

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
UL Life and Health Sciences
UL LLC



Check Certificate
Status: here

File Number A12241
Certificate 1458.180626
Initial Issue June 26, 2018

Cycle Start Date June 26, 2018
Effective Date June 26, 2018
Expiry Date May 22, 2020

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.



00-MB-S0043 Issue 15.0

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

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EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
ASO Latex kit	031100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.



Eddy Velthuis
Technical Director



File No A12241;
ISO 13485:2003; ISO 9001:2008

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

Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
www.lornelabs.com

Registered office as above. Registered in England No. 04540797. VAT No. 800 9655 66

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
CRP Latex kit	850100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.



Eddy Velthuis
Technical Director

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
RF Latex kit	830100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- **BS EN ISO 13485:2012**
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.



Eddy Velthuis
Technical Director



File No A12241
ISO 13485:2003, ISO 9001:2008

Lorne Laboratories Limited
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Registered office as above. Registered in England No. 04540797. VAT No. 800 3655 66

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
Strep Test kit	860050

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 24 March 2016.



Eddy Velthuis
Technical Director



File No A12241
ISO 13485:2003; ISO 9001:2008

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

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Registered office as above. Registered in England No. 04540797. VAT No. 800 3655 66





EC CERTIFICATE

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate,
Danehill, Lower Earley, Berkshire RG6 4UT, UK

EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV, (excluding sections 4 and 6) of Council Directive 98/79/EC on In Vitro
Diagnostic Medical Devices

Scope of Certificate:

The design and manufacture of in vitro diagnostic reagents for
identification of blood groups

Device Classification:

Annex II, List A and B

Device Descriptions:

Please refer to Attachment 1

Model:

Please refer to Attachment 1

File Number A12241

Certificate No. 354.170425

Cycle Start Date 23 May 2017

Effective Date 23 May 2017

Expiry Date 22 May 2022

Authorised by

B. Rodgers

B. Rodgers
Certification Manager
For and on Behalf of UL International (UK) Ltd

We hereby declare that an examination of the full quality assurance system has been carried out per report 11640248 following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV (with the exemption of sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 98/79/EC, Annex IV, Section 5. For Annex II, List A devices where they are covered by this certificate, an EC Design Examination certificate according to 98/79/EC, Annex IV, Section 4 is required. This certificate is issued with 1 attachment listing model numbers.

Notified Body

0843

UL International (UK) Limited
Womersley House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1UR, United Kingdom

NDD A4 S3 FQ 00-NB-F0051 Issue: 6.0



EC CERTIFICATE

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate,
Danehill, Lower Earley, Berkshire RG6 4UT, UK

Attachment 1 of 1

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

Device Description	Model	Classification
Anti-A Monoclonal	600005/600010/600000	Annex II List A
Anti-B Monoclonal	610005/610010/610000	Annex II List A
Anti-A,B Monoclonal	620005/620010/620000	Annex II List A
Anti-C Monoclonal	690005	Annex II List A
Anti-E Monoclonal	691005	Annex II List A
Anti-c Monoclonal	692005	Annex II List A
Anti-e Monoclonal	693005	Annex II List A
Anti-K Monoclonal	760005/760010	Annex II List A
Anti-D Clone 2 Monoclonal	710010/710000	Annex II List A
Anti-D Clone 1 Monoclonal	730010/730000	Annex II List A
Anti-D Duodone Monoclonal	740010/740000	Annex II List A
Anti-Jka Polyclonal	323002/323000	Annex II List B
Anti-Jkb Polyclonal	324002/324000	Annex II List B
Anti-Fyb Polyclonal	317002/317000	Annex II List B
AHG Elite Clear	415010/415100/415000	Annex II List B
AHG Elite Green	435010/435100/435000	Annex II List B
Anti-Fya Monoclonal	774000/774002	Annex II List B
Anti-C+D+E Monoclonal	700005/700010/700000	Annex II List A
Anti-Human IgG Clear	401010/401000	Annex II List B
Anti-Human IgG Green	402010/402000	Annex II List B
Monoclonal Rh Control	640010	Annex II List A
Monoclonal D Negative Control	650010	Annex II List A

File Number A12241

Certificate No. 354.170425

Cycle Start Date 23 May 2017

Effective Date 23 May 2017

Expiry Date 22 May 2022

Authorised by

B. Rodgers

B. Rodgers
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body

0843

UL International (UK) Limited
Womersley House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1UR, United Kingdom

NDD A4 S3 FQ 00-NB-F0051 Issue: 6.0

Date: 21-01-20

To Whom It May Concern

Letter of Authorisation

This is to confirm that GBG-MLD SRL of str. Tighina 65, of 607, MN-2001, Chisinau, Republic of Moldova is an authorised distributor for Lorne Laboratories Limited in Moldova.

GBG-MLD SRL is authorised to present proposals, offer quotations, accept orders and participate in tender number 18/0003 for the National Blood Transfusion Center for products on behalf of Lorne Laboratories Limited. This authorisation is valid until 31.12.2021.

The undersigned herewith states that the above is true and correct.



Ian John
Managing Director

LORNE LABORATORIES LIMITED
Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT
United Kingdom

And duly authorised to sign this Authorisation on behalf of Lorne Laboratories Limited



File No A12341
ISO 13485:2003; ISO 9001:2008

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

Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
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Registered office as above, Registered in England No. 04540797, VAT No. 800 3655 66



IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO n.
CERTIFICATE No.

4265/4/C

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

KIMA S.R.L.

UNITÀ OPERATIVE / OPERATIVE UNITS

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

EA: 29

Commercializzazione di prodotti del Gruppo: kit diagnostici,
terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi,
provette con vuoto predeterminato e aghi sterili.

*Trading of the products of the Group: diagnostic kits, culture media for microbiology,
plastic disposable labware, test tubes with predetermined vacuum and sterile needles.*

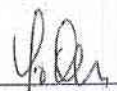
Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato,
si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate,
please contact the number +39 02 725341 or email address info@icim.it.

Data emissione
First issue
18/01/2007

Emissione corrente
Current issue
18/01/2019

Data di scadenza
Expiring date
17/01/2022


ICIM S.p.A.

Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)
www.icim.it



SGQ N° 004 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements



www.cisq.com

CISQ è la Federazione Italiana di Organismi di
Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management
system Certification Bodies.





THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/ICIM SPA has issued an IQNet recognized certificate that the organization:

GRUPPO VACUTEST KIMA

Head Office and Operative Unit

Via dell'Industria, 12 - I-35020 Arzergrande (PD)

Operative Units

MEUS S.r.l. - Via Leonardo Da Vinci, 24B-26-28 - Zona Industriale Tognana - I-35028 Piove di Sacco (PD)

MEUS S.r.l. - Via dell'Industria, 2-16 - I-35020 Arzergrande (PD)

ROLL S.r.l. - Via Leonardo Da Vinci, 24A - Zona Industriale Tognana - I-35028 Piove di Sacco (PD)

KIMA S.r.l. - Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - I-35028 Piove di Sacco (PD)

VACUTEST KIMA S.r.l. - Via dell'Industria, 12 - I-35020 Arzergrande (PD)

VACUTEST KIMA S.r.l. - Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - I-35028 Piove di Sacco (PD)

has implemented and maintains a

Quality Management System

for the following scope:

Design and production of test tubes with predetermined vacuum for collection of haematological samples, biological liquids and urine samples. Production of test tubes for micro-collection of haematological samples. Design and production of Holders for vacuum sampling. Design and production of diagnostic kits for blood and biological liquids analysis. Design and production of culture media for microbiology. Design and production of sterile needles and devices for collection of haematological samples. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles. Design and production of moulds for plastic labware. Injection moulding of thermoplastic materials for medical devices.

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: 2019-01-18

First issued on: 2007-01-18

Expires on: 2022-01-17

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: IT-103425



Alex Stoichitoiu
President of IQNET



Ing. Claudio Provetti
President of CISQ

IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com





CISQ is a member of



*IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world.
IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.*

CERTIFICATO n.
CERTIFICATE No.

