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
United Kingdom
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

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 01 100 1810008

Certificate Holder: **MACHEREY-NAGEL GmbH & Co. KG**
Neumann-Neander-Str. 6-8
52355 Düren
Germany

including the locations according to annex

Scope: Design and development, production and distribution of products for filtration, rapid tests, water analysis, chromatography and bioanalysis

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

Validity: The certificate is valid from 2018-08-29 until 2020-05-28.

2018-09-03

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 1810008

No.	Location	Scope
/01	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Str. 6-8 52355 Düren Germany	Design and development, production and distribution of products for filtration, rapid tests, water analysis, chromatography and bioanalysis
/02	MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany	Design and development, production, distribution, service and administration
/03	MACHEREY-NAGEL GmbH & Co. KG Papiermühle 50 52349 Düren Germany	Waste disposal
/04	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Storage
/05	MACHEREY-NAGEL GmbH & Co. KG Monschauer Str. 64 52355 Düren Germany	Production

2018-09-03

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Орган по сертификации
ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ
«АЛЬФА РЕГИСТР»
Россия, 121096, г. Москва, ул. 2-я Филевская, д. 7, корп. 6, этаж 1, пом. III, ком. 6
Аттестат аккредитации № СДС.РТС.ОС.002384-17
www.alfaregister.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ

№ СДС.РТС.СМК.00976-19

Срок действия: с 17.01.2019 по: 17.01.2022

СЕРТИФИКАТ ВЫДАН

Общество с ограниченной ответственностью «АГАТ СофТ»
(ООО «АГАТ СофТ»)

Россия, 129343, г. Москва, проезд Серебрякова, дом № 14, строение 15, помещение 7
ИНН 7716586011

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО СИСТЕМА МЕНЕДЖМЕНТА КАЧЕСТВА

применительно к производству и сервисному обслуживанию учрежденческо-производственных автоматических телефонных станций (IP-АТС), систем записи, систем оповещения, плат и устройств компьютерной телефонии

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ ГОСТ Р ИСО 9001-2015 (ISO 9001:2015)

Руководитель органа по сертификации

Ю.Ю. Козлов

Эксперт

С.С. Алехина

Зарегистрирован в реестре системы добровольной сертификации «РосТехСертификация» 17.01.2019г

Система добровольной сертификации «РосТехСертификация» зарегистрирована в едином реестре зарегистрированных систем добровольной сертификации РОССТАНДАРТА. Регистрационный номер РОСС RU.31175.04ЖНЖ0
Настоящий сертификат обязывает организацию поддерживать состояние выполняемых работ в соответствии с правилами функционирования системы добровольной сертификации «РосТехСертификация»

002891

Орган по сертификации
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www.alfaregister.ru

РАЗРЕШЕНИЕ НА ПРИМЕНЕНИЕ ЗНАКА СООТВЕТСТВИЯ

№ СДС.РТС.РП.00622-19

Срок действия: с 17.01.2019 по 17.01.2022

РАЗРЕШЕНИЕ ВЫДАНО

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Россия, 129343, г. Москва, проезд Серебрякова, дом № 14, строение 15, помещение 7
ИНН 7716586011

На основании сертификата № СДС.РТС.СМК.00976-19 от 17.01.2019 г.
НАСТОЯЩЕЕ РАЗРЕШЕНИЕ ПРЕДОСТАВЛЯЕТ ПРАВО НА ПРИМЕНЕНИЕ ЗНАКА СООТВЕТСТВИЯ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «РосТехСертификация»

Условия применения знака соответствия

фирменные бланки предприятия, договоры, печатные и рекламные издания

Руководитель
органа по сертификации

Ю.Ю. Козлов

Система добровольной сертификации «РосТехСертификация» зарегистрирована в едином реестре зарегистрированных систем добровольной сертификации РОССТАНДАРТА. Регистрационный номер РОСС RU.31175.04ЖНЖ0
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003285

АО «Опцион», Москва, 2018 г., «В». Лицензия № 05-05-09/003 ФНС РФ. ТЗ № 516. Бланк не является ценной бумагой. По заказу ООО «АЛЬФА РЕГИСТР». Тел.: (495) 726-47-42, www.opcion.ru

EC-Declaration of Conformity

According to Directive 98/79/EC on in-vitro-diagnostic devices, Annex III

Manufacturer: nal von minden GmbH, Carl-Zeiss Str.12, 47445 Moers
Classification: Other Products

We herewith declare on our sole responsibility that all batches of below mentioned In-vitro-diagnostic devices are conform with the Essential Requirements Annex I of the directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. The products are suitable for the intended application (only professional users).

