EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: /
Name and address of the manufacturer: /
Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante:

BOEN HEALTHCARE CO., LTD
Unit 602, International Center, No.535, Shenxu Road,
Suzhou, 215021, Jiangsu, China

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: /
the medical device: /
le dispositif médical: /
il dispositivo medico:

Vacuum Blood Collection Tube

der Klasse: /
of class: /
de la classe: /
di classe:

Common/Others IVD
(Devices of NOT Annex II and NOT self-test)

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II
(IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d’évaluation de la conformité: /
Procedura di valutazione della conformità:

Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 /
EG Annex III (expect point 6) of IVDD 98/79/EC
Annexe III (sauf le point 6) de l'IVDD 98/79 / CE
Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE

Registrier-Nr.: /
Registration No.: /
N°d’enregistrement: /
Numero di registrazione:

Digitally signed by Ceaicovschi Tudor
Date: 2022.03.29 09:58:37 EEST
Reason: MoldSign Signature
Location: Moldova

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

CE

Suzhou, 201.05.26

General Manager

Ort, Datum / Place, date /
Lieu, date / Luogo, data

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

Vacuum Blood Collection Tube, Gel & Clot Activator Tube

Material: PET, Glass
Color: Yellow

Cat. No.	Specification	Volume	Additive	Qty/case (Glass)	Qty/case (PET)
630201	13×75mm	3ml	Gel & Clot Activator	1800	1800
630202	13×75mm	4ml	Gel & Clot Activator	1800	1800
630203	13×75mm	5ml	Gel & Clot Activator	1800	1800
630204	13X100mm	5ml	Gel & Clot Activator	1200	1200
630205	13×100mm	6ml	Gel & Clot Activator	1200	1200
630206	13×100mm	8ml	Gel & Clot Activator	1200	1200
630207	16x100mm	8ml	Gel & Clot Activator	1200	1200
630208	16×100mm	9ml	Gel & Clot Activator	1200	1200
630209	16×100mm	10ml	Gel & Clot Activator	1200	1200

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.

4426

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

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DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product name	Catalogue number
RPR Carbon kit	044150A 044500A

MANUFACTURER

Name	Lorne Laboratories
Address	Unit 1 Cutbush Park Industrial Estate Danehill Lower Earley Berks, RG6 4UT
Country	United Kingdom

MEANS OF CONFORMITY

I hereby declare that the products listed above comply 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).

This declaration is valid from 17 May 2015.

_____

Eddy Velthuis
Technical Director

VACUTEST kima

www.vacutestkima.it

DICHIARAZIONE DI CONFORMITÁ CE
EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE *"Dispositivi Medico-Diagnostici In Vitro" e s.m.i.*
according to Annex III of the Directive 98/79/EC on "In Vitro Diagnostic Medical Devices" as amended

fabbricante / *manufacturer*: ***VACUTEST KIMA S.r.l. - articoli per laboratori analisi / disposable labware***

indirizzo / *address*: ***Via dell'Industria, 12 35020 Arzergrande (PD) - Italia***

telefono / *phone* **+39-049-9720624** fax / *fax* **+39-049-9720182** posta elettronica / *e-mail* **info@vacutestkima.it**

identificazione dei prodotti / *product identification*:

Sistema di prelievo di sangue e altri liquidi biologici mediante provette con vuoto predeterminato in plastica "VACUTEST KIMA".

"VACUTEST KIMA" vacuum blood and biological liquids collection tubes in plastic.

nome commerciale / *brand name*: **"VACUTEST KIMA"**

classificazione dei prodotti / *product classification*: **dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.**
devices other then those mentioned in Annex II of the Directive 98/79/EC as amended

Si dichiara

sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. *"Dispositivi Medico–Diagnostici In Vitro"*.
Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

Hereby we declare

under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on "In Vitro Diagnostic Medical Devices".

All the supporting documents, as required by Annex III, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data / *place and date*: **Arzergrande, 01/01/2015**

firma / *signature*: **Assicuratore Qualità / Quality Manager**
Giovanni Chiarin

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THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com
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.

4265/5/A

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

MEUS S.r.l.

Unità Operative / *Operative Units*
Via Leonardo Da Vinci, 24B-26-28 - Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia
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 stampi per articoli in plastica per laboratorio analisi.
Via dell'Industria 2-16 - 35020 Arzergrande (PD) – Italia
Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico.

