration curve. The concentration of patient samples may then be estimated from the calibration curve by interpolation.

Using data reduction software a 4-Parameter-Fit with lin-log coordinates for optical density and concentration is the data reduction method of choice.

PERFORMANCE CHARACTERISTICS

Calibration

The assay system is calibrated against the international reference preparation WHO 67/183 for AMA-M2 as 100 IU/ml.

Measuring range

The calculation range of this ELISA assay is 0 - 200 IU/ml

Expected values

In a normal range study with samples from healthy blood donors the following ranges have been established with this ELISA assay: Cut-off 10 IU/ml

Interpretation of results

Negative: < 10 IU/ml
Positive: ≥ 10 IU/ml

Linearity

Samples containing high levels of specific antibody were serially diluted in sample buffer to demonstrate the dynamic range of the assay and the upper / lower end of linearity. Activity for each dilution was calculated from the calibration curve using a 4-Parameter-Fit with lin-log coordinates.

Sample	Dilution	Observed IU/ml	Expected IU/ml	O/E [%]
WHO	1:100	108.5	100.0	109
.	1:200	51.2	50.0	102
.	1:400	25.2	25.0	101
.	1:800	12.8	12.5	102
.	1:1600	6.1	6.3	98
.	1:3200	3.1	3.1	99
1	1:100	49.5	49.5	100
.	1:200	25.0	24.8	101
.	1:400	12.2	12.4	99
.	1:800	5.9	6.2	95

Limit of detection

Functional sensitivity was determined to be: 1 IU/ml

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.

Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 6 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay		
Sample	Mean IU/ml	CV %
1	39.8	7.0
2	81.3	3.8
3	177.3	3.6

Inter-Assay		
Sample	Mean IU/ml	CV %
1	40.1	6.2
2	84.6	11.8
3	180.4	3.8

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

Study population	n	n Pos	%
Primary biliary cirrhosis (PBC)	143	139	97.2
Rheumatoid Arthritis	60	1	1.7
Normal human sera	267	18	6.7

		Clinical Diagnosis		
		POS	NEG	
ORG 516	POS	139	19	470
	NEG	4	308	
Sensitivity:		143	327	470
Sensitivity:		97.2 %		
Specificity:		94.2 %		
Overall agreement:		95.1 %		

LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually.

The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establish its own ranges according to ISO 15189 or other applicable laboratory guidelines.

REFERENCES

1. Berg, P.A. and Klein, R. Diagnose der primär-biliären Zirrhose. IVD Nachrichten 1990; 1/1: 6 -7.
2. Berg, P.A. and Klein, R. Heterogeneity of anti-mitochondrial antibodies. Sem. Liver Dis. 1989; 9: 103 - 116.
3. Berg, P.A. and Klein, R. Immunology of primary biliary cirrhosis. Ballière's Clin.Gastroenterol. 1987; 1: 675 - 706.
4. Baum, H. and Palmer, C. The PBC specific antigen. Mol. Aspects Med. 1985; 8: 201 - 234.
5. Fussey, S.P.M., Guest, J.R., James, O.F W. et al. Identification and analysis of the major M2 autoantigens in primary biliary cirrhosis. PNAS, USA 1988; 85: 8654 - 8658.

Notice to the user (European Union):

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established .

Change Control

Former version: *ORG 516_IFU_EN_QM113145_2013-12-16_2.1* Reason for revision: *Introduction electronic IFU on homepage*

- 1 Pipet **100 µl** calibrator, control or patient sample
→ Incubate for **30 minutes** at room temperature
→ Discard the contents of the wells and wash 3 times with **300 µl** wash solution
- 2 Pipet **100 µl** enzyme conjugate
→ Incubate for **15 minutes** at room temperature
→ Discard the contents of the wells and wash 3 times with **300 µl** wash solution
- 3 Pipet **100 µl** substrate solution
→ Incubate for **15 minutes** at room temperature
- 4 Add **100 µl** stop solution
→ Leave untouched for **5 minutes**
→ Read at **450 nm**

ORGENTEC Diagnostika GmbH

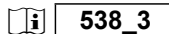
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ORG 538 ANAscreen

INTENDED PURPOSE

ANAscreen is an ELISA-based test system for the qualitative measurement of IgG class autoantibodies against SS-A 60, SS-A 52, SS-B, RNP-70, Sm, RNP/Sm, Scl-70, centromere B, Jo-1 in human serum or plasma samples. This product is intended for professional in vitro diagnostic use only.

The test is used for screening of patients with suspected autoimmune connective tissue diseases, e.g. systemic lupus erythematosus, mixed connective tissue disease, Sjogren's syndrome, scleroderma, and polymyositis/dermatomyositis. Evaluation of a test result should always take into account all clinical and laboratory diagnostic findings.

SYMBOLS USED ON LABELS

	In vitro diagnostic medical device		Microplate
	Manufacturer		Calibrator
	Catalogue number		Control negative
	Sufficient for 96 determinations		
	Batch code		
	Use by		
	Temperature limitation		
	Keep away from sunlight		
	Do not reuse		Sample Buffer P
			Enzyme Conjugate
	Date of manufacture		
	CE marked according to 98/79/EC		TMB Substrate
			Stop solution
	Consult instructions for use		Wash Buffer
	Electronic Instruction For Use: version		Ready to use

PRINCIPLE OF THE TEST

A mixture of purified antigens SS-A 60, SS-A 52, SS-B, RNP-70, Sm, RNP/Sm, Scl-70, Centromere B and Jo-1 is coated on to microwells.

