Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810008**

Certificate Holder: **MACHEREY-NAGEL GmbH & Co. KG**
Valencienner Str. 11
52355 Düren
Germany

including the locations according to annex

Scope: Design, development, production and distribution of products for filtration, rapid tests, water analysis, bioanalysis and chromatography, as well as service and administration.

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

Validity: The certificate is valid from 2023-05-29 until 2026-05-28.

2023-04-18

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	c/o MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany	Design, development, production and distribution of products for filtration, rapid tests, and water analysis, as well as service and administration
/02	c/o MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Str. 6-8 52355 Düren Germany	Design, development and production of products for bioanalysis and chromatography
/04	c/o MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Storage

2023-04-18

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Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1038121-1

Organization: MACHEREY-NAGEL GmbH & Co. KG
Valencienner Str. 11
52355 Düren
Germany

Scope: Design and development, manufacture and distribution of in vitro diagnostic test strips including self-testing devices and reflectometers used in the field of urine and gastric fluid analysis, as well as in vitro diagnostic products for bioanalytical sample preparation.

(see attachment for sites included)

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.: 1127255-40
Effective date: 2023-05-29
Expiry date: 2026-05-28
Issue date: 2023-04-12

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Irene Carraretto
TÜV Rheinland LGA Products GmbH
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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1038121-1

Organization: MACHEREY-NAGEL GmbH & Co. KG
Valencienner Str. 11
52355 Düren
Germany

The scope of certification covers the following sites:

No.	Facility	Scope
/01	c/o MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany	Design and development, manufacture and distribution of in vitro diagnostic test strips including self-testing devices and reflectometers used in the field of urine and gastric fluid analysis, as well as in vitro diagnostic products for bioanalytical sample preparation.
/02	c/o MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Str. 6-8 52355 Düren Germany	Design and development, manufacture and quality control of in vitro diagnostic products for bioanalytical sample preparation.
/03	c/o MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 1127255-40
Effective date: 2023-05-29
Expiry date: 2026-05-28
Issue date: 2023-04-12

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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

EU Certificate

Technical Documentation Assessment
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter II

Registration No.:	IX 1038121-2
Manufacturer:	MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany
EUDAMED Single Registration No.:	DE-MF-000005636
Classification:	Product of class B, near-patient testing
General product group name:	CLINICAL CHEMISTRY - RAPID TESTS & POC IVR 0608 Devices intended to be used for screening, determination or monitoring of physiological markers W01010602 - URINE TESTING (CC) - RT & POC
Product name:	Medi-Test Urine Test Strips professional use
Models and types:	Medi-Test Glucose (93001, 93024, 93001.202255) Medi-Test Glucose/Keton (93025, 93020, 93020.205567) Medi-Test Protein 2 (93004, 93027, 93004.203880) Medi-Test Keton (93005, 93028) Medi-Test Nitrit (93006, 93029) Medi-Test Combi 2 (93015, 93015.004, 93037, 93037.204483, 93015.203880) Medi-Test Combi 3 (93050.205567) Medi-Test Combi 3A (93007, 93030) Medi-Test Combi 5 (93009, 93032)

The Notified Body hereby declares that the requirements of Annex IX, Chapter II, Section 4 and 5.1 / 5.2 of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and maintains a technical documentation defined by Annex IX, Chapter II, Section 4 and 5.1 / 5.2 of the aforementioned regulation. In addition to this certificate an EU quality management system certificate and for class D devices a batch verification is required before placing the listed products on the market.

Report No.:	1165873-20
Effective date:	2024-11-21
Expiry date:	2028-05-15
Issue date:	2024-11-21

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/746 concerning medical devices with the identification number 0197.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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EU Certificate

Technical Documentation Assessment
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter II

Registration No.:	IX 1038121-2
Manufacturer:	MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany
EUDAMED Single Registration No.:	DE-MF-000005636

Medi-Test Combi 5N (93035, 93036, 93035.203880)
Medi-Test Combi 5S (93055, 93055.203880)
Medi-Test Combi 5L (93008.143993)
Medi-Test Combi 6A (93034)
Medi-Test Combi 7 (93022)
Medi-Test Combi 7L (93031, 93031.143993)
Medi-Test Combi 8 (93016.203880)
Medi-Test Combi 8L (93021)
Medi-Test Combi 9 (93023, 930879, 93023.204483)
Medi-Test Combi 10L (93058, 93079)
Medi-Test Combi 11 (93060, 930871, 93060.004, 93060.005)
Medi-Test Combi 10 SGL (93067, 93067.004, 93067.005, 93067.203880, 93067.205567, 93067.204910, 93067.2)