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*

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. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi.

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. Design and production of moulds for plastic labware.

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.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and Specific Scheme.

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	EMISSIONE CORRENTE	DATA DI SCADENZA
FIRST ISSUE	*CURRENT ISSUE*	*EXPIRING DATE*
18/01/2007	18/01/2022	17/01/2025

Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

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SGQ N° 004 A

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ICIM

CERTIFICATO n.
CERTIFICATE No.

4265/5/B

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

ROLL S.r.l.

UNITÀ OPERATIVA / *OPERATIVE UNIT*

Via Leonardo Da Vinci, 24A - 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*

Progettazione e produzione di Holders (camicie) per prelievo sottovuoto. Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.

Design and production of Holders for vacuum sampling. Design and production of diagnostic kits for blood and biological liquids analysis. 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.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and Specific Scheme.

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.

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FIRST ISSUE	*CURRENT ISSUE*	*EXPIRING DATE*
18/01/2007	18/01/2022	17/01/2025

Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

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CERTIFICATO n.
CERTIFICATE No. **4265/5/D**

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

VACUTEST KIMA S.r.l.

Sede / *Head office*
Via dell'Industria, 12 - 35020 Arzergrande (PD) – Italia
Uffici direzionali e amministrativi
Unità Operative / *Operative Units*
Via dell'Industria, 12 - 35020 Arzergrande (PD) – Italia
Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. 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.
Via Leonardo Da Vinci, 22 – 35028 Piove di Sacco (PD)
Uffici commerciali e magazzino.

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*

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. 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.

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. 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.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and Specific Scheme.

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.

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Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

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CISQ is the Italian Federation of management system Certification Bodies.

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Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1034230-1

Organization: nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Germany

Scope: Design and development, manufacture and distribution of in vitro diagnostic test kits and reagents for the detection or determination of cardiac markers, tumor markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing as well as associated in vitro diagnostic devices for sampling and analysis systems for rapid tests.

Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs and lancets.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1089325-40
Effective date: 2021-12-02
Expiry date: 2024-12-01
Issue date: 2021-11-29

TÜV Rheinland LGA Products GmbH · TÜVRheinland® · Zertifizierungsstelle

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

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Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

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Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1034230-1

Organization: nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Germany

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o nal von minden GmbH Carl-Zeiss-Str. 12 47445 Moers Germany	Manufacture and distribution
/02	c/o nal von minden GmbH Friedenstr. 32 93053 Regensburg Germany	Design and development and distribution
/03	c/o nal von minden GmbH Robert-Bosch-Breite 34 37079 Göttingen Germany	Design and development and manufacture
/04	c/o nal von minden GmbH Raseweg 4 37124 Rosdorf Germany	Administration and distribution

Report No.: 1089325-40
Effective date: 2021-12-02
Expiry date: 2024-12-01
Issue date: 2021-11-29

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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

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D-ZM-14169-01-02

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EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60131398 0001

Report No.: 21200072 015

Manufacturer:
nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Deutschland

Products:
- IVDs for the detection of infectious disease markers
- IVDs for the detection of the tumor marker PSA
- Urine tests for self-testing

(see attachment for products and sites included)

Replaces Certificate, Registration No.: HL 60114562 0001

Expiry Date: 2023-11-27

The Notified Body hereby declares that the requirements of Annex IV, excluding section 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.

Effective Date: 2018-11-28

Date: 2018-11-27

Notified Body

Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HL 60131398 0001
Report No.: 21200072 015

Manufacturer: nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Deutschland

Products included:

In vitro diagnostica for self-testing:
- HCG pregnancy tests
- LH ovulation tests
- Single- and multi-constituent test strips for urinalysis

In vitro diagnostica rapid tests:
- Chlamydia trachomatis Rapid Tests
- PSA Rapid Tests

Site included:

nal von minden GmbH
Friedenstr. 32
93053 Regensburg
Germany

Activities: Design and development

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierstelle

Date: 2018-11-27

Dipl.-Ing. Sven Hoffmann

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Certificate

Standard	**ISO 9001:2015**
Certificate Registr. No.	**01 100 1810016**

Certificate Holder:

nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Germany

including the locations according to annex

Scope:

Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances.
Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity:

The certificate is valid from 2021-09-10 until 2024-09-09.
First certification 2018

2021-09-10

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

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Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

No.	Location	Scope
/01	c/o nal von minden GmbH Carl-Zeiss-Str. 12 47445 Moers Germany	Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances.Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

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Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

/02	c/o nal von minden GmbH Friedenstr. 32 93053 Regensburg Germany	Design and development, distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances.Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

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Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

/03	c/o nal von minden GmbH Robert-Bosch-Breite 34 37079 Göttingen Germany	Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances.Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

2021-09-10

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КПП 320701001 ОКПО 29508133

Паспорт

МАСЛО ИММЕРСИОННОЕ
ГОСТ-13739-78

Наименование показателей	Нормы по ГОСТ	Результаты анализа
1.Внешний вид	Прозрачная жидкость желтоватого цвета со слабым характерным запахом.	Соответствует
2. Удельный вес		0,93
3.Показатель преломления при температуре 20 С	1,5150-1,5180	1,5152
3.Величина светопропускания р-ра масла,% не менее	70	90
4.Вязкость при 20 С	220-400	385

Срок хранения 1,5 года
Заключение ОТК: продукт соответствует ГОСТу 13739-78.

Начальник ОТК
Анализ произвел

КОПИЯ ВЕРНА

Общество с ограниченной ответственностью для документов «МИНИМЕД» г. Брянск

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 07 декабря 2015 года № ФСР 2011/11336

На медицинское изделие
Краситель - фиксатор эозин метиленовый синий по Май-Грюнвальду (МиниМед-М-Г) по ТУ 9398-004-29508133-2011

Настоящее регистрационное удостоверение выдано
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Номер регистрационного досье **№ РД-9272/51850 от 18.11.2015**

Вид медицинского изделия **170510**

Класс потенциального риска применения медицинского изделия **3**

Код Общероссийского классификатора продукции для медицинского изделия **93 9816**

приказом Росздравнадзора от 07 декабря 2015 года № 9114
допущено к обращению на территории Российской Федерации.

Руководитель Федеральной службы по надзору в сфере здравоохранения **М.А. Мурашко**

0015714

new art laboratories

NADAL® FOB Test (test cassette)

REF 272001

IVD CE

Version 1.5, 2018-04-25

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NADAL® FOB Test (Ref. 272001)

1. Intended Use

The NADAL® FOB Test is a rapid, visual immunoassay for the qualitative, presumptive detection of human haemoglobin in faecal specimens. The test is intended for use as an aid in the diagnosis of lower gastrointestinal (g.i.) pathologies. The test is designed for professional use only.

2. Introduction and Clinical Significance

Colorectal cancer is one of the most commonly diagnosed types of cancer and a leading cause of cancer-related deaths. Screening for occult blood in faeces is likely to improve the odds of the detection of colorectal cancer at an early stage, thus reducing mortality.

Previously, commercially available FOB tests utilised the Guaiac Method, which requires a special diet prior to testing in order to avoid false positive and false negative results. The NADAL® FOB Test is designed to detect human haemoglobin in faecal samples. The test is based on an immunochemical method that improves specificity of detection of lower gastrointestinal disorders including colorectal cancers and adenomas without any dietary restrictions.

3. Test Principle

The NADAL® FOB Test is used to detect human haemoglobin through the visual interpretation of colour development on the internal strip. Antibodies to human haemoglobin are immobilised in the test line region of the membrane. During testing, the specimen reacts with antibodies to human haemoglobin conjugated with coloured particles and pre-coated on the sample pad of the test. The mixture then migrates along the membrane by capillary action and interacts with components on the membrane. If there is sufficient human haemoglobin in the specimen, a coloured line will form in the test line region of the membrane. The presence of this coloured line indicates a positive test result, while its absence indicates a negative test result. The appearance of a coloured line in the control line region serves as a procedural control indicating that the proper volume of specimen has been added and membrane wicking has occurred.