4265/4

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

GRUPPO VACUTEST KIMA

Sede / Head Office

Via dell'Industria, 12 - 35020 Arzergrande (PD) - Italia

Unità Operative / Operative Units

MEUS S.r.l. - Via Leonardo da Vinci, 24B - 26 - 28 - Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia

MEUS S.r.l. - Via dell'Industria, 2 - 16 - 35020 Arzergrande (PD) - Italia

ROLL S.R.L. - Via Leonardo Da Vinci, 24A - Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia

KIMA S.R.L. - Via Leonardo da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia

VACUTEST KIMA S.r.l. - Via dell'Industria, 12 - 35020 Arzergrande (PD) - Italia

VACUTEST KIMA S.r.l. via L. Da Vinci, 22 Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

EA: 14 - 29

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine.
Produzione di provette per microprelievi di sangue. Progettazione e produzione di Holders (camicie) per prelievo sottovuoto.
Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia. Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico.
Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.

Design and production of test tubes with predetermined vacuum for collection of haematological samples, biological liquids and urine samples. Production of test tubes for micro-collection of haematological samples. Design and production of Holders for vacuum sampling. Design and production of diagnostic kits for blood and biological liquids analysis. Design and production of culture media for microbiology. Design and production of sterile needles and devices for collection of haematological samples. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles. Design and production of moulds for plastic labware. Injection moulding of thermoplastic materials for medical devices.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.

For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

Data emissione
First issue
18/01/2007

Emissione corrente
Current issue
18/01/2019

Data di scadenza
Expiring date
17/01/2022

ICIM S.p.A.

Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)
www.icim.it



SGQ N° 004 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements



www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

CERTIFICATO n. 4264/4
CERTIFICATE No.

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

GRUPPO VACUTEST KIMA

Sede / Head Office
Via dell'Industria, 12 - 35020 Arzengrande (PD) - Italia

Unità Operative / Operative Units
MEUS S.r.l. - Via Leonardo da Vinci, 24B - 28 - 28 - Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia
MEUS S.r.l. - Via dell'Industria, 2 - 16 - 35020 Arzengrande (PD) - Italia
ROLL S.r.l. - Via Leonardo da Vinci, 24A - Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia
KIMA S.r.l. - Via Leonardo da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia
VACUTEST KIMA S.r.l. - Via dell'Industria, 12 - 35020 Arzengrande (PD) - Italia
VACUTEST KIMA S.r.l. - Via L. Da Vinci, 22 Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / Quality Management System
PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

EA: 14 - 29

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine.
Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di
terreni di coltura per microbiologia. Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico.
Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per
laboratorio analisi, provette con vuoto predeterminato e aghi sterili. Progettazione e produzione di stampi per articoli in
plastica per laboratorio analisi. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.
Design and production of test tubes with predetermined vacuum for collection of haematological samples, biological liquids
and urine samples. Production of test tubes for micro-collection of haematological samples. Design and production of
holders for vacuum sampling. Design and production of diagnostic kits for blood and biological liquids analysis. Design and
production of culture media for microbiology. Design and production of sterile needles and devices for collection of
haematological samples. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic
disposable labware, test tubes with predetermined vacuum and sterile needles. Design and production of moulds for plastic
labware. Injection moulding of thermoplastic materials for medical devices.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for applicability of requirements of reference standard requirements.
Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Sistema specifico.
The rec and this validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific System.
Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato,
si prega di contattare l'IR - telefono +39 02 725241 o l'indirizzo e-mail info@icim.it
For enquiry and latest information about the status of the certification,
please contact the number +39 02 725241 or email address info@icim.it

Data emissione First issue	18/01/2007
Emissione corrente Current issue	18/01/2019
Data scadenza Expiring date	17/01/2022


ICIM S.p.A.
Piazza Don Enrico Nazario, 25 - 20095 Sesto San Giovanni (MI)
www.icim.it


SOCIETÀ A RESPONSABILITÀ LIMITATA
SISTEMI DI GESTIONE
ACCREDITATA
SISTEMI DI GESTIONE
ACCREDITATA


FEDERAZIONE
CISO

www.ciso.com
CISO è la Federazione Italiana di Organismi di
Certificazione di Sistemi di Gestione per la Qualità.
CISO is the Italian Federation of management
system certification bodies.

SGS Italia
Membro del Gruppo di Accreditamento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements



CERTIFICATO N° 505DM05

CERTIFICATE N° 505DM05

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

NUOVA APTACA S.r.l.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili
per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico.

Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi.

Commercializzazione di dispositivi medici e diagnostici in vitro.

Management of manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for analysis laboratories.

Marketing of medical and diagnostic devices in vitro.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana.
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione
First Issue Date
2007-10-30

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT
2011-10-30

Data di Rinnovo
Renewal Date
2017-10-30

Data di Delibera
Deliberation Date
2019-01-04

Data di Scadenza
Expiration Date
2020-10-29



SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements





CERTIFICATO N° 505SGQ04

CERTIFICATE N° 505SGQ04

Si certifica che il
this is to certify that:

Sistema di Gestione per la Qualità

Quality Management System

messso in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili
per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico.
Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi.
Commercializzazione di dispositivi medici e diagnostici in vitro.
Commercializzazione di articoli da laboratorio

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana.
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione
First Issue Date

1998-07-23

Settore IAF 14 - 29

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT

2011-10-30

Data di Modifica
Modified Date

2019-11-06

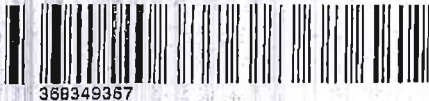
Data di Scadenza
Expiration Date

2020-10-29



SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements





368349357



Imposta di bollo assolta

Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E
DEL SERVIZIO FARMACEUTICO

UFFICIO 4 DGDMF DISPOSITIVI MEDICO - DIAGNOSTICI IN VITRO

DGDMF/04/I.5.1.e.2/2020/4

VISTA la direttiva 98/79/CE relativa ai dispositivi medico-diagnostici in vitro;

VISTO il D.lgs. n. 332/2000 recante attuazione della direttiva 98/79/CE;

VISTA l'istanza datata 13/01/2020 presentata dalla ditta Aptaca Spa con sede in Via Monte Bianco, 4 - 24010 Monza (MB) C.F. 07520900155, P.IVA 00862050960;

CONSIDERATO che la ditta istante ha effettuato i versamenti richiesti dal D.M. 16 Gennaio 2019;

VISTI gli atti d'ufficio;

*HAVING REGARD to 98/79/EC directive concerning the in vitro diagnostic medical devices;**HAVING REGARD to legislative Decree (D.lgs.) n. 332/2000 reporting the accomplishment of 98/79/EC Directive;**HAVING REGARD to the request dated 13/01/2020 submitted by the company Aptaca Spa located in Via Monte Bianco, 4 - 24010 Monza (MB) C.F. 07520900155, P.IVA 00862050960;**WHEREAS this company paid the fees required by Ministerial Decree (D.M.) January 16, 2019;**HAVING REGARD to the official deeds;*

SI ATTESTA IT IS ATTESTED

che la ditta Aptaca Spa con sede legale in Via Monte Bianco, 4 - 35020 Monza (MB), Italia, e sede operativa in Regione Monforte, 30 - 14053 - Canelli (Asti) Italia, C.F. 07520900155, P.IVA 00862050960 è il fabbricante ed ha marcato CE, come dispositivi medico - diagnostici in vitro, secondo le procedure previste dalla direttiva 98/79/CE, i seguenti prodotti:

that the Company Aptaca Spa with registered place of business in Via Monte Bianco, 4 - 24010 Monza (MB), Italy, and operative site in Regione Monforte, 30 - 14053 - Canelli (Asti), Italy, C.F. 07520900155, P.IVA 008622050960 is the manufacturer and affixed CE marking as in vitro diagnostic medical devices, according to the Directive 98/79/EC, to the following products:

31 Petri dishes Ø 35 mm, with triple vents, in PS, sterile R
61 Petri dishes Ø 60 mm, without triple vents, in PS, sterile R
81 Petri dishes Ø 80 mm, without triple vents, in PS, sterile R
91 Petri dishes Ø 90 mm, with triple vents, in PS aseptic
101 Petri dishes Ø 90 mm, without triple vents, in PS aseptic
141 Petri dishes Ø 100 mm, in PS, without triple vents, aseptic
151 Petri dishes Ø 100 mm, in PS, with triple vents, aseptic

155 Contact petri dishes Ø 55 mm, with triple vents, PS, sterile
161 Petri dishes Ø 80 mm, with triple vents, in PS, sterile R
181 Petri dishes Ø 120 mm, without triple vents, in PS, aseptic
195 Contact petri dishes Ø 90mm, with triple vents, PS, sterile R
221 Petri dishes Ø 140 mm, with triple vents, in PS, sterile R
231 Petri dishes Ø 150 mm, with triple vents, in PS, sterile R
251 Petri dishes Ø 90 mm, 2 sectors, triple vents, in PS, aseptic