The determination is based on an indirect enzyme linked immune reaction with the following steps:

Specific antibodies in the patient sample bind to the antigen coated on the surface of the reaction wells. After incubation, a washing step removes unbound and unspecifically bound serum or plasma components. Subsequently added enzyme conjugate binds to the immobilized antibody-antigen-complexes. After incubation, a second washing step removes unbound enzyme conjugate. After addition of substrate solution the bound enzyme conjugate hydrolyses the substrate forming a blue coloured product. Addition of an acid stops the reaction generating a yellow end-product. The intensity of the yellow color correlates with the concentration of the antibody-antigen-complex and can be measured photometrically at 450 nm.

WARNINGS AND PRECAUTIONS

- All reagents of this kit are intended for professional in vitro diagnostic use only.
- Components containing human serum were tested and found negative for HBsAg, HCV, HIV1 and HIV2 by FDA approved methods. No test can guarantee the absence of HBsAg, HCV, HIV1 or HIV2, and so all human serum based reagents in this kit must be handled as though capable of transmitting infection.
- Bovine serum albumin (BSA) used in components has been tested for BSE and found negative.
- Avoid contact with the substrate TMB (3,3',5,5'-Tetramethyl-benzidine).
- Stop solution contains acid, classification is non-hazardous. Avoid contact with skin.
- Control, sample buffer and wash buffer contain sodium azide 0.09% as preservative. This concentration is classified as non-hazardous.
- Enzyme conjugate contains ProClin 300 0.05% as preservative. This concentration is classified as non-hazardous.

During handling of all reagents, controls and serum samples observe the existing regulations for laboratory safety regulations and good laboratory practice:

- First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If system fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.
- Personal precautions, protective equipment and emergency procedures: Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.
- Exposure controls / personal protection: Wear protective gloves of nitril rubber or natural latex. Wear protective glasses. Used according to intended use no dangerous reactions known.
- Conditions to avoid: Since substrate solution is light-sensitive. Store in the dark.
- For disposal of laboratory waste the national or regional legislation has to be observed.

Observe the guidelines for performing quality control in medical laboratories by assaying control sera.

CONTENTS OF THE KIT

ORG 538	▽ 96	Sufficient for 96 determinations
MICROPLATE	1	One divisible microplate consisting of 12 modules of 8 wells each. Ready to use. Product code on module: Asc
CALIBRATOR	1x 1.5 ml	Calibrator, containing ANA antibodies in a serum/buffer matrix (PBS, BSA, detergent, NaN ₃ 0.09%), yellow. Ready to use.
CONTROL	1x 1.5 ml	Control negative, containing ANA antibodies serum/buffer matrix (PBS, BSA, detergent, NaN ₃ 0.09%), yellow. Ready to use.
DILUENT	20 ml	Sample Buffer P, containing PBS, BSA, detergent, preservative sodium azide 0.09%, yellow, concentrate (5 x).
CONJUGATE	15 ml	Enzyme Conjugate containing anti-human IgG antibodies, HRP labelled; PBS, BSA, detergent, preservative PROCLIN 0.05%, light red. Ready to use.
TMB	15 ml	TMB Substrate; containing 3,3', 5,5'- Tetramethylbenzidin, colorless. Ready to use.
STOP	15 ml	Stop solution; contains acid. Ready to use.
WASH	20 ml	Wash Buffer, containing Tris, detergent, preservative sodium azide 0.09%; 50 x conc.
i	1	Certificate of Analysis

MATERIALS REQUIRED

- Microplate reader capable of endpoint measurements at 450 nm; optional: reference filter at 620 nm
- Data reduction software
- Multi-channel dispenser or repeatable pipette for 100 µl
- Vortex mixer
- Pipettes for 10 µl, 100 µl and 1000 µl
- Laboratory timing device
- Distilled or deionised water
- Measuring cylinder for 1000 ml and 100 ml
- Plastic container for storage of the wash solution

This ELISA assay is suitable for use on open automated ELISA processors. Each assay has to be validated on the respective automated system. Detailed information is provided upon request.

SPECIMEN COLLECTION, STORAGE AND HANDLING

- Collect whole blood specimens using acceptable medical techniques to avoid hemolysis.
- Allow blood to clot and separate the serum or plasma by centrifugation.
- Test serum should be clear and non-hemolyzed. Contamination by hemolysis or lipemia should be avoided, but does not interfere with this assay.
- Specimens may be refrigerated at 2-8°C for up to five days or stored at -20°C up to six months.
- Avoid repetitive freezing and thawing of serum or plasma samples. This may result in variable loss of antibody activity.
- Testing of heat-inactivated sera is not recommended.

STORAGE AND STABILITY

- Store test kit at 2-8°C in the dark.
- Do not expose reagents to heat, sun, or strong light during storage and usage.
- Store microplate sealed and desiccated in the clip bag provided.
- Shelf life of the unopened test kit is 18 months from day of production.
Unopened reagents are stable until expiration of the kit. See labels for individual batch.
- Diluted Wash Buffer and Sample Buffer are stable for at least 30 days when stored at 2-8°C.
We recommend consumption on the same day.