4. Reagents and Materials Supplied

Each test kit is suitable for 20 test evaluations:

- 20 individually wrapped test cassettes
- 20 specimen collection tubes with specimens diluent buffer
- 1 package insert

5. Additional Materials Required

- Timer
- Stool collector (Ref. 272004)
- Patient information block with short instructions regarding stool specimen collection
- Specimen collection container (optional, if an undiluted stool sample is required and the dilution step is carried out only immediately before testing)

6. Storage & Stability

The test should be stored at 2-30°C until the expiry date printed on the sealed foil pouch. The test should remain in the sealed foil pouch until use. Do not freeze the test. Care should be taken to protect the components of the test kit from contamination. Do not use the test if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to inaccurate results.

7. Warnings and Precautions

- For professional *in-vitro* diagnostic use only.
- For single use only.
- Do not use the test beyond the expiration date indicated on the foil pouch.
- Do not use the test if the foil pouch is damaged.
- The test contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is, therefore, recommended that tests be treated as potentially infectious and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of samples by using a new specimen collection tube for each sample.
- Read the entire package insert carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens and test kits are being handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being assayed.
- The specimens diluent buffer contains sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of the specimens diluent buffer or extracted samples, always flush with copious quantities of water to prevent azide buildup.
- Bring all reagents to room temperature (15-30°C) before use.
- Do not add any solution to the reaction area (result area).
- Patients should not collect samples during their menstrual period or 3 days before and after it, or if they have bleeding haemorrhoids, blood in urine, or if they have straining during bowel movements.
- Do not substitute or mix components from different test kits.
- Humidity and high temperature can adversely affect test results.
- Used testing materials should be discarded according to local regulations.

8. Specimen Collection and Preparation

Store the specimen collection tube at room temperature. It is recommended to collect stool specimen using a stool collector. Avoid dilution of stool specimens with urine or water from the toilet bowl.

1. Hold the specimen collection tube upright and remove the light-blue cap. Remove the applicator stick (spiral rod). Be careful not to spill or splash buffer solution from the collection tube.
2. Collect specimens by inserting the applicator stick in three different sites of the stool sample.

Note: Please make sure to insert the applicator stick three times in a row into the stool sample. Do NOT put the applicator stick back into the tube in between collecting the 3 samples. Be careful not to spill fluid from the tube. The nature of the sample and compliance with these instructions will affect your test result.

3. Place the applicator stick, along with the sample, back into the specimen collection tube and close it properly.
4. Shake the specimen collection tube vigorously to mix the specimen and specimens diluent buffer.

Note:

The NADAL® FOB Test is intended for use with human faecal specimens only. Patients should not collect samples during their menstrual period or 3 days before and after it, or if they have bleeding hemorrhoids, blood in urine or if they experience strain during their bowel movement.

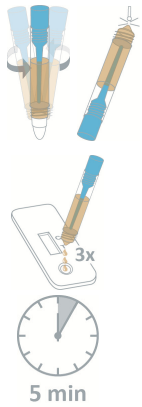
Alcohol, aspirin and other medications taken in excess may cause gastrointestinal irritation, resulting in occult bleeding. Such substances should be discontinued at least 48 hours prior to testing.

No dietary restrictions are necessary before testing.

Perform the test as soon as possible after sample collection. Do not leave specimens at room temperature for prolonged periods of time. On the whole, the storage time of samples at 2-8°C should not exceed 7 days. The transportation of samples to the clinic can be carried out at room temperature without any problems; however it should not exceed 2 hours. Bring specimens to room temperature prior to testing.

9. Test Procedure

1. Bring test cassettes and patient's samples (extracted samples) to room temperature (15°C to 30°C) prior to testing.
2. Remove a test cassette from the sealed foil pouch and place it on a clean, level surface. Label the test cassette with a patient or control identification. For best results, the assay should be performed within one hour.
3. Shake the specimen collection tube thoroughly to ensure proper mixing of the faecal sample with the specimens diluent buffer.
4. Unscrew the white protection cap from the specimen collection tube. Using a piece of tissue paper, break the tip of the collection tube using a twisting motion.
5. Hold the specimen collection tube vertically and dispense 3 drops of solution into the sample well (S) of the test cassette.
   Avoid trapping air bubbles in the sample well (S) and do not add any solution to the result area.
6. Read the result after 5 minutes. Do not interpret results after more than 10 minutes.



10. Result Interpretation

Positive:

Two coloured lines appear on the membrane. One line appears in the control line region (C) and the other one in the test line region (T).