10271 PP conical test tubes, 10 ml, with rim, not graduated Ø18 x 108 mm	10272 PP conical test tubes, 16 ml, with rim, not graduated Ø18 x 120 mm	10300 Screw cap for false bottom tubes 10200 bags of 1000 pcs	10351 50ml conical test tubes in PP, with light blue screw cap, graduated, Ø20x115mm	10352 15ml cylindrical test tubes in PP, with screw cap, graduated, Ø17 x 120 mm	10381 10ml cylindrical test tubes in PS, with screw cap, Ø16x100 mm	10382 15ml cylindrical test tubes in PS, with screw cap, Ø16 x 150 mm	10383 20ml cylindrical test tubes in PS, with screw cap, Ø16 x 150 mm	10401 Caps in PE colour neutral, for test tubes Ø12 mm	10402 Caps in PE colour neutral, for test tubes Ø16 mm	10403 CAPS FOR TUBES DIAM. 14.5 MM. FOR TUBES DIAM. 16 MM	10404 Caps in PE colour neutral, for test tubes Ø18 mm	10405 Caps in PE colour neutral, for test tubes Ø24 mm	10406 Caps in PE colour neutral, for test tubes Ø30 mm	10407 Caps in PE colour neutral, for test tubes Ø35 mm	10408 Caps in PE colour neutral, for test tubes Ø40 mm	10409 Caps in PE colour neutral, for test tubes Ø45 mm	10410 Caps in PE colour neutral, for test tubes Ø50 mm	10411 Caps in PE colour neutral, for test tubes Ø20 mm	10621 Scabbbox for transport of biological samples, rack of 10 holes, 2,900ml, in PP	10622 Scabbbox for transport of biological samples, rack of 96	10531 5ml containers in PE, with screw cap, Ø21 x 30 mm	10532 30ml containers in PE, with screw cap, Ø35 x 93 mm	10533 90ml containers in PE, with screw cap, Ø65 x 160 mm	10520 Round bowls with rim, in PP, 10 liter, Ø350 x 160 mm	10733 Safety box in PC, with lid with a ring, foam insert x 54 test tubes & 4 containers	10831 Laboratory spatulas, in high impact PS, length 150 mm, spatula-spatula type	10832 Laboratory spatulas, in high impact PS, length 180 mm, spatula-spatula type	10833 Laboratory spatulas, in high impact PS, length 180 mm, spatula-spoon type	10834 Laboratory spatulas, in high impact PS, length 210 mm, spatula-spoon type	11482 150 conical test tubes PS, screw cap yellow colour, graduated, Ø17x120mm	11491 Centrifuge conical test tubes in PS da 13.5ml, Ø16x110 mm, with white screw cap	11681 Centrifuge conical test tubes in PP da 13.5ml, Ø16x110 mm, with screw cap	12731 Sampling tanks 2,500ml, for 24h urine collection, PE, graduated, 245x115x160 mm	13501 Microscope slides 26x76 mm, art type, thick 0.9/1.0 mm	13502 Microscope slides 26x76 mm, ground edges, thick 0.9/1.0 mm	13503 Microscope slides 26x76 mm, frosted end, thick 0.9/1.0 mm	13504 Microscope slides 26x76 mm, ground edges frosted end, thickness 0.9/1.0 mm	13551 Microscope coloured slides, frosted end white colour, 26x76 mm	13552 Microscope coloured slides, frosted end blue colour, 26x76mm, thick 0.95/1.05 mm	13553 Microscope coloured slides, frosted end pink colour, 26x76mm, thick 0.95/1.05 mm	13554 Microscope coloured slides, frosted end yellow colour, 26x76mm, 0.95/1.05 mm	13555 Microscope coloured slides, frosted end green colour, 26x76mm	13556 Microscope coloured slides, frosted end orange 26x76mm, thick 0.95/1.05 mm	13557 Microscope slides with n° 1 cavity, 25x75mm, ground edges, safety covers	13558 Microscope slides with n° 2 cavity, 25x75mm, ground edges, safety covers	13570 Positive charge slides 26x76mm with white writing area	13580 Snubbed coated slides 26x76mm, with white writing area	14005 Embedding cassettes, in acetal resin, white colour, square grid	14006 Embedding cassettes, in acetal resin, yellow colour square grid
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14007 Embedding cassettes, in acetal resin, green colour, square grid	14008 Embedding cassettes, in acetal resin, pink colour, square grid	14009 Embedding cassettes, in acetal resin, light blue, square grid	14010 Embedding cassettes, in acetal resin (POM), orange, square grid	14100 Prolegative biopsy pads, 26x30 mm, in polyester foam, with controlled porosity	14105 Biopsy cassettes, in acetal resin, white colour, square grid	14106 Biopsy cassettes, in acetal resin, yellow colour square grid	14107 Biopsy cassettes, in acetal resin, green colour square grid	14108 Biopsy cassettes, in acetal resin, pink colour square grid	14109 Biopsy cassettes, in acetal resin, light blue, square grid	14116 Embedding rings in ABS, in white colour	14117 Embedding rings in ABS, in yellow colour	14118 Embedding rings in ABS, in green colour	14119 Embedding rings in ABS, in light blue colour	14120 20ml surgical containers in PP yellow screw cap, graduated, Ø31 x 40 mm	14121 40ml surgical containers in PP yellow screw cap, graduated, Ø44 x 39 mm	14122 60ml surgical containers in PP yellow screw cap, graduated, Ø44 x 39 mm	14123 80ml surgical containers in PP yellow screw cap, graduated, Ø44 x 39 mm	14124 120 ml surgical containers in PP, yellow screw cap graduated Ø52 x 77 mm	14125 Mega embedding cassettes with rectangular grid, white rectangular grid	14126 Mega embedding cassettes, in acetal resin, yellow colour rectangular grid	14127 Mega embedding cassettes, in acetal resin, green colour rectangular grid	14128 Mega embedding cassettes, in acetal resin, pink colour rectangular grid	14129 Mega embedding cassettes, in acetal resin, light blue rectangular grid	14131 30 ml containers for biopsy in PS, with pressure cap in PE, Ø34 x 41 mm	14132 50 ml containers for biopsy in PS, with pressure cap in PE, Ø39 x 52 mm	14134 100ml containers for biopsy in PS, with pressure cap in PE, Ø51 x 60 mm	14135 Super mega cassettes, in acetal resin, white colour Ø65 x 50 mm	14136 150ml containers for biopsy in PS, with pressure cap in PE, Ø65 x 67 mm	14140 250ml containers for biopsy in PS, with pressure cap in PE, Ø65 x 85 mm	14142 Surgical specimen containers, in PP, with pressure cap, 500ml, Ø120x80 mm	14143 Surgical specimen containers, in PP, with pressure cap, 1,000ml, Ø120x115 mm	14144 Surgical specimen containers, in PP, with pressure cap, 1,500ml, Ø120x150 mm	14149 160 ml surgical containers in PP, yellow screw cap graduated Ø90 x 96 mm	14190 Translucent containers in PP, for surgical specimens, 150ml, Ø 89 x 67 mm	14151 250 ml surgical containers in PP, yellow screw cap graduated Ø90 x 96 mm	14152 500 ml surgical containers in PP, yellow screw cap graduated Ø90 x 109 mm	14153 1000 ml surgical containers in PP, yellow screw cap graduated Ø113 x 138 mm	14154 Translucent containers in PP, for surgical specimens, 250ml, Ø 95 x 81.5 mm	14160 70 ml containers in PP, for surgical specimens, 50ml, Ø 117.8 x 79.15 mm	14161 Cylindrical jars with cap, 70 ml, in HDPE, inner cap	14162 Cylindrical jars with cap, 120 ml, in HDPE, inner cap	14163 Cylindrical jars with cap, 250 ml, in HDPE, inner cap	14164 Cylindrical jars with cap, 500 ml, in HDPE, inner cap	14165 Cylindrical jars with cap, 1,000 ml, in HDPE, inner cap	14166 Cylindrical jars with cap, 2,000 ml, in HDPE, inner cap	14167 Cylindrical jars with cap, 7500 ml, in HDPE, inner cap	14168 Cylindrical jars with cap, 15000 ml, in HDPE, inner cap	14170 Translucent containers in PP, for surgical specimens, 1030ml Ø 132.3 x 129.4 mm
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14787 Transparent containers PP, for surgical specimens, 2000ml Ø170x154 mm, handle	14788 Transparent containers PP, surgical specimens, 3000ml Ø190x132.3mm, handle	14789 Transparent containers PP, surgical specimens, 5000ml Ø227x161.1mm, handle	14790 Big containers PP, surgical specimens, 5,500ml, 255x180x142.8 mm, with handle	14791 Big containers PP, surgical specimens, 2,500 ml, 189x140x132 mm, without handle	14792 Big containers PP, surgical specimens, 11,000ml, 277x242x223.5 mm, with handle	14205 Embedding cassettes, in acetal resin, white colour, rectangular grid	14206 Embedding cassettes, in acetal resin, yellow colour rectangular grid	14207 Embedding cassettes, in acetal resin, green colour, rectangular grid	14208 Embedding cassettes, in acetal resin, pink colour, rectangular grid	14209 Embedding cassettes, in acetal resin, light blue, rectangular grid	14215 Embedding cassettes without lid, white color, in POM 28 x 40 x 6 mm	14216 Embedding cassettes without lid, yellow color, in POM 28 x 40 x 6 mm	14217 Embedding cassettes without lid, green color, in POM 28 x 40 x 6 mm	14218 Embedding cassettes without lid, pink color, in POM 28 x 40 x 6 mm	14220 Stainless steel lids for standard embedding cassettes, 28 x 40 mm	14245 Stackable embedding cassettes, POM, white colour	14246 Stackable embedding cassettes, POM, yellow colour	14247 Stackable embedding cassettes, POM, green colour	14248 Stackable embedding cassettes, POM, pink colour	14249 Stackable embedding cassettes, POM, light blue colour	14256 Embedding cassettes with 4 compartments, white colour, rectangular grid	14258 Embedding cassettes with 4 compartments, yellow colour, rectangular grid	14259 Embedding cassettes with 4 compartments, green colour, rectangular grid	14260 Embedding cassettes with 4 compartments, pink colour, rectangular grid	14261 Embedding cassettes with 4 compartments, blue colour, rectangular grid	14301 Stainless steel base mould, 7 x 7 x 6 mm	14302 Stainless steel base mould, 15 x 15 x 6 mm	14303 Stainless steel base mould, 24 x 24 x 6 mm	14304 Stainless steel base mould, 30 x 24 x 6 mm	14305 Stainless steel base mould, 37 x 24 x 6 mm	14306 Stainless steel base mould, for mega cassettes	14307 Stainless steel base mould, for super mega cassettes	14401 Disposable base mould in PVC, 7 x 7 x 6 mm DIM. 7x7x6 mm	14402 Disposable base mould in PVC, 15 x 15 x 6 mm DIM. 15x15x6 MM	14403 Disposable base mould in PVC, 24 x 24 x 6 mm DIM. 24x24x6 MM	14404 Disposable base mould in PVC, 30 x 24 x 6 mm DIM. 30x24x6 MM	14405 Disposable base mould in PVC, 37 x 24 x 6 mm DIM. 37x24x6 MM	14406 Disposable base mould in PVC, for mega cassettes	14407 Disposable base mould in PVC, for super mega cassettes	14501 Biopsy bags for histological processing, in polyester, 30x40 mm	14502 Biopsy bags for histological processing, in polyester, 45x60 mm	14503 Biopsy bags for histological processing, in polyester, 75x95 mm	15101 Slides for urine sedimentation in PMMA	15102 K4 with 100 slides for urinary sediments (10 cells) + 1000 special pasteur pipettes	15103 Slides urinary sediments kit + Pasteur pipette + staining solution	15104 Slides Stenheimer + Malbin staining solution for urinary sediment, 35ml dropping bottle	15361 10ml cylindrical test tubes in PS, screen-printed graduation, with screw cap
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[illegible][illegible]