PROCEDURAL NOTES

- Do not use kit components beyond their expiration dates.
- Do not interchange kit components from different lots and products.
- All materials must be at room temperature (20-28°C) prior to use.
- Prepare all reagents and samples. Once started, perform the test without interruption.

- Double determinations may be done. By this means pipetting errors may become obvious.
- Perform the assay steps only in the order indicated.
- Always use fresh sample dilutions.
- Pipette all reagents and samples into the bottom of the wells.
- To avoid carryover or contamination, change the pipette tip between samples and different kit controls.
- Wash microwells thoroughly and remove the last droplets of wash buffer.
- All incubation steps must be accurately timed.
- Do not re-use microplate wells.

PREPARATION OF REAGENTS

WASH

Dilute the contents of one vial of the buffered wash solution concentrate (50x) with distilled or deionised water to a final volume of 1000 ml prior to use.

DILUENT

Sample Buffer P: Prior to use dilute the contents (20 ml) of one vial of sample buffer 5x concentrate with distilled or deionised water to a final volume of 100 ml.

Preparation of samples

Dilute patient samples 1:100 before the assay: Put 990 µl of prediluted sample buffer in a polystyrene tube and add 10 µl of sample. Mix well. Note: Calibrators / Controls are ready to use and need not be diluted.

TEST PROCEDURE

Prepare enough microplate modules for all calibrators / controls and patient samples.

- Pipette **100 µl** of calibrators, controls and prediluted patient samples into the wells.
Incubate for **30 minutes** at room temperature (20-28 °C).
Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
- Dispense **100 µl** of enzyme conjugate into each well.
Incubate for **15 minutes** at room temperature.
Discard the contents of the microwells and **wash 3 times** with **300 µl** of wash solution.
- Dispense **100 µl** of TMB substrate solution into each well.
Incubate for **15 minutes** at room temperature
- Add 100 µl** of stop solution to each well of the modules
Incubate for **5 minutes** at room temperature.
Read the optical density at 450 nm (reference 600-690nm) and calculate the results.
The developed colour is stable for at least 30 minutes. Read during this time.

Example for a pipetting scheme:

	1	2	3	4	5	6	7	8	9	10	11	12
A	CAL											
B	C-											
C	P1											
D	P2											
E	P3											
F												
G												
H												

P1, ... patient sample CAL calibrator C- Control negative

VALIDATION

Test results are valid if the optical densities at 450 nm for calibrators / controls and the results for controls comply with the reference ranges indicated on the Certificate of Analysis enclosed in each test kit.
If these quality control criteria are not met the assay run is invalid and should be repeated.

CALCULATION OF RESULTS

First optical density (OD) of cut-off is calculated by multiplying optical density of the calibrator by the test specific factor 0.5:

$$\text{OD cut-off} = \text{OD Calibrator} * 0.5$$

Then the optical density of a sample is compared to the optical density of the cut-off:

Negative: OD sample < OD cut-off

Positive: OD sample ≥ OD cut-off

For detailed results the optical density of a sample is expressed as Index value:

$$\text{Index} = \text{OD sample} / \text{OD cut-off}$$

PERFORMANCE CHARACTERISTICS

Calibration

The assay system is calibrated against the internationally recognized reference sera from CDC, Atlanta USA.

Measuring range

not applicable

Expected values

In a normal range study with samples from healthy blood donors the following ranges have been established with this ELISA assay: Cut-off Index 1.0

Interpretation of results

Negative: Index < 1.0
Borderline: Index 1.0 - 1.2
Positive: Index > 1.2

Linearity

Patient samples containing high levels of specific antibody were serially diluted in sample buffer. Activity for each dilution step was calculated as Index-Value.

Sample	Dilution	Observed Index	Expected Index	O/E [%]
1	1:100	5.8	5.8	100
.	1:200	2.7	2.9	93
.	1:400	1.6	1.5	110
.	1:800	0.8	0.7	110
.	1:1600	0.4	0.4	106
2	1:100	4.9	4.9	100
.	1:200	2.7	2.5	110
.	1:400	1.3	1.2	106
.	1:800	0.6	0.6	98
.	1:1600	0.3	0.3	90

Limit of detection

not applicable

not applicable

Reproducibility

Intra-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 24 determinations in a single run. Results for precision-within-assay are shown in the table below.

Inter-assay precision: Coefficient of variation (CV) was calculated for each of three samples from the results of 6 determinations in 5 different runs. Results for run-to-run precision are shown in the table below.

Intra-Assay		
Sample	Mean Index	CV %
1	1.1	3.5
2	1.9	2.4
3	3.2	2.2

Inter-Assay		
Sample	Mean Index	CV %
1	1.2	6.5
2	1.9	4.0
3	3.3	3.8

Interfering substances

No interference has been observed with haemolytic (up to 1000 mg/dl) or lipemic (up to 3 g/dl triglycerides) sera or plasma, or bilirubin (up to 40 mg/dl) containing sera or plasma. Nor have any interfering effects been observed with the use of anticoagulants (Citrate, EDTA, Heparine). However for practical reasons it is recommended that grossly hemolyzed or lipemic samples should be avoided.