Negative:

Only one coloured line appears in the control region (C). No coloured line appears in the test line region (T).

Invalid:

The control line (C) fails to appear.

Results from any test which has not produced a control line at the specified reading time should be discarded. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your distributor.

Note:

The intensity of colour in the test line region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of colour in the test line region should be considered positive. Note that this is a qualitative test only and it cannot be used to determine the concentration of analytes in the specimen.

Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

11. Quality Control

An internal procedural control is included in the test cassette.

A coloured line appearing in the control line region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.

However, when the faecal sample is tested, the background may appear slightly yellowish due to the original colour of the sample. This is acceptable as long as it does not interfere with the interpretation of test result. The test is invalid if the background fails to clear and obscures the reading of the result.

12. Limitations

- The NADAL® FOB Test is for professional *in-vitro* diagnostic use only. It should only be used for the qualitative detection of human haemoglobin.
- The presence of blood in stool specimens may be due to causes other than colorectal bleeding, such as hemorrhoids, blood in urine or stomach irritation.
- Negative results do not exclude bleeding, since some polyps and colorectal region cancers can bleed intermittently or not at all. Additionally, blood may not be uniformly distributed in faecal samples and colorectal polyps at an early stage may not bleed.
- Urine and excessive dilution of specimens with toilet water may cause erroneous test results.
- The NADAL® FOB Test may show decreased sensitivity for upper gastrointestinal bleeding, as blood degrades as it passes through the gastrointestinal tract.
- Not all colorectal bleeding is due to precancerous or cancerous polyps. As with all diagnostic tests, a confirmed di-

agnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.

13. Performance Characteristics

Analytical Sensitivity

Specimens containing human haemoglobin with concentration equal to or higher than 40 ng/ml produce positive results. In some cases specimens containing human haemoglobin with concentrations of less than 40 ng/ml can also produce positive results.

Hook or Prozone effect:

The working range of the NADAL® FOB Test is 2 µg/g to 25 mg/g faeces (= 40 ng/ml up to 500,000 ng/ml). At higher concentrations the test shows a "high dose Hook or Prozone effect". In case of presumable Hook-Effect, please dilute the sample and repeat the measurement.

Analytical Specificity:

The NADAL® FOB Test is specific for human haemoglobin and shows no cross-reaction with haemoglobin from bovine, turkey, pig, rabbit, chicken, horse and goat blood at concentrations up to 1 mg/mL.

Interfering Substances

The NADAL® FOB Test shows no cross-reaction with the listed substances:

Analytes	Concentration	Analytes	Concentration
Ascorbic acid	20 mg/dL	Urea	2000 mg/mL
Oxalic acid	60 mg/dL	Glucose	2000 mg/dL
Bilirubin	100 mg/dL	Caffeine	40 mg/dL
Uric acid	60 mg/dL	Albumin	2000 mg/dL
Acetylsalicylic acid	20 mg/dL		

		NADAL® FOB Test		
		+	–	Total
Another rapid test	+	325	9	334
	–	16	1024	1040
	Total	341	1033	1374

Relative Sensitivity:

97.3% (95.56%-99.04%)*

Relative Specificity:

98.4% (97.64%-99.16%)*

Overall Agreement:

98.2% (97.47%-98.89%)*

*95% Confidence Interval

Note:

A recently published study by the Shinshu-University School of Medicine in Japan examined the cost-value ratio of multiple measurements. It shows that the relative sensitivity increases with the amount of tests and its relative specificity slightly decreases.

Results:

Amount of tests	sensitivity	specificity
1	58%	96%
2	89%	95%
3	100%	94%

14. References

1. Dam, J.V., et. al.; Fecal Blood Screening for Colorectal Cancer; Archive of Internal Medicine; (1995) 155:2389-2402
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3. Lieberman, D.; Screening/Early Detection Model for Colorectal Cancer, Why Screen? Cancer Supplement; (1994) 74(7) : 2023-2027
4. Miller, A.B.; An Epidemiological Perspective on Cancer Screening; Clinical Biochemistry (1995) 28(1) : 41-48
5. Ransohoff, D.F. and Lang, C.A.; Improving the Fecal Occult- Blood Test: The New England Journal of Medicine; (1996) 334 (3) : 189-190
6. Screening for Colorectal Cancer-United States, 1992-1993, and New Guidelines; Mobility and Mortality Weekly Report; (1995) 45 (5): 107-110
7. St. John, D.J.B., et. al.; Evaluation of New Occult Blood Test for Detection of Colorectal Neoplasia; Gastroenterology; (1993) 104:1661-1668
8. Yamamoto M.; Nakama H.; Cost-effectiveness analysis of immunochemical occult blood screening for colorectal cancer among three fecal sampling methods: Hepatogastroenterology; 2000 Mar-Apr; 47(32):396-9.