10352V/55 CONICAL TT IN PP 17X120MM 10ML SCREW CAP - sterile	10352V/55 CONICAL test tubes in PP, with screw cap and label
10352V/55/55 10ml conical test tubes in PP, with screw cap and label graduated, sterile	10352V/55/55 10ml conical test tubes in PP, with screw cap and label graduated, sterile
10352V/101 conical test tubes in PP, with red screw cap,	10352V/101 conical test tubes in PP, with red screw cap,
graduated, 171 x 120 mm.	graduated, 171 x 120 mm.
10352V/52 10ml conical test tubes in PP, with screw cap, graduated, sterile	10352V/52 10ml conical test tubes in PP, with screw cap, graduated, sterile
10352V/SG/100 CONICAL TEST TUBES IN PP 17X120MM- 15 ML - SCREW CAP, STERILE	10352V/SG/100 CONICAL TEST TUBES IN PP 17X120MM- 15 ML - SCREW CAP, STERILE
10352V/SG/50B CONICAL TT PP 17X120 - 50ML 50 PCS/BOX - BLUE CAP CAP CAP, STERILE	10352V/SG/50B CONICAL TT PP 17X120 - 50ML 50 PCS/BOX - BLUE CAP CAP CAP, STERILE
10352V/SG/50S 15ml conical test tubes in PP, with screw cap, graduated, sterile	10352V/SG/50S 15ml conical test tubes in PP, with screw cap, graduated, sterile
10381V/101 cylindrical test tubes in PS, with white screw cap, 171 x 120 mm.	10381V/101 cylindrical test tubes in PS, with white screw cap, 171 x 120 mm.
10381V/1E CYL. TUBES WISCREW CAP IN PS DIAM. VOL:10 ML WITH LABEL	10381V/1E CYL. TUBES WISCREW CAP IN PS DIAM. VOL:10 ML WITH LABEL
10381V/1E/SG 10ml cylindrical test tubes in PS, with screw cap, Ø16 x 100 mm, sterile	10381V/1E/SG 10ml cylindrical test tubes in PS, with screw cap, Ø16 x 100 mm, sterile
10381V/1MO 10ml cylindrical test tubes in PP, with screw cap, Ø16 x 100 mm.	10381V/1MO 10ml cylindrical test tubes in PP, without cap, Ø16x100mm not graduated
10381V/1MO/SG 10ml cylindrical test tubes in PP, with screw cap, Ø16 x 100 mm, sterile	10381V/1MO/SG 10ml cylindrical test tubes in PP, with screw cap, Ø16 x 100 mm, sterile
10381V/1MO/SG/CS 10ml cylindrical test tubes in PP, with screw cap, 100 mm, sterile	10381V/1MO/SG/CS 10ml cylindrical test tubes in PP, with screw cap, 100 mm, sterile
10381V/1MO/SG/SG 10ml cylindrical test tubes in PP, with yellow screw cap, Ø16 x 100 mm	10381V/1MO/SG/SG 10ml cylindrical test tubes in PP, with yellow screw cap, Ø16 x 100 mm
10381V/1MO/1650 10ml cylindrical test tube PP, white screw cap Ø16 x 100 mm	10381V/1MO/1650 10ml cylindrical test tube PP, white screw cap Ø16 x 100 mm
10381V/101 cylindrical test tubes in PS, with screw cap not mounted, Ø16 x 100 mm.	10381V/101 cylindrical test tubes PS, red screw cap not mounted, Ø16 x 100 mm.
10381V/101 cylindrical test tubes PS, red screw cap not assembled, Ø16 x 100 mm.	10381V/101 cylindrical test tubes in PS, screw cap not mounted assembled, Ø16 x 100 mm.
10381V/101 cylindrical test tubes in PS, with screw cap, Ø16 x 100 mm, sterile	10381V/101 cylindrical test tubes in PS, with screw cap, Ø16 x 100 mm, sterile
10381V/SG/150 10ml cylindrical test tubes in PS, screw cap, 150 mm, sterile	10381V/SG/150 10ml cylindrical test tubes in PS, screw cap, 150 mm, sterile
10381V/SG/20 CYLINDRICAL TT 10 ML SCREW CAP 16X100 PS STERILE 20 PCS/BAG	10381V/SG/20 CYLINDRICAL TT 10 ML SCREW CAP 16X100 PS STERILE 20 PCS/BAG
10381V/SG/25 10ml cylindrical test tubes in PS, screw cap, Ø16x100mm sterile	10381V/SG/25 10ml cylindrical test tubes in PS, screw cap, Ø16x100mm sterile
10381V/SG/CS 10ml cylindrical test tubes in PS, with screw cap, 161x100 mm sterile	10381V/SG/CS 10ml cylindrical test tubes in PS, with screw cap, 161x100 mm sterile
10381V/SG/CS/100 10ml cylindrical test tubes in PS, with screw cap, 16x100 mm	10381V/SG/CS/100 10ml cylindrical test tubes in PS, with screw cap, 16x100 mm
10381V/TA/SG 10ml cylindrical test tube PS, light blue screw cap, Ø16 x 100 mm, sterile	10381V/TA/SG 10ml cylindrical test tube PS, light blue screw cap, Ø16 x 100 mm, sterile
10382M/0 15ml cylindrical test tubes in PP, with screw cap, Ø16x120 mm 216x120 mm	10382M/0 15ml cylindrical test tubes in PP, with screw cap, Ø16x120 mm 216x120 mm
10382M/0/SG 15ml cylindrical test tubes PP screw cap, Ø16x120 mm, sterile	10382M/0/SG 15ml cylindrical test tubes PP screw cap, Ø16x120 mm, sterile
10382V/100/SG/CS 15ml cylindrical test tubes in PP, with screw cap, Ø16x120 mm, sterile	10382V/100/SG/CS 15ml cylindrical test tubes in PP, with screw cap, Ø16x120 mm, sterile
10382V/15 15ml cylindrical test tubes in PS, with screw cap not assembled, Ø16 x 120 mm.	10382V/15 15ml cylindrical test tubes in PS, with screw cap not assembled, Ø16 x 120 mm.
10382V/SG 15ml cylindrical test tubes in PS, with screw cap, Ø16 x 120 mm, sterile	10382V/SG 15ml cylindrical test tubes in PS, with screw cap, Ø16 x 120 mm, sterile
10382V/SG/CS 15ml cylindrical test tubes in PS, with screw cap, Ø16x120 mm, sterile	10382V/SG/CS 15ml cylindrical test tubes in PS, with screw cap, Ø16x120 mm, sterile
10382V/TA/SG 15ml cylindrical test tubes in PS, with screw cap, Ø16x120 mm sterile	10382V/TA/SG 15ml cylindrical test tubes in PS, with screw cap, Ø16x120 mm sterile
10383P/2 20ml cylindrical test tubes in PS, with screw cap not assembled, Ø16 x 160 mm.	10383P/2 20ml cylindrical test tubes in PS, with screw cap not assembled, Ø16 x 160 mm.
10383M/2 20ml cylindrical test tubes in PS, with red screw cap, Ø16 x 160 mm	10383M/2 20ml cylindrical test tubes in PS, with red screw cap, Ø16 x 160 mm
10383V/SG 20ml cylindrical test tubes in PS, with screw cap, Ø16 x 160 mm, sterile	10383V/SG 20ml cylindrical test tubes in PS, with screw cap, Ø16 x 160 mm, sterile
10383V/SG/CS 20ml cylindrical test tubes in PS, with screw cap, sterile not wrapped	10383V/SG/CS 20ml cylindrical test tubes in PS, with screw cap, sterile not wrapped
10383V/SG/CS/SG 20ml cylindrical test tube in PS, light blue screw cap, Ø16 x 160 mm, sterile	10383V/SG/CS/SG 20ml cylindrical test tube in PS, light blue screw cap, Ø16 x 160 mm, sterile
10383V/SG/SG 20ml cylindrical test tube in PS, yellow screw cap, Ø16 x 160 mm, sterile	10383V/SG/SG 20ml cylindrical test tube in PS, yellow screw cap, Ø16 x 160 mm, sterile
10383V/SG 20ml cylindrical test tubes in PS, with rim, graduated, Ø12 x 86 mm, with label	10383V/SG 20ml cylindrical test tubes in PS, with rim, graduated, Ø12 x 86 mm, with label
10383V/SG/SG 5ml cylindrical test tubes in PP, with rim, graduated, Ø12 x 86 mm, with label	10383V/SG/SG 5ml cylindrical test tubes in PP, with rim, graduated, Ø12 x 86 mm, with label