Study results

Study population	n	n Pos	%
SLE	63	60	95.2
Sjogren's syndrome	10	10	100.0
MCTD	10	10	100.0
Poly-/dermatomyositis	8	7	87.5
Scleroderma	10	10	100.0
CREST syndrome	9	9	100.0
Normal human sera	148	3	2.0

		Clinical Diagnosis		
		POS	NEG	
ORG 538	POS	106	3	258
	NEG	4	145	
		110	148	

Sensitivity: 96.4 %
 Specificity: 98.0 %
 Overall agreement: 97.3 %

LIMITATIONS OF THE PROCEDURE

This assay is a diagnostic aid. A definite clinical diagnosis should not be based on the results of a single test, but should be made by the physician after all clinical and laboratory findings have been evaluated concerning the entire clinical picture of the patient. Also every decision for therapy should be taken individually.

The above pathological and normal reference ranges for antibodies in patient samples should be regarded as recommendations only. Each laboratory should establish its own ranges according to ISO 15189 or other applicable laboratory guidelines.

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Notice to the user (European Union):

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established .

Change Control

Former version: *ORG 538_IFU_EN_QM113172_2013-12-16_1.2* Reason for revision: *Introduction electronic IFU on homepage*

- 1 Pipet **100 µl** calibrator, control or patient sample
→ Incubate for **30 minutes** at room temperature
→ Discard the contents of the wells and wash 3 times with **300 µl** wash solution
- 2 Pipet **100 µl** enzyme conjugate
→ Incubate for **15 minutes** at room temperature
→ Discard the contents of the wells and wash 3 times with **300 µl** wash solution
- 3 Pipet **100 µl** substrate solution
→ Incubate for **15 minutes** at room temperature
- 4 Add **100 µl** stop solution
→ Leave untouched for **5 minutes**
→ Read at **450 nm**

1. Product identifier

Code **ORG 538**

Name **ANAscreen**

ANAscreen is a medical device for the qualitative screening of IgG class autoantibodies against RNP-70, RNP/Sm, Sm, SS-A, SS-B, Scl 70, Centromer B and Jo-1 in human serum or plasma. Intended for professional in vitro diagnostic use only.

Manufacturer / Supplier

ORGENTEC Diagnostika GmbH
Carl-Zeiss-Straße 49-51
55129 Mainz - Germany
Phone: +49 6131 / 92580
Fax: +49 6131 / 925858
orgentec@orgentec.com
www.orgentec.com

2. Hazards identification

Product is **not classified as hazardous** according to the European Regulation 1999/45/EC or 1272/2008/EC.
Human health hazards: No specific hazard.

3. Composition / Information on ingredients

Coated microplate: Purified antigen coated onto polystyrene microwells.

Calibrators/controls: Human antibodies < 1% in phosphate buffered saline with Tween 20 as detergent, sodium azide 0.09% as preservative and BSA for stabilization.

Enzyme conjugate: Peroxidase conjugated anti-human antibody < 0.0001% in phosphate buffered saline with ProClin 300 as preservative and bovine serum albumin (BSA) for stabilization.

Sample buffer: Phosphate buffered saline with sodium azide 0.09% as preservative and BSA for stabilization.

Wash buffer: Tris buffered saline with Tween 20 as detergent and sodium azide 0.09% as preservative.

Substrate solution: Aqueous solution of TMB (3,3',5,5'-Tetramethylbenzidin) 0.032% with organic solvent 2-pyrrolidone < 10%, sodium perborate, citrate, EDTA, and Kathon CG as preservative.

Stop solution: Aqueous solution of phosphoric acid 4.5%.

Active substances in all mixtures do not meet the criteria for classification according to 1272/2008/EC.

4. First aid measures

Skin Contact: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If stop solution comes into contact with skin, wash thoroughly with water.

Eye Contact: After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary. Remove contact lenses if this can be done easily.

Respiratory tract: Take person to the fresh air.

Swallowing: Rinse the mouth and spit the fluids out. Drink 1 - 2 glasses of water immediately. During spontaneous vomiting hold the head of the casualty low with the body in a prone position in order to avoid the penetration of vomit into the air tube.

5. Firefighting measures

Extinguishing Media: Use dry chemical powder, water spray, foam or carbon dioxide.

6. Personal precautions, protective equipment and emergency procedures

Observe laboratory safety regulations.

Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth.

Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled.

When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

7. Handling and storage

Handling: Special measures are not required.

Storage: Store at 2 to 8 °C. Protect from light.

8. Exposure controls / personal protection

Respiratory protection: Not required

Hand protection: Wear protective gloves of nitril rubber or natural latex.

Eye protection: Wear protective glasses.

9. Physical and chemical properties

Coated microplate: Polystyrol microwells in foil pouch.

Calibrators: Yellow fluid in glass bottle.

Enzyme conjugate: Red fluid in polyethylene bottle.

Sample buffer: Yellow fluid in polyethylene bottle.

Wash buffer: Colorless fluid in polyethylene bottle.

Substrate solution: Colorless fluid in polyethylene bottle.

Stop solution: Colorless fluid in polyethylene bottle.

10. Stability and reactivity

Stability of components is given on the labels. Used according to intended use no dangerous reactions known.

Conditions to avoid: Substrate solution is light-sensitive. Store substrate solution in the dark.

11. Toxicological information

Used according to intended use no toxicological reactions known.