Relevant standards and guidelines are applied.

1010002N-20	NADAL® Cholera O1/O139 Test
1010002N-20_SSL	NADAL® Cholera O1/O139 Test
1120003N-20	NADAL® Candida albicans Test
1130002N-30	NADAL® HSV 1 IgG/IgM Test
1130002N-30_SSL	NADAL® HSV 1 IgG/IgM Test
1130003N-30	NADAL® HSV 2 IgG/IgM Test
1130003N-30_SSL	NADAL® HSV 2 IgG/IgM Test
1200001	NADAL® Lactoferrin Test
1201004N-10	NADAL® Ferritin Test
1201004N-10_SSL	NADAL® Ferritin Test
1212001	NADAL® Calprotectin Test
1212001_SSL	NADAL® Calprotectin Test
1212002	NADAL® Claprotectin/Lactoferrin Test
1222001	NADAL® Enterovirus Test
1222001_SSL	NADAL® Enterovirus Test
1232001	NADAL® Campylobacter Test
1242001	NADAL® Salmonella spp. Test
1242001_SSL	NADAL® Salmonella spp. Test
1242002	NADAL® Salmonella typhi Test
1242002_SSL	NADAL® Salmonella typhi Test
1252001	NADAL® Listeria Test
1252001_SSL	NADAL® Listeria Test
1262001	NADAL® Shigella Test
1262001_SSL	NADAL® Shigella Test
1262002	NADAL® Shigella dysenteriae Test
1062002_SSL	NADAL® Shigella dysenteriae Test

161001	NADAL® hLH Ovulation Test
161001_SSL	NADAL® hLH Ovulation Test
162001	NADAL® hLH Ovulation Test
162001_SSL	NADAL® hLH Ovulation Test
164001	NADAL® hLH Ovulation Test
165001	NADAL® hLH Ovulation Test
165001_SSL	NADAL® hLH Ovulation Test
165003	NADAL® hLH Ovulation Test
165003_SSL	NADAL® hLH Ovulation Test
166001	NADAL® hLH Ovulation Test
172003N-10	NADAL® FSH Menopause Test
194002	NADAL® pH-Test
1941333	NADAL® Infectious Diseases Puffer
201001	NADAL® Syphilis Test
201001_SSL	NADAL® Syphilis Test
202001	NADAL® Syphilis Test
202001_SSL	NADAL® Syphilis Test
203001	NADAL® Syphilis Test
203002	NADAL® Syphilis Test
203002_SSL	NADAL® Syphilis Test
2090001	NADAL® Entamoeba Test
2090001_SSL	NADAL® Entamoeba Test
2201001N-10	NADAL® IgE Test
2210001N-20	NADAL® Ebola Test
221001A	NADAL® Strep A Test
221005	NADAL® Strep A Reagenz 1
221006	NADAL® Strep A Reagenz 2
221050N-50	NADAL® Strep A plus Test
221050N-50_SSL	NADAL® Strep A plus Test

222001A	NADAL® Strep A Test
222007	NADAL® Strep A plus Test
222008	NADAL® Strep A plus Test
222008_SSL	NADAL® Strep A plus Test
222011	NADAL® Strep A plus Test
222049NBUL-20	NADAL® Strep A Scan Test
232001	NADAL® Strep B Test
232001_SSL	NADAL® Strep B Test
232005	NADAL® Strep B Reagenz 1
232006	NADAL® Strep B Reagenz 2
241005N-10	NADAL® Influenza A+B Test
241006N-25	NADAL® Influenza A+B Test
242001	NADAL® Influenza A+B Test
242006N-10	NADAL® Influenza A/B Test
252001	NADAL® Mononucleosis Test
252003	NADAL® Mononucleosis Test
252003N-20	NADAL® Mononucleosis Test
252017N-05	NADAL® Mononucleosis Test
262001	NADAL® H.Pylori Ab Test
262001_SSL	NADAL® H.Pylori Ab Test
262002	NADAL® H.Pylori Ag Test
262004NBUL-10	NADAL® H. pylori Ag Scan Test
272001	NADAL® FOB Test
272001_SSL	NADAL® FOB Test
272007	NADAL® FOB & Hb/Hp Extraktionsröhrchen
272011N-25	NADAL® Hb/Hp Complex plus Test
272015	NADAL® Hb/Hp Complex Test
272015_SSL	NADAL® Hb/Hp Complex Test
272016	NADAL® FOB plus Test
272031RU	NADAL® Hb/Hp Complex Test
272031RU-01	NADAL® Hb/Hp Complex Test
272031RU_SSL	NADAL® Hb/Hp Complex Test
272035	NADAL® FOB60 plus Test
272035_SSL	NADAL® FOB60 plus Test