[illegible]



ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

№ ФСР 2009/06043

от 05 ноября 2009 года

Настоящее регистрационное удостоверение выдано
Обществу с ограниченной ответственностью «Медиклон»,
(ООО «Медиклон»),

Россия, 127276, Москва, Ботаническая улица, д.35, корпус 1
и подтверждает, что медицинское изделие

Набор реагентов для определения групп крови человека систем ABO,
Резус и Kell (Цоликлоны анти-A, анти-B, анти-AB, анти-A1, анти-АсII,
анти-D супер, анти-D (IgG), анти-C супер, анти-c супер, анти-E супер,
анти-e супер, анти-Kell супер) по ТУ 9398-101-51203590-2009
производства

Общество с ограниченной ответственностью «Медиклон»,
(ООО «Медиклон»),

Россия, 127276, Москва, Ботаническая улица, д.35, корпус 1
место производства:

Россия, 127276, Москва, Ботаническая улица, д.35, корпус 1

класс потенциального риска 2а

ОКП 93 9816

вид медицинского изделия –

соответствующее регистрационному досье № 67875 от 22.09.2009

приказом Росздравнадзора от 05 ноября 2009 года № 8861-Пр/09

и приказом от 17 июля 2013 года № 3237-Пр/13 с замене
допущено к обращению на территории Российской Федерации.

Приложение: на 1 листе

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения

М.А. Муранко



**ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ
№ ФСР 2009/06043**

Лист 1

- поликлон анти-А - моноклональные антитела (IgM) к антигену А;
- поликлон анти-В - моноклональные антитела (IgM) к антигену В;
- поликлон анти-АВ - моноклональные антитела (IgM) к антигенам А и В;
- поликлон анти-А1 - фитогемагглютинин к антигену А1;
- поликлон анти-Асл - моноклональные антитела (IgM) к антигенам А1 и А2;
- поликлон анти-D супер - моноклональные антитела (IgM) к антигену D;
- поликлон анти-D (IgG) - моноклональные антитела (IgG) к антигену D;
- поликлон анти-С супер - моноклональные антитела (IgM) к антигену С;
- поликлон анти-с супер - моноклональные антитела (IgM) к антигену с;
- поликлон анти-Е супер - моноклональные антитела (IgM) к антигену Е;
- поликлон анти-е супер - моноклональные антитела (IgM) к антигену е;
- поликлон анти-Kell супер - моноклональные антитела (IgM) к антигену К;

≡

Приказом от 17 июля 2013 года № 3237-Пр/13 о замене допущено к обращению на территории Российской Федерации.

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения

05 ноября 2009 года



М.А. Мурашко





ООО "Медиклон"

127276 Москва, Ботаническая ул., 35, т/ф: +7495 231-2272 +7499 502-1214

ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем
ABO, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-AB)
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г.

Наименование: Цоликлон Анти-В во флаконах по 10 мл с синими крышками

Серия: 095810

Единица: 100 мл

Изготовлен: 21.10.2019

Количество единиц: 40

Годен до: 21.10.2021

Объем серии: 10000 мл.

Паспорт: B095810 от 21.10.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1 Цоликлон анти-А	Прозрачная жидкость красного цвета.	Соответствует
1.2 Цоликлон анти-В	Прозрачная жидкость синего цвета.	
1.3 Цоликлон анти-AB	Прозрачная бесцветная жидкость.	
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и O(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(II) и O(I) Цоликлон анти-AB не должен давать агглютинации с эритроцитами группы O(I)	Соответствует Соответствует Соответствует
2.1.1 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64 Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III)	Соответствует 10 секунд Соответствует 1:32 - 1:64
2.3 Титр	Титр Цоликлона анти-AB в реакции агглютинации на плоскости с эритроцитами групп А(II) 1:32 - 1:64 и В(III) 1:64	Соответствует 1:64 Соответствует 1:32 - 1:64

Цоликлон соответствует требованиям ТУ-9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон»

М.С. Орлова



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ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем
ABO, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-AB)
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г.

Наименование: Цоликлон Анти-А во флаконах по 10 мл с красными крышками

Серия: 096111

Единица: 100 мл

Изготовлен: 05.11.2019

Количество единиц: 40

Годен до: 05.11.2021

Объем серии: 10000 мл.