UriSTIX 10 GLS (93067.134408)
Medi-Test URYXXON Stick 10 (93068, 930872, 93068.004, 93068.005)
UriSTIX 6 (93078.134408)
UriSTIX 10 (93058.134408)
Urispec PLUS 3 PLUS (93030.114379.2)
Urispec PLUS 5+ Leuco PLUS (93078.114379.2)
Urispec PLUS 9+ LEUKO PLUS (93058.114379.2)
Urispec PLUS 10 SL PLUS (93067.114379.2)
Urispec PLUS 11 SYS PLUs (93060.114379.2)
Urine test strip 5+Leuko (93078.114379.3)

Report No.:	1165873-20
Effective date:	2024-11-21
Expiry date:	2028-05-15
Issue date:	2024-11-21

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EU Certificate

Technical Documentation Assessment
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter II

Registration No.:	IX 1038121-2
Manufacturer:	MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany
EUDAMED Single Registration No.:	DE-MF-000005636
	Urine test strip 9+ Leuko (93058.114379.3) hoyer-6 (930943)
Basic UDI-DI:	4046681151040VR
Intended use:	Medi Test urine test strips are used as a diagnostic aid or screening test for the analysis of human urine. The semiquantitative test strips can be evaluated manually by visually comparing the respective test paper color reaction with the color scale. Test strip variants for the automatic reflectometric analysis with the devices URYXXON® 500 and URYXXON® Relax are labelled accordingly. The test strips can analyse up to 11 different parameters: blood, urobilinogen, bilirubin, protein, nitrite, ketone, ascorbic acid, glucose, pH, density and leukocytes.
Authorized representative(s):	N/A

Report No.:	1165873-20
Effective date:	2024-11-21
Expiry date:	2028-05-15
Issue date:	2024-11-21

Katja Mierisch
TÜV Rheinland LGA Products GmbH
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This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/746 concerning medical devices with the identification number 0197.

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EU Certificate

Technical Documentation Assessment
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter II

Registration No.:	IX 1038121-2
Manufacturer:	MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany
EUDAMED Single Registration No.:	DE-MF-000005636

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-05-16
1	New model added and formal changes in the scope	2024-11-21

Report No.:	1165873-20
Effective date:	2024-11-21
Expiry date:	2028-05-15
Issue date:	2024-11-21

Katja Mierisch
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EU Declaration of Conformity

EU Declaration of Conformity for *In-vitro* Diagnostic Products

The conformity is declared according to Annex IV of the European IVD Regulation 2017/746.

Name of manufacturer: MACHEREY-NAGEL GmbH & Co. KG

Address: Valencienner Str. 11
D - 52355 Düren
Germany

Single Reg. number (SRN): DE-MF-000005636

Name of product: Medi-Test Control

Reference numbers: 93038

Intended purpose: Medi-Test Control is a control solution for functionality control of the Medi-Test Urine test strips and the URYXXON® Relax and URYXXON® 500 devices. Solution N simulates a urine sample with all values in the negative or normal range. Solution P provides a positive color reaction on the Medi-Test urine test strips. After dipping into the control solutions the urine test strips can be evaluated visually with the color scale or can be read-out on the URYXXON® Relax and URYXXON® 500 instruments. The results of the urine parameters blood, urobilinogen, bilirubin, protein, nitrite, ketones, glucose, pH, density and leukocytes are compared with the target values shown in the table as provided in the IFU. The Medi-Test Control solutions are intended to be used by professional users only. Medi-Test control is not for self-testing and not for near-patient testing.

Basic UDI-DI: 4046681151033VU

Risk class: ☐ A ☒ B ☐ C ☐ D

☒ professional use
☐ self-testing
☐ near-patient testing

Conformity Route:
☐ Self-Declaration of Conformity (Class A)
☒ Technical Documentation Assessment Class B/C – Annex IX
☐ Technical Documentation Assessment Class B/C for Self-Testing – Annex IX
☐ Technical Documentation Assessment Class B/C for Near-Patient Testing – Annex IX

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Certificates:	☒ EU Certificate Quality Management System, Registration No.: HX 1038121-1, valid until 2028-05-15 ☐ EU Certificate Technical Documentation Assessment Annex IX Registration No.: IX 1038121-1, valid until 2028-05-15 ☐ EU Certificate Technical Documentation Assessment Annex IX, chapter II Registration No.: IX 1038121-2, valid until 2028-05-15 ☐ EU Certificate Technical Documentation Assessment Annex IX Registration No.: IX 1038121-3, valid until 2028-05-15 ☐ EU Certificate Technical Documentation Assessment Annex IX Registration No.: IX 1038121-4, valid until 2028-05-15
Notified body (NB):	TÜV Rheinland LGA Products GmbH Tillystr. 2. 90431 Nürnberg (NB Ident. No.: 0197)
Applicable Common Specifications:	n.a.

We confirm that the product listed above is manufactured and QC controlled in compliance with the European IVD Regulation 2017/746. The manufacturer is exclusively responsible for the declaration of conformity.