Rev. 5, 2018-04-25 OM/UJ

Symbol	Deutsch	English	Français	Español	Italiano	Polski
CE	CE Konformitätszeichen	CE marking of conformity	Conforme aux normes européennes	Conformidad europea	Conformità europea	Znak zgodności CE
	Gebrauchsanweisung beachten	Consult instructions for use	Consulter la notice d'utilisation	Consúltense las instrucciones de uso	Consultare le istruzioni per l'uso	Przestrzegać instrukcji obsługi
IVD	*in-vitro*-Diagnostika	*in-vitro* diagnostic medical device	Dispositif médical de diagnostic *in-vitro*	Producto sanitario para diagnóstico *in-vitro*	Dispositivo medico-diagnostico *in-vitro*	Tylko do diagnostyki *in-vitro*
	Temperaturbegrenzung	Temperature limitation	Limites de température	Límite de temperatura	Limiti di temperatura	Temperatura przechowywania
LOT	Chargenbezeichnung	Batch code	Numéro de lot	Código de lote	Codice lotto	Numer serii
	Nicht zur Wiederverwendung	Do not reuse	Ne pas réutiliser	No reutilizar	Non riutilizzare	Tylko do jednorazowego użytku
	Verwendbar bis	Use by	Utiliser jusqu'au	Fecha de caducidad	Utilizzare entro	Data ważności
REF	Bestellnummer	Catalogue Number	Référence du catalogue	Número de catálogo	Riferimento di Catalogo	Numer katalogowy
	Hersteller	Manufacturer	Fabricant	Fabricante	Fabbricante	Producent
Σ	Ausreichend für <n> Ansätze	Sufficient for <n> tests	Suffisant pour "n" tests	Suficiente para <n> utilizaciones	Sufficiente per "n" saggi	Wystarczający na <n> Powtórzeń

Symbol	Português	Český	Suomi	Svenskt	Nederlands	Dansk	Norsk
CE	Conformidade com as normas europeias	CE certifikát	CE-merkitty	CE-märkning	CE-markering	CE-mærkning	CE standardisert
	Consultar as instruções de utilização	Viz návod k použití	Katso käyttöohjetta	Läs bruksanvisningen	Raadpleeg de gebruiksaanwijzing	Se brugsanvisningen	Les bruksanvisning nøye
IVD	Dispositivo médico para diagnóstico *in-vitro*	Diagnostický zdravotnický prostředek *in-vitro*	*in-vitro* - diagnostiikkaan tarkoitettu lääkinnällinen laite	Medicinteknisk produkt avsedd för *in-vitro*-diagnostik	Medisch hulpmiddel voor in-vitrodiagnostiek	Medicinsk udstyr til *in-vitro*-diagnostik	*in-vitro* diagnostic medisinsk enhet
	Limites de temperatura	Teplotní omezení	Lämpötilarajat	Temperatur-begränsning	Temperatuurlimiet	Temperatur-begrænsning	Temperatur begrensning
LOT	Código do lote	Kód šarže	Eräkoodi	Satsnummer	Code van de partij	Batchkode	Merking
	Não reutilizar	Pro jednorázové použití	Kertakäyttöinen	Får inte återanvändas	Niet opnieuw gebruiken	Må ikke genbruges	Må ikke brukes om igjen
	Prazo de validade	Spotřebujte do	Käytettävä viimeistään	Används före	Houdbaar tot	Udløbsdato	Tidtaking
REF	Número de catálogo	Katalogov éčíslo	Luettelonumero	Listnummer	Catalogus nummer	Best il l ingsnummer	Katalog nummer
	Fabricante	Výrobce	Valmistaja	Tillverkare	Fabrikant	Fabrikant	Produsent
Σ	Suficiente para <n> test	Dostačuje pro <n> testů	Lukumäärä <n> test	Räcker till <n> test	Voldoende voor <n> test	Tilstrækkeligt til <n> test	Tilstrekkelig for<n> tester

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LORNE LABORATORIES LTD.