12. Ecological information

Used according to intended use no ecological reactions known.

13. Disposal considerations

Waste should be disposed of in accordance with federal, state and local environmental control regulations.

When disposing of conjugate solution, sample buffer or wash buffer flush drains with copious amounts of water.

Disposal of packaging according to the instructions of the public authorities.

14. Transport information

This product is not subject to official transport regulations.

15. Regulatory information

1907/2006/EC Registration, evaluation and authorization of chemicals regulation (REACH)

1272/2008/EC Classification, labelling and packaging regulation (CLP, globally harmonized system GHS)

replaces 67/548/EWG and 1999/45/EG, amending 1907/2006/EG

453/2010/EC Compilation of safety data sheets regulation (SDS), amending 1907/2006/EC

This product is not classified according to the EU regulations 1272/2008. No labeling requirement.

16. Other information

Revision: editorial corrections.

Safety data for product including all components. This product is intended for professional laboratory use only.

Notice to Reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.



EG-Konformitätserklärung
CE-Declaration de Conformité / EC-Declaration of Conformity
CE
Nr./No. 145

Wir / Nous / We

sifin diagnostics gmbh,
Berliner Allee 317-321, 13088 Berlin, Germany

erklären in eigener Verantwortung, dass
déclarons sous notre propre responsabilité que / declare on our own responsibility that

das Medizinprodukt (IVD):
le dispositif médical (IVD):
the medical device (IVD):

Anti-Salmonella OMA
Anti-Salmonella OMB
Anti-Salmonella OMC
Anti-Salmonella OMD
Anti-Salmonella OME
Anti-Salmonella OMF
Anti-Salmonella OMG

Sonstiges Produkt

Other device/Autre dispositif

allen Anforderungen der Richtlinie 98/79/EG entspricht.
remplit toutes les exigences de la Directive 98/79/EG qui le concernait.
meets all the provisions of the Directive 98/79/EG which apply to it.

Angewandte harmonisierte Normen:
Normes harmonisés appliqués:
Applied harmonized standards:

DIN EN ISO 13485:2012, DIN EN 13612:2002,
DIN EN 13641:2002, DIN EN ISO 14971:2013,
DIN EN ISO 15223-1:2017, DIN EN ISO 18113-1:2013,
DIN EN ISO 18113-2:2013, DIN EN ISO 23640:2015

Konformitätsbewertungsverfahren:
Procédure d'évaluation de la conformité:
Conformity assessment procedure:

Anhang III
Annexe III
Annex III

Gültig bis:
Valable jusqu'au:
Valid until:

2018-10

Berlin, 01.03.2018

Dr. T. Schwarz

Sicherheitsbeauftragter für Medizinprodukte
Agent de sécurité /Safety Officer



EG-Konformitätserklärung
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Testreagenzien Anti-Salmonella O, Vi
Réactifs de test Anti-Salmonella O, Vi
Test Reagents Anti-Salmonella O, Vi

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the medical devices (IVD):

Testreagenzien Anti-Salmonella O, Vi
Réactifs de test Anti-Salmonella O, Vi
Test Reagents Anti-Salmonella O, Vi

TR1201	Anti-Salmonella Group B
TR1201-01	Anti-Salmonella Group B
TR1202	Anti-Salmonella Group C
TR1203	Anti-Salmonella Group D
TR1203-01	Anti-Salmonella Group D
TR1204	Anti-Salmonella Group E
TR1301	Anti-Salmonella O:2
TR1302	Anti-Salmonella O:4
TR1302-01	Anti-Salmonella O:4
TR1303	Anti-Salmonella O:5
TR1303-01	Anti-Salmonella O:5
TR1304	Anti-Salmonella O:6 ₁
TR1305	Anti-Salmonella O:7
TR1306	Anti-Salmonella O:8
TR1307	Anti-Salmonella O:9
TR1307-01	Anti-Salmonella O:9
TR1308	Anti-Salmonella O:10
TR1323	Anti-Salmonella O:11
TR1325	Anti-Salmonella O:13
TR1309	Anti-Salmonella O:14
TR1310	Anti-Salmonella O:15
TR1328	Anti-Salmonella O:16
TR1329	Anti-Salmonella O:17
TS1330	Anti-Salmonella O:18
TR1311	Anti-Salmonella O:19
TR1312	Anti-Salmonella O:20
TR1331	Anti-Salmonella O:21

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Testreagenzien Anti-Salmonella O, Vi Réactifs de test Anti-Salmonella O, Vi Test Reagents Anti-Salmonella O, Vi