272037	NADAL® FOB & Hb/Hp patient set
272040	NADAL® FOB II Test
272041	NADAL® FOB60 Test
272041_SSL	NADAL® FOB60 Test
272042	NADAL® FOB75 Test
272043	NADAL® FOB75 II Tet
282000	NADAL® Troponin I Test
282001	NADAL® Troponin I Test
282001_SSL	NADAL® Troponin I Test
282003	NADAL® Cardiac Combo Test
282015	NADAL® Troponin I Test
292001N-05	NADAL® MyoglobinTest
302001	NADAL® CK-MB Test
302001_SSL	NADAL® CK-MB Test
311003N-10	NADAL® CrP Test
311003N-20	NADAL® CrP Test
311004	NADAL® CRP plus Test
311006	NADAL® CRP plus Test
312001	NADAL® CrP Test
312002	NADAL® High Sensitivity CrP Test
312017	NADAL® CRP Quant RFID Chip
312017_SSL	NADAL® CRP Quant RFID Chip
312021NBUL-20	NADAL® CRP Quant Test
312021NBUL-40	NADAL® CRP Quant Test
322003N-30	NADAL® Tuberkulose IgG/IgM Test
322003N-30_SSL	NADAL® Tuberkulose IgG/IgM Test
331001	NADAL® Microalbumin Test
331004N-50	NADAL® Mikroalbumin Test
351006	NADAL® D-Dimer Test
351006_SSL	NADAL® D-Dimer Test
351006N-25	NADAL® D-Dimer Test
351007	NADAL® D-Dimer cassette
431001N-03	NADAL® PROM Amniotic fluid Test
431001N-03_SSL	NADAL® PROM Amniotic fluid Test

431001N-10	NADAL® PROM Amniotic fluid Test
431001N-10_SSL	NADAL® PROM Amniotic fluid Test
431001N-20	NADAL® PROM Amniotic fluid Test
431006N-01	NADAL® PROM Amniotic fluid Test
431006N-03	NADAL® PROM Amniotic fluid Test
431006N-10	NADAL® PROM Amniotic fluid Test
431006N-20	NADAL® PROM Amniotic fluid Test
432000N-03	NADAL® fFN Test
432000N-10	NADAL® fFN Test
432000N-20	NADAL® fFN Test
472003N-10	NADAL® Malaria 4 Species Test
472003N-25	NADAL® Malaria 4 Species Test
472003N-25_SSL	NADAL® Malaria 4 Species Test
472008	NADAL® Malaria 4 species Test
472009	NADAL® Malaria Pf/Pv Ab Test
472030N-10	NADAL® Malaria Pf/Pan Ag 4 Species Test
472030N-25	NADAL® Malaria Pf/Pan Ag 4 Species Test
472036N-25	NADAL® Malaria Pf Ag 4 Species Test
472036N-25_SSL	NADAL® Malaria Pf Ag 4 Species Test
481008	NADAL® Adenovirus Respiratory Test
481013	NADAL® Adenovirus positive control
481015	NADAL® Rota-Adenovirus Test
481015_SSL	NADAL® Rota-Adenovirus Test
481015N-20	NADAL® Rota-Adenovirus Test
481016	NADAL® Adenovirus Test
481016_SSL	NADAL® Adenovirus Test
481017	NADAL® Rotavirus Test
481049NBUL-10	NADAL® Rota-Adenovirus Scan