Düren, 27.11.2025

ppa. Dr. Markus Meusel (QAM, Manager Reg. Affairs)

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en Instructions for use Medi-Test urine test strips

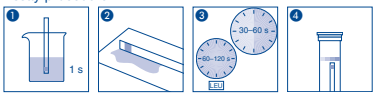
Intended purpose

Medi-Test urine test strips are used as a diagnostic aid or screening test for the analysis of human urine. The semiquantitative test strips can be evaluated manually by visually comparing the respective test paper color reaction with the color scale. Test strip variants for the automatic reflectometric analysis with the devices URYXXON® 500 and URYXXON® Relax are labelled accordingly. The test strips can analyse up to 11 different parameters: blood, urobilinogen, bilirubin, protein, nitrite, ketone, ascorbic acid, glucose, pH, density and leukocytes. The Medi-Test urine test strips are for use by healthcare professionals. The test strips are suitable for near-patient use outside of a laboratory. They are not suitable for self-testing.

Test strips are contained in an aluminum box with desiccant stopper. The performance data, the number of test strips of each product and the explanation of the symbols used are listed on the last page of this instructions for use.

The type and combination of the parameters can be found in the printed information on the folding box and the color scale of the Medi-Test product.

Assay procedure



1. Immerse test strip in the urine for approx. 1 second. The test fields must be wetted with urine.
2. After removing the test strip from the urine sample, briefly dab the lateral edge onto an absorbent paper tissue. Do not set the test strip down and hold the test strip horizontally during the reaction time.
3. Wait for a reaction time of 30 – 60 seconds (leukocyte test field 60 – 120 seconds).
4. Compare reaction color(s) with the color scale and read corresponding value(s).

For reflectometric evaluation of the test strips please consult the manual of the corresponding devices.

Notes

Use only urine samples which have stood for a maximum of 4 hours at room temperature.

Use only clean containers for urine collection which are free of residues. For control of dipping and reaction time use a timer accurate to the second.

Substances which cause abnormal urine coloration can impair the analysis of the test strips. More information can be found in the descriptions of the individual parameters.

Do not touch the reaction zones. Always remove only the number of test strips needed. Immediately close the package tightly after removing test strips. Do not use damaged test strips or tins.

In general, individual test strip results can allow a definitive diagnosis and targeted therapy only in connection with other medical findings. The effect of medications or their metabolites on the test is not known in all cases.

Users with impaired color vision must be assisted by a person with normal color vision for the color comparison.

Store test strips out of the reach of children.

Do not reuse test strips.

For use only outside of the body.

Quality control by the user

The test strips should be verified only with positive and negative control solutions. Medi-Test Control (supplier: MACHEREY-NAGEL, REF 93038) is recommended as a control solution. The positive and negative controls should be performed when using a new test strip batch, and after 30 days in each case to verify the storage conditions. Each laboratory should determine its own target values for adequate performance standards and review the test methods and sequences if these standards are not met.

Parameters

BLO Blood

Blood in the urine is a diagnostic parameter for severe disease of the kidneys and urinary tract.

The evidence is based on the pseudoperoxidase activity of the haemoglobin or myoglobin which catalyses the oxidation of a color indicator by an organic hydroperoxide to form a blue-green dye. The test detects values starting from 4 erythrocytes/µL urine which correspond to a concentration of approx. 0.012 mg haemoglobin or myoglobin/dL urine. Intact erythrocytes are indicated by punctiform discolorations of the test field. Any green coloration should be interpreted as a positive finding. The color comparison fields correspond to the following concentrations:

0 (negative) · approx. 5 – 10 · approx. 50 · approx. 250 ery/µL or an amount of haemoglobin from 0 (negative) · approx. 10 · approx. 50 · approx. 250 ery/µL

Reactive substances*: tetramethylbenzidine 31 µg, cumene hydroperoxide 315 µg.

For Combi 11: tetramethylbenzidine 85 µg, cumene hydroperoxide 422 µg.

Normal concentrations of ascorbic acid (≤ 40 mg/dL) do not influence the test result.

In the case of Combi 11, ascorbic acid concentrations > 2.5 mg/dL lead to false-negative results.**

False-positive reactions can be caused by residues of cleaning agents which contain peroxide or other cleaning agents, as well as menstrual blood.***

URO Urobilinogen

An elevated urobilinogen excretion suggests liver dysfunction and increased haemoglobin decomposition.

The test field contains a stable diazonium salt which forms a reddish azo dye with urobilinogen. Depending on the intrinsic color of the urine, concentrations starting from 1.0 mg urobilinogen/dL urine can be detected. The normal excretion rate is 1 mg/dL. Values above this are pathological. A complete lack of urobilinogen in the urine cannot be detected with test strips. The color comparison fields are allocated to the following urobilinogen concentrations:

norm. (normal) · 2 · 4 · 8 · 12 mg/dL or

norm. (normal) · 35 · 70 · 140 · 200 µmol/L

Reactive substances*: diazonium salt 75 µg.