GREAT BRITAIN

SYPHILIS SEROLOGY KIT

DIRECTIONS FOR USE

RPR CARBON KIT: For Detection Of Syphilis.

SUMMARY

At one time, syphilis was a major medical disease with a host of different manifestations transmitted primarily through sexual contact. The advent of penicillin in 1943 changed this. The etiologic agent of syphilis is *Treponema pallidum*, a spiral bacterium (spirochete). The spirochete causes some damage to the heart and the liver, releasing some tissue fragments. The patient's immune system produces antibodies, called reagins, against these fragments. There are two different techniques for the detection of syphilis. TPHA tests, which detect antibodies to *Treponemal pallidum*, and non-treponemal serologic tests, which detect Reagin in infected people.

INTENDED PURPOSE

The reagent is a test reagent intended to be used to qualitatively and semi-quantitatively determine the presence or absence of Reagin (antibodies against Syphilis) in the serum or plasma of patients when tested in accordance with the recommended techniques stated in this IFU.

PRINCIPLE

When used by the recommended techniques, the reagent will agglutinate (clump) in the presence of reagin. No agglutination usually indicates the absence of reagin (see **Limitations**).

KIT DESCRIPTION

Lorne RPR Carbon Kit is a non-treponemal serologic test for the detection of syphilis. The RPR Carbon Antigen contains micro particulate carbon, which aids in the microscopic reading of results. The reagents do not contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the user. All the reagents are supplied at optimum dilution for use with all recommended techniques without the need for further dilution or addition. For lot reference number and expiry date see **Vial Labels**.

STORAGE

Do not freeze. Reagent vials should be stored at 2 - 8ºC on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity.

SPECIMEN COLLECTION

Specimens should be drawn with or without anticoagulant using an aseptic phlebotomy technique. If testing is delayed specimens can be stored at 2-8ºC for 7 days or for up to 3 months at or below –20ºC. Specimens must be free from bacterial contamination, fibrin, haemolysis and lipaemia.

PRECAUTIONS

1. The kit is for *in vitro* diagnostic use only.
2. Do not use kit past expiration date (see **Vial and Box Labels**).
3. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
4. The reagents in this kit have been processed to reduce the bio-burden, but are not supplied sterile. Once a vial has been opened the contents should remain viable up until the expiry date.
5. No known tests can guarantee products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.
6. RPR Positive Control: H319 - Causes serious eye irritation. Follow the precautionary statement given in the SDS.

DISPOSAL OF KIT REAGENT AND DEALING WITH SPILLAGES

For information on disposal of kit reagent and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

CONTROLS AND ADVICE

1. It is recommended that the RPR Positive and Negative Controls are tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. Shake all the reagents well before use to ensure homogeneity.
3. Do not interchange components between different kits.
4. All the reagents must be allowed to reach 18-25ºC before use.
5. The circles on the agglutination cards should never be touched with fingers, as this may invalidate the test results.
6. Use of kit and interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of country where reagents are in use.
7. The user must the determine suitability of the kit for use in other techniques.

KIT COMPONENTS PROVIDED

1) RPR Carbon Reagent (White cap, 1x3 mL (150 tests) or 2x5 mL (500 tests)): Carbon particles coated with a lipid complex (cardiolipin, lecithin and cholesterol) in phosphate buffer 20 mmol/L, pH 7.0 containing a preservative.
2) RPR Positive Control (Red cap, 1 mL): Artificial serum with reagin titer ≥ 1/4.
3) RPR Negative Control (Blue cap, 1 mL): Animal serum containing a preservative
4) Dispensing bottle (Green cap, 1 x 2 ml).
5) Dispensing Needle (x1).
6) Disposable agglutination slides.
7) Plastic stirrers.

MATERIALS AND EQUIPMENT REQUIRED BUT NOT SUPPLIED

a) Pipette capable of accurately delivering 50 µl
b) Mechanical rotating table capable of rotating at 80-100 rpm.
c) 9 g/L saline solution.