TS1332	Anti-Salmonella O:22
TR1335	Anti-Salmonella O:25
TR1313	Anti-Salmonella O:27
TR1336	Anti-Salmonella O:28
TR1339	Anti-Salmonella O:30
TR1314	Anti-Salmonella O:34
TR1341	Anti-Salmonella O:35
TR1344	Anti-Salmonella O:38
TR1345	Anti-Salmonella O:39
TR1346	Anti-Salmonella O:40
TR1347	Anti-Salmonella O:41
TR1348	Anti-Salmonella O:42
TR1349	Anti-Salmonella O:43
TR1350	Anti-Salmonella O:44
TR1351	Anti-Salmonella O:45
TR1315	Anti-Salmonella O:46
TR1353	Anti-Salmonella O:47
TR1354	Anti-Salmonella O:48
TR1355	Anti-Salmonella O:50
TR1356	Anti-Salmonella O:51
TR1357	Anti-Salmonella O:52
TR1358	Anti-Salmonella O:53
TR1359	Anti-Salmonella O:54
TR1360	Anti-Salmonella O:55
TR1361	Anti-Salmonella O:56
TR1362	Anti-Salmonella O:57
TR1363	Anti-Salmonella O:58
TR1364	Anti-Salmonella O:59
TR1365	Anti-Salmonella O:60
TR1366	Anti-Salmonella O:61
TR1367	Anti-Salmonella O:62
TR1368	Anti-Salmonella O:63
TR1369	Anti-Salmonella O:65
TR1370	Anti-Salmonella O:66
TR1371	Anti-Salmonella O:67
TR1316	Anti-Salmonella Vi

Sonstige Produkte
Autres dispositifs/Other devices

allen Anforderungen der Richtlinie 98/79/EG entsprechen.
rempliront toutes les exigences de la Directive 98/79/EG qui le concernait.
meet all the provisions of the Directive 98/79/EG which apply to it.

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Testreagenzien Anti-Salmonella O, Vi
Réactifs de test Anti-Salmonella O, Vi
Test Reagents Anti-Salmonella O, Vi

Angewandte harmonisierte Normen: DIN EN ISO 13485:2016,
Normes nationales appliqués: DIN EN 13612:2002,
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DIN EN ISO 15223-1:2017,
DIN EN ISO 18113-1:2013,
DIN EN ISO 18113-2:2013,
DIN EN ISO 23640:2015

Konformitätsbewertungsverfahren: Anhang III
Procédure d'évaluation de la conformité: Annexe III
Conformity assessment procedure: Annex III

Gültig bis: 2022-05-25
Valable jusqu'au:
Valid until:

Berlin, 23.10.2021



Dr. Kathrin Landgrebe
Sicherheitsbeauftragte für Medizinprodukte
Agent de sécurité / Safety Officer



EG-Konformitätserklärung
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Testreagenzien Anti-Salmonella H
Réactifs pour tests Anti-Salmonella H
Test Reagents Anti-Salmonella H

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the medical devices (IVD):

Testreagenzien Anti-Salmonella H
Réactifs pour tests Anti-Salmonella H
Test Reagents Anti-Salmonella H

TR1401	Anti-Salmonella H:a
TR1402	Anti-Salmonella H:b
TR1403	Anti-Salmonella H:c
TR1404	Anti-Salmonella H:d
TR1405	Anti-Salmonella H:E
TR1405-01	Anti-Salmonella H:E
TR1407	Anti-Salmonella H:f
TR1406	Anti-Salmonella H:g
TR1406-01	Anti-Salmonella H:g
TR1408	Anti-Salmonella H:g,m
TR1408-01	Anti-Salmonella H:g,m
TR1409	Anti-Salmonella H:h
TR1410	Anti-Salmonella H:i
TR1410-01	Anti-Salmonella H:i
TR1411	Anti-Salmonella H:k
TR1412	Anti-Salmonella H:L
TR1412-01	Anti-Salmonella H:L
TS1413	Anti-Salmonella H:m
TR1438	Anti-Salmonella H:n
TS1414	Anti-Salmonella H:p
TS1415	Anti-Salmonella H:q
TR1416	Anti-Salmonella H:r
TS1417	Anti-Salmonella H:s
TS1418	Anti-Salmonella H:t
TS1419	Anti-Salmonella H:u
TS1420	Anti-Salmonella H:v
TS1421	Anti-Salmonella H:w
TS1422	Anti-Salmonella H:x
TR1423	Anti-Salmonella H:y

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Testreagenzien Anti-Salmonella H Réactifs pour tests Anti-Salmonella H Test Reagents Anti-Salmonella H

TR1424	Anti-Salmonella H:z
TS1425	Anti-Salmonella H:Z4,Z23
TS1426	Anti-Salmonella H:Z6
TR1427	Anti-Salmonella H:Z10
TS1428	Anti-Salmonella H:Z15
TR1440	Anti-Salmonella H:Z23
TS1429	Anti-Salmonella H:Z24
TS1449	Anti-Salmonella H:Z28
TS1430	Anti-Salmonella H:Z29
TS1431	Anti-Salmonella H:Z32
TR1445	Anti-Salmonella H:Z35
TR1447	Anti-Salmonella H:Z38
TR1448	Anti-Salmonella H:Z41
TR1437	Anti-Salmonella H:1
TR1437-01	Anti-Salmonella H:1
TR1433	Anti-Salmonella H:2
TR1433-01	Anti-Salmonella H:2
TS1434	Anti-Salmonella H:5
TR1435	Anti-Salmonella H:6
TS1436	Anti-Salmonella H:7

Sonstige Produkte
Autres dispositifs/Other devices

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Testreagenzien Anti-Salmonella H
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2022-05-25

Berlin, 23.10.2021

Dr. Kathrin Landgrebe
Sicherheitsbeauftragte für Medizinprodukte
Agent de sécurité / Safety Officer

Регистрационное удостоверение № ФСР 2009/05559 от 04.12.2015 г.