Паспорт: A096111 от 05.11.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1 Цоликлон анти-А	Прозрачная жидкость красного цвета.	Соответствует
1.2 Цоликлон анти-В	Прозрачная жидкость синего цвета.	
1.3 Цоликлон анти-AB	Прозрачная бесцветная жидкость.	
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и O(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(II) и O(I) Цоликлон анти-AB не должен давать агглютинации с эритроцитами группы O(I)	Соответствует Соответствует Соответствует
2.1.1 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64 Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III)	Соответствует 10 секунд Соответствует 1:32 - 1:64
2.3 Титр	Титр Цоликлона анти-AB в реакции агглютинации на плоскости с эритроцитами групп А(II) 1:32 - 1:64 и В(III) 1:64	Соответствует 1:64 Соответствует 1:32 - 1:64

Цоликлон соответствует требованиям ТУ-9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон»

М.С. Орлова



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ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем
ABO, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОН Анти-D Супер)
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-D Супер во флаконах по 10 мл с зелеными крышками

Серия: 292711 Единица: 100 мл
Изготовлен: 05.11.2019 Количество единиц 40
Годен до: 05.11.2021 Объем серии: 10000 мл.
Паспорт: Дс292711 от 05.11.2019

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1. Внешний вид	Прозрачная жидкость светло-бежевого цвета	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-D Супер не должен агглютинировать D(-) эритроциты.	Соответствует
2.2 Гемагглютинирующая способность	Четкая реакция агглютинации должна наступить в течение 30 сек. после смешивания реагента с D(-) эритроцитами	Соответствует 30 сек.
2.3 Титр	Титр Цоликлона Анти-D Супер в реакции агглютинации на плоскости с D(+) эритроцитами 1:32 Титр Цоликлона Анти-D Супер в реакции прямой агглютинации с D(+) эритроцитами в микропласте не ниже 1:256	Соответствует 1:32 1:256

Цоликлон соответствует требованиям ТУ - 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон»

М.С.Орлова



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ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем
ABO, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОНЫ Анти-A, Анти-B и Анти-AB)
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-AB

Серия: 098611 Единица: 100 мл
Изготовлен: 05.11.2019 Количество единиц 10
Годен до: 05.11.2021 Объем серии: 10000 мл.
Паспорт: АВ098611 от 05.11.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1 Цоликлон анти-A	Прозрачная жидкость красного цвета.	Соответствует
1.2 Цоликлон анти-B	Прозрачная жидкость синего цвета.	
1.3 Цоликлон анти-AB	Прозрачная бесцветная жидкость.	
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-A не должен давать агглютинации с эритроцитами групп B(III) и O(I) Цоликлон анти-B не должен давать агглютинации с эритроцитами групп A(II) и O(I) Цоликлон анти-AB не должен давать агглютинации с эритроцитами групп O(I)	Соответствует Соответствует Соответствует
2.1 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов A1 и B с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10 секунд
2.3 Титр	Титр Цоликлона анти-A в реакции агглютинации на плоскости с эритроцитами группы A(II) 1:32 - 1:64 Титр Цоликлона анти-B в реакции агглютинации на плоскости с эритроцитами группы B(III)	Соответствует 1:32 - 1:64
	Титр Цоликлона анти-AB в реакции агглютинации на плоскости с эритроцитами групп A(II) 1:32 - 1:64 и B(III) 1:64	Соответствует 1:64 Соответствует 1:32 - 1:64

Цоликлон соответствует требованиям ТУ - 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон»

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ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем
ABO, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОН Анти-Kell Супер)
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-Kell Супер

Серия: 196410

Единица: 100 мл

Изготовлен: 21.10.2019

Количество единиц: 10

Годен до: 21.10.2021

Объем серии: 10000 мл

Паспорт: K196410 от 21.10.2019

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1. Внешний вид	Прозрачная желтоватая или розоватая жидкость.	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-Kell супер не должен агглютинировать эритроциты K(-)	Соответствует
2.2 Гемагглютинирующая способность	Четкая реакция агглютинации для плоскости должна наступать в течение 30 сек. после смешивания	Соответствует
2.2 Активность	Титр Цоликлона Анти-Kell Супер в реакции прямой агглютинации в микроплате не ниже 1:16	Соответствует 1:16

Цоликлон соответствует требованиям ТУ - 9398-101-51203590-2009
Заведующая ОТК ООО «Медиклон»

М.С. Орлова



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ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем
ABO, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОН Анти-D (IgG))
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-D(IgG)

Серия: 292110

Единица: 100 мл

Изготовлен: 28.10.2019

Количество единиц: 10

Годен до: 28.10.2021

Объем серии: 10000 мл

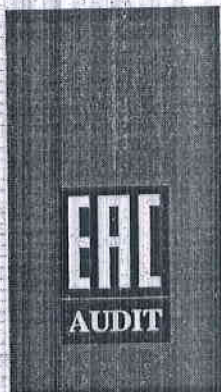
Паспорт: Дж292110 от 28.10.2019

Наименование показателя	Характеристика нормы	Результаты испытаний
1. Внешний вид	Прозрачная жидкость светло-бежевого цвета	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-D не должен агглютинировать D(-) эритроциты.	Соответствует
2.2 Гемагглютинирующая способность	Агглютинация эритроцитов D+ с Цоликлоном в пробирочном тесте с желатином должна появиться не позднее 15 мин.	Соответствует
2.3 Титр	Титр Цоликлона анти-D в пробирочном тесте с желатином 1:128. Титр Цоликлона в непрямом антиглобулиновом тесте: 1:512	Соответствует

Цоликлон соответствует требованиям ТУ - 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон»

М.С. Орлова



ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»

РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1

ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»

РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028

ИНН 7717616798 ОГРН 1087746489060

Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17

Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru



№003749

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.00813

Общество с ограниченной ответственностью «МиниМед»

(наименование лица)

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

(юридический адрес лица)

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

(фактический адрес лица)

ИНН: 3234007127

ОГРН: 1023202138332

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

системы менеджмента качества изделий медицинских Общества с ограниченной ответственностью «МиниМед» требованиям ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования» применительно к Производство лабораторной посуды, медицинских изделий, приборов и принадлежностей, красителей, реагентов и наборов реагентов для in-vitro диагностики

Дата регистрации: 19-03-2019

Срок действия до: 18-03-2022

Руководитель органа
по сертификации:



(подпись)

В. И. Погодин

(подпись)

Е. Д. Курбатова

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С
ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ
ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

Федеральное агентство по техническому регулированию и метрологии

НОПСС

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "НОПСС". РОСС RU.31988.04ЖСН2

Орган по сертификации ООО "Невский Альянс"
ОГРН 1147847286960 ИНН 7842525530

www.nopss.ru

АКТ

О ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

К СЕРТИФИКАТУ № С1256

ВЫДАН

ООО «МиниМед»

ИНН 3234007127

Настоящий акт удостоверяет, что система менеджмента качества
соответствует требованиям ГОСТ ISO 9001-2015

Сертификат выдан: 24 сентября 2019

Действителен до: 24 сентября 2020

Руководитель органа
по сертификации



Подпись

Платонов Б. А.



Федеральное агентство по техническому регулированию и метрологии



Система добровольной сертификации "НОПСС". РОСС RU.31827.04ЖСН1

Орган по сертификации ООО "Невский Альянс". ОГРН 1147847286960 ИНН 7842525530

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СЕРТИФИКАТ СООТВЕТСТВИЯ

Общество с ограниченной ответственностью
выдан

«МиниМед»

ИНН 3234007121 / ОГРН 1023202138332

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

Подтверждает, что система менеджмента качества
соответствует требованиям ГОСТ ISO 9001-2015 (ISO 9001:2015)

При осуществлении работ согласно приложению №1 к настоящему сертификату

Сертификат выдан на основании решения экспертной комиссии

от 24.09.2018

Срок действия до 24 сентября 2021

Номер в едином реестре системы СИ 256

Руководитель органа
по сертификации:

Подпись

Платонов Б.А.



Настоящий сертификат обязывает организацию поддерживать состояние выполняемых работ в соответствии с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации СДС "НОПСС" и подтверждаться при прохождении ежегодного инспекционного контроля.

Федеральное агентство по техническому регулированию и метрологии



Система добровольной сертификации "НОПСС". РОСС RU.31827.04ЖСН1

Орган по сертификации ООО "Невский Альянс". ОГРН 1147847286960 ИНН 7842525530

www.norss.ru

ПРИЛОЖЕНИЕ №1

К сертификату соответствия № СИ256

Применительно к видам деятельности:

Производство лабораторной посуды, медицинских изделий, приборов и принадлежностей, красителей, реагентов и наборов реагентов для in-vitro диагностики.