	Test
491000N-10	NADAL® RSV Test
491000N-10_SSL	NADAL® RSV plus Test
491003N-25	NADAL® RSV Test
491003N-25_SSL	NADAL® RSV Test
491005	NADAL® RSV Test
491008NBUL-20	NADAL® RSV Scan Test
491009	NADAL® RSV-Adenovirus Respiratory Test
495001	NADAL® MRSA Latextest
495001_SSL	NADAL® MRSA Latextest
501006	NADAL® E.coli O157 Test
501006_SSL	NADAL® E.coli O157 Test
501012	NADAL® EHEC Verotoxin 1/2 Test
501012_SSL	NADAL® EHEC Verotoxin 1/2 Test
511006	NADAL® Cryptosporidium Test
511006_SSL	NADAL® Cryptosporidium Test
521001	NADAL® Giardia Test
521001_SSL	NADAL® Giardia Test
521009	NADAL® Giardia Test
521009_SSL	NADAL® Giardia Test
521010	NADAL® Crypto/Giardia Test
521010_SSL	NADAL® Crypto/Giardia Test
532001_SSL	NADAL® Dengue IgG/IgM Test
532001N-25	NADAL® Dengue IgG/IgM Test
532002N-25	NADAL® Dengue Ag Test
532003N-25	NADAL® Dengue Ag+IgG/IgM Test
532003N-25_SSL	NADAL® Dengue Ag+IgG/IgM Test
532004N-25	NADAL® Dengue IgG/IgM Test
532004N-25_SSL	NADAL® Dengue IgG/IgM Test
532011N-25	NADAL® Dengue IgG/IgM Test
532012N-25	NADAL® Dengue NS1 Ag Test
532016N-25	NADAL® Dengue NS1 Ag+IgG/IgM Test
532016N-	NADAL® Dengue NS1 Ag+IgG/IgM

25_SSL	Test
542001N-25	NADAL® Tetanus Test
552005	NADAL® Legionella Test
552005_SSL	NADAL® Legionella Test
552006	NADAL® Legionella Test
552006_SSL	NADAL® Legionella Test
552020	NADAL® Legionella Test
552020_SSL	NADAL® Legionella Test
562003N-10	NADAL® BCA/Hb Combo Test
562003RU	NADAL® BCA/Hb Combo Test
572004N-10	NADAL® S. pneumoniae Test
572005	NADAL® Legionella/S. pneumoniae Test
580005N-25	NADAL® TSH Test
582003	NADAL® C. difficile Toxin A/B Test
582003_SSL	NADAL® C. difficile Toxin A/B Test
582004	NADAL® C. difficile GDH Ag Test
582008	NADAL® C. difficile Toxin A/B Test
582009	NADAL® C. perfringens Ag Test
582009_SSL	NADAL® C. perfringens Ag Test
582016N-10	NADAL® C. difficile Toxin A/B+GDH Test
600002N-30	NADAL® Rheumatoid Factors Test
600002N-30_SSL	NADAL® Rheumatoid Factors Test
611005N-10	NADAL® Gonorrhea Test
612004N-25	NADAL® CCA (Bilharzia) Test
622001N-30	NADAL® HAV IgM Test
622040N-30	NADAL® HEV IgM Test
622070N-30	NADAL® HAV IgG/IgM Test
622070N-30_SSL	NADAL® HAV IgG/IgM Test
652001N-30	NADAL® Chagas IgG Test
652001N-30_SSL	NADAL® Chagas IgG Test
662001N-30	NADAL® Leishmania Test
672001N-30	NADAL® Filariasis IgG/IgM Test
672001N-30_SSL	NADAL® Filariasis IgG/IgM Test