Паспорт

Набор реагентов «Масло иммерсионное» по ТУ 9398-011-29508133-2009

Серия	93	Дата изготовления	02.09.2021
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1. Назначение

Используется для апохроматических и ахроматических объективов микроскопов всех видов, кроме люминесцентных, предназначенных для работы в видимой области спектра.

2. Технические требования

Наименование показателя	Характеристика и норма по ТУ	Результаты анализа
Внешний вид	Прозрачная бесцветная жидкость со слабым желтоватым оттенком	соответствует
Вязкость кинематическая при температуре 20°C, мм ² /с	От 220	1275
Показатель преломления при температуре 20°C	От 1,5150 до 1,5180	1,5154
Коэффициент пропускания масла, %	Не менее 70	440 нм – 98,4 540 нм – 100,0

Иммерсионное масло легко удаляется с поверхности препарата, фронтальной линзы и оправы объектива; инертно к окрашенным и неокрашенным препаратам.

Упаковка – флакон-капельница вместимостью 100,0 мл обеспечивает аккуратное и экономичное нанесение масла на препарат.

Срок годности – 1,5 года с даты изготовления.

3. Транспортирование и хранение

Транспортирование должно проводиться всеми видами крытого транспорта в соответствии с правилами перевозки грузов, действующими на данном виде транспорта. Хранение - в упаковке предприятия-изготовителя в прохладном месте при относительной влажности воздуха не более 80% в местах, защищенных от воздействия прямых солнечных лучей, атмосферных осадков и агрессивных сред в течение всего срока годности.

4. Гарантии изготовителя

Изготовитель гарантирует соответствие качества набора реагентов «Масло иммерсионное» требованиям ТУ 9398-011-29508133-2009 при соблюдении потребителем условий транспортирования, хранения и применения в течение всего срока годности.

Начальник ПТО



Бабич В.А.



ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 04 декабря 2015 года № ФСР 2009/05559

На медицинское изделие

Набор реагентов «Масло иммерсионное» по ТУ 9398-011- 29508133-2009

Настоящее регистрационное удостоверение выдано

Общество с ограниченной ответственностью "МиниМед"

(ООО "МиниМед"), Россия,

241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А

Производитель

Общество с ограниченной ответственностью "МиниМед"

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Место производства медицинского изделия

241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17а/1

Номер регистрационного досье № РД-9304/51845 от 19.11.2015

Вид медицинского изделия -

Класс потенциального риска применения медицинского изделия 1

Код Общероссийского классификатора продукции для медицинского изделия 93 9816

приказом Росздравнадзора от 04 декабря 2015 года № 8988
допущено к обращению на территории Российской Федерации.

**Руководитель Федеральной службы
по надзору в сфере здравоохранения**



М.А. Мурашко

0015737

EC DECLARATION OF CONFORMITY

ZAO "Vector-Best" hereby ensures under own responsibility and declares that the products listed on pages 2,4 are in conformity with applicable provisions and fulfill the essential requirements of Annex I Directive 98/79/EC of 27 October 1998 regarding in vitro diagnostic medical devices.

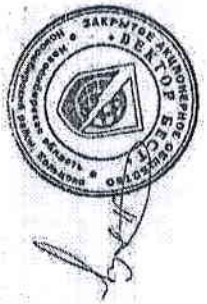
Classification of products: Other devices (all devices except Annex II and self-testing devices)

Conformity assessment procedure: Annex III (not including section G).

Manufacturer:
ZAO "Vector-Best"
Address: AHC, Koksovo,
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Tel: +7 (383) 363 20 60,
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Date: 2013/04/12



Murat Khuzainov
General Director ZAO «Vector-Best»

No.	Product name	Identification data	REF
1.	Vectohcp A-IgM	ELISA kit for determination of IgM to hepatitis A virus	D-0352
2.	Vectohcp A-IgG	ELISA kit for quantitative and qualitative determination of IgG to hepatitis A virus	D-0362
3.	Vectohcp TTV-IgG	ELISA kit for determination of IgG to TT virus	D-0802
4.	Vectohcp E-IgG	ELISA kit for determination of IgG to hepatitis E virus	D-1056
5.	Vectohcp E-IgM	ELISA kit for determination of IgM to hepatitis E virus	D-1058
6.	Vectohcp G-IgG	ELISA kit for determination of IgG to hepatitis G virus	D-1252
7.	LymeBest-IgG	ELISA kit for determination of IgG to infectious borreliosis agents	D-1452
8.	LymeBest-IgM	ELISA kit for determination of IgM to infectious borreliosis agents	D-1454
9.	RecombBest antipallidum-IgG	ELISA kit for determination of IgG to Treponema pallidum	D-1852
10.	RecombBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1856
11.	RecombBest antipallidum-IgM	ELISA kit for determination of IgM to Treponema pallidum	D-1858
12.	RecombBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1857
13.	VectohSV-1,2 - IgG	ELISA kit for determination of IgG to herpes simplex virus types 1 and 2	D-2152
14.	VectohSV - IgM	ELISA kit for determination of IgM to herpes simplex virus types 1 and 2	D-2154
15.	VectohHV-8 - IgG	ELISA kit for determination of IgG to human herpes virus type 8	D-2160
16.	VectohHV-8 - IgG	ELISA kit for determination of IgG to human herpes virus type 8	D-2166
17.	Ureaplasma urealyticum - IgG-EIA-BEST	ELISA kit for determination of IgG to Ureaplasma urealyticum antigens	D-2254
18.	Ureaplasma urealyticum - IgA-EIA-BEST	ELISA kit for determination of IgA to Ureaplasma urealyticum antigens	D-2258
19.	VectoParotitis-IgG	ELISA kit for determination of IgG to parotitis virus	D-2602
20.	VectoParotitis-IgM	ELISA kit for determination of IgM to parotitis virus	D-2604
21.	Toxocara-IgG-EIA-BEST	ELISA kit for determination of IgG to toxocara antigens	D-2752
22.	Opisthorchiasis - IgG-EIA-BEST	ELISA kit for determination of IgG to opisthorchiasis antigens	D-2952
23.	Echinococcus-IgG-EIA-BEST	ELISA kit for determination of IgG to Echinococcus	D-3356