QUALITATIVE TECHNIQUE

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample and one drop of each Positive and Negative Controls into separate circles on the slide test.
3. Swirl the RPR Carbon Reagent gently before using. Invert the dropper assembly and press gently to remove air bubbles from the micropipette.
4. Place the micropipette in a vertical position and perpendicular to the slide, and add one drop (20 µL) of this reagent next to the samples to be tested.
5. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample
6. Place the slide on a mechanical rotating table at 80-100 r.p.m. for 8 min. False positive results could appear if the test is read after more than 8 minutes.

INTERPRETATION OF QUALITATIVE RESULTS

1. **Reactive:** Visible agglutination (medium to large clumps) constitutes a positive result and within the accepted limitations of the test procedure, indicates the presence of reagin.
2. **Weak-Reactive:** Weak agglutination (small clumps) around the periphery of the test area constitutes a weak positive result and within the accepted limitations of the test procedure, indicates the presence of reagin.
3. **Negative:** No agglutination constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of reagin.

SEMI QUANTITATIVE TECHNIQUE

1. The semi-quantitative test can be performed in the same way as the quantitative technique using dilutions of the serum in 9 g/L saline solution.
2. Make doubling dilutions of specimen as follows:

Dilution	Serum	Saline
1/2	100 µl undiluted serum	100 µl
1/4	100 µl 1/2 diluted serum	100 µl
1/8	100 µl 1/4 diluted serum	100 µl
1/16	100 µl 1/8 diluted serum	100 µl

3. Test the specimen dilutions in the same way as for the quantitative technique above.
4. Read the test and note the last positive dilution series.

STABILITY OF THE REACTIONS

Slide tests should be interpreted straight after the 8-minute rotating period to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of the reagent.

LIMITATIONS

1. RPR carbon test is non-specific for syphilis. All Reactive samples should be retested with treponemic methods such as TPHA and FTA-Abs to confirm the results.
2. A Non Reactive result by itself does not exclude a diagnosis of syphilis. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.
3. False positive results have been reported in diseases such as infectious mononucleosis, viral pneumonia, toxoplasmosis, pregnancy and autoimmune diseases.
4. Bilirubin (≤ 20 mg/dL), hemoglobin (≤ 10 g/L) and lipids (≤ 10 g/L), do not interfere. Rheumatoid factors (≥ 300 IU/mL), interfere. Other substances may interfere[5].
5. False positive or negative results may also occur due to:
   a) Not expelling air from end of needle
   b) Not maintaining dispensing bottle and needle in a vertical position when dispensing the antigen.
   c) When transferring the specimen from the collecting tube some of the specimen being drawn up in to the teat
   d) Contamination of test materials
   e) Improper storage of test materials or omission of reagents
   f) Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The kit has been characterised by all the procedures mentioned in the **Recommended Techniques**.
2. Prior to release, each lot of Lorne RPR Syphilis Kit is tested by the **Recommended Techniques** to ensure suitable reactivity.
3. The reagent sensitivity is calibrated against the WHO 1st International Standard for human syphilitic plasma (NIBSC reference number 05/132).
4. **Prozone effect:** No prozone effect was detected up to titers ≥1/128.
5. **Diagnostic sensitivity:** 100%
6. **Diagnostic specificity:** 100 %.

DISCLAIMER

1. The user is responsible for the performance of the kit by any method other than those mentioned in the **Recommended Techniques**.
2. Any deviations should be validated prior to use using established laboratory procedures.

BIBLIOGRAPHY

1. David S.Jacobs et al. Laboratory Test Handbook, 3rd edition, Lexi-Comp Inc, 1994.

AVAILABLE KIT SIZES

Kit Size	Catalogue Number
150 Tests Per Kit	044150A
500 Tests Per Kit	044500A

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire, RG6 4UT
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Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
E-mail: info@lornelabs.com

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013, Malta

NADAL® H. pylori Ag test 1x20 test cassettes

detectable analytes: Helicobacter pylori Ag

Samples: faeces, qualitative determination Ag

Description

Contents per pack:

20 test cassettes, Storage: 2-30°C

20 sample collection tubes, Storage: 2-30°C

1 package insert

Technical Data

SKU	262002
Package Size	1x20 test cassettes
Brand	NADAL®