682002N-20	NADAL® Chikungunya IgM Test
692001N-30	NADAL® Typhoid IgG/IgM Test
692001N-30_SSL	NADAL® Typhoid IgG/IgM Test
712001	NADAL® AFP Test
712001_SSL	NADAL® AFP Test
722003	NADAL® CEA Test
722003_SSL	NADAL® CEA Test
790001	NADAL® Celiac Disease tTG Test
790002	NADAL® Celiac Disease tTG/Gliadine Test
795002	NADAL® ASO Latextest
795003	NADAL® ASO Latextest
795005	NADAL® CRP Latextest
795006	NADAL® CRP Latextest
795008	NADAL® Rheumatoid Factors Latextest
795008_SSL	NADAL® Rheumatoid Factors Latextest
795009	NADAL® Rheumatoid Factors Latextest
795010	NADAL® RPR Carbon Latextest
795011	NADAL® RPR Carbon Latextest
795015	NADAL® VDRL Latextest
795016	NADAL® VDRL Latextest
795016_SSL	NADAL® VDRL Latextest
795017	NADAL® Waaler Rose Latextest
795018	NADAL® Waaler Rose Latextest
795018_SSL	NADAL® Waaler Rose Latextest
795024	NADAL® IM Latextest
795024_SSL	NADAL® IM Latextest
795027	NADAL® TPHA Test
795027_SSL	NADAL® TPHA Test
795028	NADAL® TPHA Test
795028_SSL	NADAL® TPHA Test
795030	NADAL® Rose Bengale Latextest
840003N-10	NADAL® Trichomonas vaginalis Test
850003	NADAL® Astrovirus Test
850003_SSL	NADAL® Astrovirus Test
860001	NADAL® Bence Jones Protein Test
860001_SSL	NADAL® Bence Jones Protein Test
920001	NADAL® Norovirus Test
920001_SSL	NADAL® Norovirus Test
920002	NADAL® Norovirus GI/GII Test
920002_SSL	NADAL® Norovirus GI/GII Test
920002N-01	NADAL® Norovirus GI/GII Test
920002N-01_SSL	NADAL® Norovirus GI/GII Test

This document is valid until 2019-12-04.

Moers, 05.12.2017
nal von minden GmbH

nal von minden GmbH
Carl-Zeiss-Straße 12
47445 Moers
Tel: +49 2841 99820-0
Fax: +49 2841 99820-1
info@nal-vonminden.de

Sandra von Minden
CEO
nal von minden GmbH

KABE LABORTECHNIK

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY

Name und Adresse des Herstellers: Name and address of the manufacturer:	**KABE LABORTECHNIK GmbH** **Jägerhofstraße 17** **51588 Nümbrecht-Elsenroth** **Deutschland / Germany**

Wir erklären in alleiniger Verantwortung, dass die In-Vitro-Diagnostika der Produktgruppe /
We declare under our sole responsibility that the in-vitro-diagnostica of product group

• **Probenröhren** • **neutrale Probenröhren** • mit oder ohne Verschlussstopfen • **präparierte Probenröhren** • zur Zählung der Thrombozyten aus Venen- oder Kapillarblut • zur Zählung der Retikulozyten • für hämatologische Untersuchungen • zur Gewinnung des Blutcitratgemisches für den Hepato Quick • zur Gewinnung des Blutcitratgemisches für gerinnungsphysiologische Untersuchungen • zur Serumgewinnung • zur Plasmagewinnung • zur Stabilisierung des Enzyms der sauren Phosphatase • zur Blutzuckerbestimmung • zur Bestimmung der Katecholamine	• **test tubes** • **untreated test tubes** • w/o closing stopper • **treated test tubes** • for platelet count from venous or capillary blood • for reticulocyte count • for haematological analyses • for preparing the blood-citrate mixture for the Hepato Quick • for preparing the blood-citrate mixture for coagulation physiological analyses • for serum collection • for plasma collection • for stabilising the enzyme of acid phosphatase • for blood sugar determination • for determination of the catecholamine
• **neutrale Reaktionsgefäße** • mit oder ohne Verschlussstopfen	• **untreated reaction vessels** • w/o closing stoppers
• **Verschlussstopfen** für Probenröhren und Reaktionsgefäße	• **closing stoppers** for test tubes and reaction vessels
der Klasse / of class	**Andere IVD-Produkte** **Other IVD-devices**

den einschlägigen Bestimmungen der IVD-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Konformitätserklärung gilt für die durch die KABE LABORTECHNIK GmbH freigegebenen Chargen.

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it.
This declaration is valid for the batches released by KABE LABORTECHNIK GmbH.

Konformitätsbewertungsverfahren: Conformity assessment procedure:	**Richtlinie 98/79/EWG Anhang III** **Directive 98/79/EC Annex III**

KABE LABORTECHNIK GmbH
Jägerhofstraße 17
51588 Nümbrecht-Elsenroth
Telefon 02293 / 596

Nümbrecht-Elsenroth, 24.09.2019

André Kolpe, Geschäftsführer / Managing director

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

has established and applies a quality management system for medical devices for the following scope:

Design and development, production and distribution of in vitro diagnostic devices and consumption materials for sample withdrawal, preparation and storage as well as single-use medical devices

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-10-16
Certificate Registration No.:	SX 60133221 0001
An audit was performed. Report No.:	21234760 009
This Certificate is valid until:	2021-10-15

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-10-12

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

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

CISQ is a member of

IQNet

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.