НОПСС



Руководитель органа
по сертификации:

Подпись

Платонов Б.А.





ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 11 января 2016 года № ФСР 2009/04160

На медицинское изделие

Набор реагентов для окраски по Граму «Диахим-Набор для окраски по Граму»
по ТУ 9398-019-27428909-2008

Настоящее регистрационное удостоверение выдано

Общество с ограниченной ответственностью "Научно-производственная фирма
"АБРИС+" (ООО "НПФ"АБРИС+"), Россия,
196084, Санкт-Петербург, ул. Цветочная, д. 16, лит. М, 2-й этаж

Производитель

Общество с ограниченной ответственностью "Научно-производственная фирма
"АБРИС+" (ООО "НПФ"АБРИС+"), Россия,
196084, Санкт-Петербург, ул. Цветочная, д. 16, лит. М, 2-й этаж

Место производства медицинского изделия

192019, Санкт-Петербург, ул. Профессора Качалова, д. 15а, лит. А

Номер регистрационного досье № РД-9488/61061 от 11.12.2015

Вид медицинского изделия 107820

Классе потенциального риска применения медицинского изделия 2а

Код Общероссийского классификатора продукции для медицинского изделия 93 9816

приказом Росздравнадзора от 11 января 2016 года № 48
допущено к обращению на территории Российской Федерации.

Руководитель Федеральной службы
по надзору в сфере здравоохранения

М.А. Мурашко

0016961



CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE
EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/CE
PRORROGA/EXTENSION — Fecha inicial/ Initial date: 04/12/2008
Fecha de última prórroga/ Last extension date: 27/11/2013

Certificado n°/Certificate no	Fecha de validez/Date of validity	ON n°/NB no
2008 12 0588 ED	Desde/From 19/11/2018 Hasta/To 18/11/2023	0318

A favor de /In favour of:

Fabricante/Manufacturer:
Nombre/Name: DIA. Pro Diagnostic Bioprobes S.r.l.
Dirección/Address: Via G. Carducci, 27 - 20099 - Sesto San Giovanni - Milano (Italy).
Representante autorizado ante la UE/Authorized EU representative:
Nombre/Name: Idem Dirección/Address: Idem

Para el producto/For the product:

Categoría/Category: Productos Sanitarios para Diagnóstico "In Vitro" / In Vitro Diagnostic Medical Devices
Grupo genérico/Generic group: Diagnóstico de enfermedades infecciosas / Diagnostic of infectious diseases
Tipo/Type: Especificados en Anexos de este Certificado/Specified in Annexes to this Certificate.

Elaborado en/In the facilities:

DIA. Pro Diagnostic Bioprobes S.r.l.
Via G. Carducci, 27 - 20099 - Sesto San Giovanni - Milano (Italy).

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total N° 2003 12 0388 CT/ This certificate must be accompanied by the EC Full Quality Assurance System Certificate N° 2003 12 0388 CT.

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente N° 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ This certificate is issued on the assessment of the design documentation contained in dossier N° 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS



Fdo. M^a Jesús Lamas Díaz

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ORGANISMO NOTIFICADO 0318
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Fax: (+34) 91 822 59 98

CERTIFICADO DE EXAMEN CE DE DISEÑO
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2008 12 0588 ED	Desde/From 19/11/2018 Hasta/To 18/11/2023	0318

A favor de /In favour of:

Fabricante/Manufacturer:
Nombre/Name: Dia. Pro Diagnostic Bioprobes S.r.l.
Dirección/Address: Via G. Carducci, 27 - 20099 - Sesto San Giovanni - Milano (Italy).
Representante autorizado ante la UE/Authorized EU representative:
Nombre/Name: Idem Dirección/Address: Idem

Tipo de producto / Device type: Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas / Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.

Clasificación/Classification: Lista A, Anexo II / List A, Annex II

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis B, mediante técnicas de Inmunoabsorción enzimática (ELISA) / Reagents and reagent products for the determination, confirmation and quantification in human specimens of markers of Hepatitis B infection, by Enzyme-linked immunosorbent assay (ELISA) [NANDO: IVD 0203]

HBs Ag one Version ULTRA ELISA cualitativo / ELISA qualitative

- SAGIULTRA.CE (192 tests)
- SAGIULTRA.CE.96 (96 tests)
- SAGIULTRA.CE.480 (480 tests)
- SAGIULTRA.CE.960 (960 tests)
- SAGIULTRA.CE.DB (192 tests - for Dia Blood application)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS



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Fax: (+34) 91 822 59 98



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PRÓRROGA/EXTENSION — Fecha inicial/ Initial date: 11/12/2003
Fecha de última prórroga/ Last extension date: 27/11/2013

Certificado n°/Certificate no	Fecha de validez/Date of validity	ON n°/NB no
2003 12 0390 ED	Desde/From 19/11/2018 Hasta/To 18/11/2023	0318

A favor de/In favour of:

Fabricante/Manufacturer:

Nombre/Name: Dia. Pro Diagnostic Bioprobes S.r.l.
Dirección/Address: Via G. Carducci, 27 - 20099- Sesto San Giovanni - Milano (Italy).
Representante autorizado ante la UE/Authorized EU representative:
Nombre/Name: Idem Dirección/Address: Idem

Tipo de producto / Device type: Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas / Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.

Clasificación/Classification: Lista A, Anexo II / List A, Annex II

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis B, mediante técnicas de Inmunoabsorción enzimática (ELISA) Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis B infection, by Enzyme-linked immunosorbent assay (ELISA)
[NANDO: IVD 0203]

HBs Ab ELISA cualitativo-cuantitativo / ELISA qualitative-quantitative

- SAB-CE (96 tests)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS



Fdo. M^a Jesús Lamas Díaz

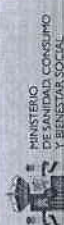
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2003 12 0390 ED	Desde/From 19/11/2018 Hasta/To 18/11/2023	0318

A favor de/In favour of:

Fabricante/Manufacturer:

Nombre/Name: DIA. Pro Diagnostic Bioprobes S.r.l.
Dirección/Address: Via G. Carducci, 27 - 20099- Sesto San Giovanni - Milano (Italy).
Representante autorizado ante la UE/Authorized EU representative:

Nombre/Name: Idem Dirección/Address: Idem

Para el producto/For the product:

Categoría/Category: Productos Sanitarios para Diagnóstico "In Vitro" / In Vitro Diagnostic Medical Devices
Grupo genérico/Generic group: Diagnóstico de enfermedades infecciosas / Diagnostic of infectious diseases
Tipo/Type: Especificados en Anexos de este Certificado/Specified in Annexes to this Certificate.

Elaborado en/In the facilities:

Dia. Pro Diagnostic Bioprobes S.r.l.
Via G. Carducci, 27 - 20099- Sesto San Giovanni - Milano (Italy).

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Madrid, 19 de noviembre de 2018
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MINISTERIO
DE SANIDAD, CONSUMO
Y BIENESTAR SOCIAL

CERTIFICADO DE EXAMEN CE DE DISEÑO
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Fecha de última prórroga/Last extension date: 27/11/2013

Certificado n°/Certificate no	Fecha de validez/Date of validity	ON n°/NB no
2003 12 0392 ED	Desde/From 19/11/2018 Hasta/To 18/11/2023	0318

A favor de/In favour of:

Fabricante/Manufacturer:
Nombre/Name: DIA. Pro Diagnostic Bioprobes S.r.l.
Dirección/Address: Via G. Carducci, 27 - 20099 - Sesto San Giovanni - Milano (Italy).
Representante autorizado ante la UE/Authorized EU representative:
Nombre/Name: Idem Dirección/Address: Idem

Para el producto/For the product:

Categoría/Category: Productos Sanitarios para Diagnóstico "In Vitro" / In Vitro Diagnostic Medical Devices
Grupo genérico/Generic group: Diagnóstico de enfermedades infecciosas / Diagnostic of infectious diseases
Tipo/Type: Especificados en Anexos de este Certificado/Specified in Annexes to this Certificate.

Elaborado en/In the facilities:

Dia. Pro Diagnostic Bioprobes S.r.l.
Via G. Carducci, 27 - 20099 - Sesto San Giovanni - Milano (Italy).