24.	Ascend-IgG-EIA-BEST	antigens	ELISA kit for determination of IgG to Ascans lumbricoides	D-3452
25.	Lamblija-antibodies-EIA-BEST		ELISA kit for determination of IgG, IgM and IgA to Lamblija antibodies	D-3552
26.	Lamblija-IgM-EIA-BEST		ELISA kit for determination of IgM to Lamblija antibodies	D-3554
27.	Lamblija-antigen-EIA-BEST		ELISA kit for determination of Lamblija antigen	D-3556
28.	Helicobacter pylori-Caga-antigen-EIA-BEST		ELISA kit for determination of total antibodies to Caga Helicobacter pylori	D-3752
29.	ISH-EIA-BEST		ELISA kit for determination of concentration of thyroid-stimulating hormone	X-3952
30.	T3 total-EIA-BEST		ELISA kit for determination of concentration of total triiodothyronine	X-3954
31.	T4 total-EIA-BEST		ELISA kit for determination of concentration of total thyroxine	X-3956
32.	Anti-TPO-EIA-BEST		ELISA kit for determination of antibody concentration to thyroperoxidase	X-3968
33.	PAPP-A-EIA-BEST		ELISA kit for determination of concentration of pregnancy-associated plasma protein A	D-4160
34.	Mycoplasma hominis-IgG-EIA-BEST		ELISA kit for determination of IgG to Mycoplasma hominis	D-4352
35.	Mycoplasma hominis-IgA-EIA-BEST		ELISA kit for determination of IgA to Mycoplasma hominis	D-4356
36.	Mycoplasma pneumoniae-IgG-EIA-BEST		ELISA kit for determination of IgG to Mycoplasma pneumoniae	D-4362
37.	Mycoplasma pneumoniae-IgM-EIA-BEST		ELISA kit for determination of IgM to Mycoplasma pneumoniae	D-4366
38.	Veddochmean - CHF - IgG		ELISA kit for determination of IgG to Crimsean-Congo hemorrhagic fever virus	D-5052
39.	Veddochmean - CHF - IgM		ELISA kit for determination of IgM to Crimsean-Congo hemorrhagic fever virus	D-5054
40.	CEA-EIA-BEST		ELISA kit for determination of coposulation of carcinoembryonic antigen	T-8454
41.	AFP-EIA-BEST		ELISA kit for determination of concentration of Alpha-Fetal Protein	T-8456
42.	CA-125-EIA-BEST		ELISA kit for determination of concentration of oncomarker CA-125	T-8466
43.	CA 19-9-EIA-BEST		ELISA kit for determination of concentration of CA 19-9	T-8470
44.	CA 15-3-EIA-BEST		ELISA kit for determination of concentration of oncomarker CA 15-3	T-8472
45.	NSE-EIA-BEST		ELISA kit for determination of concentration of neuron specific enolase	T-8476

46.	Ferritin-EIA-BEST		ELISA kit for determination of concentration of ferritin	T-8552
47.	IgE total-EIA-BEST		ELISA kit for determination of concentration of total IgE	A-8660
48.	IgG total-EIA-BEST		ELISA kit for determination of concentration of total IgG	A-8662
49.	IgM total-EIA-BEST		ELISA kit for determination of concentration of total IgM	A-8664
50.	IgA total-EIA-BEST		ELISA kit for determination of concentration of total IgA	A-8666
51.	Gamma-Interferon-EIA-BEST		ELISA kit for determination of concentration of gamma-interferon	A-8752
52.	Interleukine-4-EIA-BEST		ELISA kit for determination of concentration of interleukine-4	A-8754
53.	Alpha-TNF-EIA-BEST		ELISA kit for determination of concentration of alpha-tumor necrosis factor	A-8756
54.	Alpha-Interferon-EIA-BEST		ELISA kit for determination of concentration of alpha-interferon	A-8758
55.	Interleukine-6-EIA-BEST		ELISA kit for determination of concentration of interleukine-6	A-8768
56.	Interleukine-2-EIA-BEST		ELISA kit for determination of concentration of interleukine-2	A-8772
57.	Procalcitonin-EIA-BEST		ELISA kit for determination of concentration of procalcitonin	A-9004
58.	NTproBNP-EIA-BEST		ELISA kit for determination of concentration of N-terminal prohomone of brain natriuretic peptide	A-9102
59.	Troponin I-EIA-BEST		ELISA kit for determination of concentration of troponin I	A-9106