ICIM

CERTIFICATO n. / *CERTIFICATE No.* **4264/4/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 EN ISO 9001:2015

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.

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	18/01/2019	17/01/2022

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

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

FEDERAZIONE CISQ

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.

0449CM_03_IT

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
И СОЦИАЛЬНОГО РАЗВИТИЯ

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ

№ ФСР 2009/05681

от **15 сентября 2009 года** Срок действия: **не ограничен.**

Настоящее удостоверение выдано

ЗАО "Термо Фишер Сайентифик",
Россия, 196240, Санкт-Петербург, ул. Кубинская, д.73, корпус 1, лит.А

и подтверждает, что изделие медицинского назначения
(изделие медицинской техники)

Дозаторы пипеточные, одно- и многоканальные, "Блэк"
по ТУ 9443-008-33189998-2009

производства

ЗАО "Термо Фишер Сайентифик",
Россия, 196240, Санкт-Петербург, ул. Кубинская, д.73, корпус 1, лит.А

класс потенциального риска **2а** ОКП **94 4370**

соответствующее комплекту регистрационной документации

КРД № 33014 от 09.07.2009

приказом Росздравнадзора **от 15 сентября 2009 года № 7252-Пр/09**

разрешено к производству, продаже и применению на территории Российской Федерации

Руководитель Федеральной службы
по надзору в сфере здравоохранения
и социального развития **Н.В. Юргель**

006376

Бланк изготовлен ЗАО «ОПЦИОН» (лицензия № 05-05-09/003 ФНС РФ, уровень В), договор РД № 08/63, тел. (495) 648 6068, 608 7617, г. Москва, 2008 г.

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 60119814 0001

Report No.: 21265422 001

Manufacturer:
Macherey-Nagel GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Deutschland

Products:
Products for self-testing

(see attachment for products and sites included)

Replaces Certificate, Registration No.: HL 60076687 0001

Expiry Date: 2022-05-28

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: 2017-05-29

Date: 2017-05-29

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HL 60119814 0001
Report No.: 21265422 001

Manufacturer:
Macherey-Nagel GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Deutschland

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

Additional site for warehousing and logistics:

Bahnstr. 120
52355 Düren, Germany

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2017-05-29

Dipl.-Ing. Sven Hoffmann

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Сертификат №:
59878-2009-AQ-MCW-FINAS

Дата начальной сертификации:
20 декабря 2000

Действителен:
21 июня 2018 - 31 августа 2021

Настоящим удостоверяется, что система менеджмента организации:

АО «ТЕРМО ФИШЕР САЙЕНТИФИК»

Кубинская, д.73, литер А, корпус 1, Санкт-Петербург, Российская Федерация, 196240

была признана соответствующей стандарту:
ISO 9001:2015

Настоящий сертификат действителен для следующей области:
ПРОИЗВОДСТВО ДОЗАТОРОВ ПИПЕТОЧНЫХ И СПЕЦИАЛЬНОГО ДИАГНОСТИЧЕСКОГО ПЛАСТИКА.

Место и дата:
Москва, 21 июня 2018

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT
IAF
FINAS
Finnish Accreditation Service
S001 (EN ISO/IEC 17021)

От выпускающего офиса:
DNV GL – Business Assurance
Трехпрудный переулок 9, стр. 2, Москва, Российская Федерация

S. Grubine

Сергей Грубин
Представитель руководства

Невыполнение условий Договора на сертификацию делает данный Сертификат недействительным.
Аккредитованный офис: DNV GL BUSINESS ASSURANCE FINLAND OY AB, Keilasatama 5, 02150 Espoo, Finland. TEL:+358 10 292 4200.
assurance.dnvgl.com

Федеральное агентство по техническому регулированию и метрологии

НОПСС

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

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

www.nopss.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ

выдан

Общество с ограниченной ответственностью «МиниМед»

ИНН 3234007127 / ОГРН 1023202138332

241520, Брянская область, Брянский район, с. Супонево, 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 С1256

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «НОПСС» РОСС RU.31827.04ЖСН1

Руководитель органа по сертификации: **Подпись** _____ **Платонов Б.А.**

НОПСС СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ

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

НОПСС

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

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

www.nopss.ru

ПРИЛОЖЕНИЕ №1

К сертификату соответствия № С1256

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.

НОПСС СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