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Madrid, 19 de noviembre de 2018
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ORGANISMO NOTIFICADO 0318

CERTIFICADO DE EXAMEN CE DE DISEÑO
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2003 12 0392 ED	Desde/From 19/11/2018 Hasta/To 18/11/2023	0318

A favor de/In favour of:

Fabricante/Manufacturer:
Nombre/Name: Dia. Pro Diagnostic Bioprobes S.r.l.
Dirección/Address: Via G. Carducci, 27 - 20099 - Sesto San Giovanni - Milano (Italy).
Representante autorizado ante la UE/Authorized EU representative:
Nombre/Name: Idem Dirección/Address: Idem

Tipo de producto / Device type: Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas / Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.

Clasificación/Classification: Lista A, Anexo II / List A, Annex II

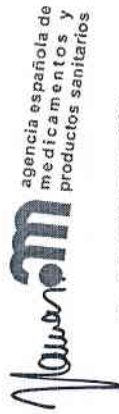
Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis C, mediante técnicas de Inmunoabsorción enzimática (ELISA) / Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis C infection, by Enzyme-linked immunosorbent assay (ELISA) [NANDO: IVD 0203]

HCV Ab ELISA cualitativo / ELISA qualitative

- CVAB CE (192 tests)
- CVAB CE 96 (96 tests)
- CVAB CE 480 (480 tests)
- CVAB CE 960 (960 tests)
- CVAB CE DB (192 tests - for Dia Blood application)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS



Fdo. M^a Jesús Lamas Díaz

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Fax: (+34) 91 622 52 89

ORGANISMO NOTIFICADO 0318

Product List – CE Marked

Certified by

ISO 13485:2012

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

2015-10

08102015-CSch

08102015-CSch

NovaLisa®	Virology
Prod. No.	Name
ADVAG0040	Adenovirus IgA
ADVAG0010	Adenovirus IgG
ADVAM0010	Adenovirus IgM
CHIG0590	Chikungunya Virus IgG capture
CHIM0590	Chikungunya Virus IgM µ-capture
CMVG0110	Cytomegalovirus (CMV) IgG
CMVM0110	Cytomegalovirus (CMV) IgM
DENG0120	Dengue Virus IgG
DENM0120	Dengue Virus IgM
DVM0640	Dengue Virus IgM µ-capture
EBVA0150	Epstein-Barr Virus (VCA) IgA
EBVG0150	Epstein-Barr Virus (VCA) IgG
EBVM0150	Epstein-Barr Virus (VCA) IgM
EBVG0580	Epstein-Barr Virus (EBNA) IgG
HANG0670	Hantavirus IgG
HANM0670	Hantavirus IgM
HSVG0250	Herpes simplex Virus 1+2 (HSV) IgG
HSVH0250	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
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
RUBM0400	Rubella Virus IgM µ-capture
TICG0440	TBE / FSME IgG
TICM0440	TBE / FSME IgM
PTICG044	TBE / FSME IgG plus

VZVA0490
VZVG0490
VZVM0490

Varicella-Zoster Virus (VZV) IgA
Varicella-Zoster Virus (VZV) IgG
Varicella-Zoster Virus (VZV) IgM

NovaLisa® Bacteriology

Prod. No.	Name
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
CPA0730	Chlamydia pneumoniae IgA
CPG0730	Chlamydia pneumoniae IgG
CPM0730	Chlamydia pneumoniae IgM
HELA0220	Helicobacter pylori IgA
HELG0220	Helicobacter pylori IgG
PHELA022	Helicobacter pylori IgA plus
PHELG022	Helicobacter pylori IgG plus
BORG0320	Lyme Borrelia IgG
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

3

08102015-CSch

TREG0470 Treponema pallidum

NovaLisa® Parasites

Prod. No.	Name
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
ENTG0140	Entamoeba histolytica IgG
GIA0160S	Giardia lamblia antigen
LEGG0650	Legionella Pneumophila IgG
LEGM0650	Legionella Pneumophila IgM
LEIG0310	Leishmania infantum IgG
MAL0620	Malaria
STRO0690	Strongyloides
TOXA0460	Toxoplasma gondii IgA
TOXG0460	Toxoplasma gondii IgG
TOXGA460	Toxoplasma gondii IgG Avidity Test
TOXM0460	Toxoplasma gondii IgM µ-capture

NovaLisa® Worms

Prod. No.	Name
ASCG0020	Ascaris lumbricoides IgG
ECHG0130	Echinococcus IgG
SCHG0410	Schistosoma mansoni IgG
TAE0420	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

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NovaLisa® Hormones

THYROID HORMONES
(ELISAs for the determination of thyroid hormones and antibodies)

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

NovaLine

Prod. No.	Name
RUBG2400	Rubella Virus IgG Immunoblot
TRYG2570	Chagas IgG LineBlot

Hormones

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

Prod. No.	Name
DSNOV001	Cortisol
DSNOV002	Testosterone
DSNOV003	17 beta-Estradiol
DSNOV004	17-OH Progesterone
DSNOV005	DHEA-S
DSNOV006	Progesterone
DSNOV007	Free Estrol
DSNOV008	Androstenedione
DSNOV009	Free Testosterone
DSNOV011	Total Estrol
DSNOV012	Aldosterone

STEROID HORMONES IN URINE
(ELISAs for the determination of steroid hormones in urine)

Prod. No.	Name
DSNOV010	Urinary Cortisol

STEROID HORMONES IN SALIVA
(ELISAs for the determination of steroid hormones in saliva)

Prod. No.	Name
DSNOV20	Cortisol Saliva
DSNOV21	Testosterone Saliva
DSNOV22	17 beta-Estradiol Saliva

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DSNOV24	DHEA-S Saliva
DSNOV25	Progesterone Saliva
DSNOV26	Estriol Saliva
DSNOV27	Androstenedione Saliva

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

Prod. No.	Name
DSNOV030	LH
DSNOV031	FSH
DSNOV032	Prolactin
DSNOV033	AFP
DSNOV034	beta HCG

THYROID HORMONES
(ELISAs for the determination of thyroid hormones and antibodies)

Prod. No.	Name
DSNOV051	Free T3
DSNOV052	Free T4
DSNOV053	Total T3
DSNOV054	Total T4
DSNOV057	Thyroglobulin

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

Prod. No.	Name
DSNOV111	Insulin
DSNOV112	C-Peptide

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

Prod. No.	Name
DSNOV093	CIC-C1q
DSNOV094	CIC-C3d
DSNOV096	CH-50

TUMOR MARKERS

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

Prod. No.	Name
DN0V060	CEA
DN0V061	CA 125
DN0V062	CA 15-3
DN0V063	CA 19-9

MISCELLANEOUS

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

Prod. No.	Name
DN0V100	Ferritin
DN0V101	HGH
DN0V102	IgE

NovaLisa® Autoimmune

Autoimmune

(ELISAs for the determination of specific autoimmune antibodies)

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

Rheumatology

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

Prod. No.	Name
RFM3010	Rheumatoid Factor IgM

Autoimmune

ANCA / VASCULITIS

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

Prod. No.	Name
DN0V125	Anti PR 3 (c-ANCA)
DN0V126	Anti-MPO (p-ANCA)

DIABETES MONITORING

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

Prod. No.	Name
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DN0V185	Anti GAD
DN0V187	Anti IA2

GASTRO ENTEROLOGY

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

Prod. No.	Name
DN0V140	Anti Deamidated Gliadin Peptide (DGP) IgG
DN0V141	Anti Deamidated Gliadin Peptide (DGP) IgA

THROMBOSIS

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

Prod. No.	Name
DN0V157	Anti Cardiolipin IgG
DN0V158	Anti Cardiolipin IgM
DN0V159	Anti Phospholipid screen

THYROID

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

Prod. No.	Name
DN0V117	TSH Receptor Autoantibody

RHEUMATOLOGY

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

Prod. No.	Name
DN0V171	Anti dsDNA IgG
DN0V174	Anti ENA Screen
DN0V175	Anti ANA Screen
DN0V182	Anti-CCP

NovaLisa®

Recombinant Antigens

Prod. No.	Name
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

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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
TREG0470	Treponema pallidum

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
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

NovaLisa® Quantitative Assays

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
HELA0220	Helicobacter pylori IgA
HELG0220	Helicobacter pylori IgG
PHELA022	Helicobacter pylori IgA plus
PHELG022	Helicobacter pylori IgG plus
RUBG0400	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

Antigen Assays

Prod. No.	Name
GIAU160S	Giardia lamblia 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

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
TREG0470	Treponema pallidum
TRIG0480	Trichinella spiralis IgG

NovaLisa® Liquor Diagnostic

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