The detection is inhibited by higher concentrations of formaldehyde (> 60 mg/dL). Nitrite concentrations > 2.5 mg/dL and prolonged exposure of the urine to light can lead to low or false-negative values.** Overly high or false-positive results can be caused by dyes (e. g. betanin) or medications excreted in the urine.***

BIL Bilirubin

Elevated bilirubin excretion indicates forms of obstruction (e. g. impaired bile flow) and hepatic dysfunction.

Coupling the bilirubin with a diazonium salt in an acid environment generates an orange-brown azo dye. Values starting at 1.0 mg bilirubin/dL urine are indicated and should be interpreted as a positive finding. The bilirubin excretion of a healthy individual is shown as negative. The color comparison fields are allocated to the following bilirubin concentrations:

0 (negative) · 1 (+) · 2 (++) · 4 (+++) mg/dL or

0 (negative) · 17 (+) · 35 (++) · 70 (+++) µmol/L

Reactive substances*: diazonium salt 29 µg.

The detection is inhibited by higher concentrations of ascorbic acid (> 40 mg/dL) and nitrite (> 2.5 mg/dL). Prolonged exposure of the urine to light can lead to low or false-negative values.** Excreted dyes (e. g. betanin) and medications (e. g. phenazopyridine > 0.1 mg/dL) can simulate a positive result as well as urine indican at a concentration of > 10 mg/dL.***

PRO Protein

The detection is used as a diagnostic aid to identify kidney diseases.

The test is based on the principle of the protein error of indicators, that is, at a constantly buffered pH value, the color change takes place in the presence of albumin from yellow to green-blue. Other proteins react with less sensitivity. The test detects values starting at 10 mg albumin/dL urine. Any green discoloration should be interpreted as a positive finding. The color comparison fields are allocated to the following albumin concentrations:

negative · 30 · 100 · 500 mg/dL or

negative · 0.3 · 1.0 · 5.0 g/L

Reactive substances*: tetrabromophenol blue 11 µg.

False-positive findings can occur in the case of extremely alkaline urine (pH > 9), disinfectant residues (e. g. benzalkonium chloride > 12.5 mg/dL) in the urine container or in the presence of quinine (> 30 mg/dL).***

NIT Nitrite

Nitrite in the urine is a diagnostic parameter for urinary tract infections.

This test indirectly detects microorganisms which can reduce nitrate to nitrite. The test is based on the Griess reaction. The test paper contains an amine and a coupling component. Diazotisation with subsequent coupling results in a pink-colored azo dye. The test detects values starting at 0.025 mg nitrite/dL urine. A pink color suggests a bacterial urinary tract infection. The color intensity depends on the nitrite concentration, however it does not allow any statement to be made regarding the severity of the infection. A negative result cannot rule out a urinary tract infection. The color comparison fields correspond to the following evaluations:

negative · positive

Reactive substances*: sulphanilic acid 95 µg; quinoline derivative 37 µg.

False-negative results can occur in the case of antibiotic therapy, and in the case of an overly low nitrate level in the urine as a result of low-nitrate food or severe dilution (diuresis). Microbes without the ability to form nitrite can also be present. A false-positive reaction color can be caused by phenazopyridine (> 0.1 mg/dL) or dyes (e. g. betanin) excreted in the urine.***

KET Ketone

The determination is used as an aid for diagnosing pathological ketonuria as a result of metabolic disders.

The test is based on the principle of Legal's test. Acetoacetic acid and acetone react with sodium nitroprusside in an alkaline environment to form a purple color complex. Acetoacetic acid reacts with the test field more sensitively than acetone. Values starting at 4 mg acetoacetic acid/dL or 50 mg acetone/dL urine are indicated. A purple color suggests a positive finding. The color comparison fields are allocated to the following acetoacetic acid concentrations:

0 (negative) · 25 (+) · 100 (++) · 300 (+++) mg/dL or

0 (negative) · 2.5 (+) · 10 (++) · 30 (+++) mmol/L

Reactive substances*: sodium nitroprusside 180 µg.

Phthalein compounds in up to concentrations of 125 mg/dL (highest concentration tested) do not interfere with this test.***

ASC Ascorbic acid

The detection of ascorbic acid in the urine suggests a high ascorbic acid intake. No pathological effects are known. The ascorbic acid test field is used to assess and evaluate the blood test field in the Combi 11.

The detection is based on the decoloration of Tilman's reagent. The presence of ascorbic acid is indicated by a color change from blue to red. The test detects values starting from 5 mg ascorbic acid/dL urine. The color fields are allocated to the following concentrations:

0 (negative) · 10 (+) · 20 (++) mg/dL or

0 (negative) · 0.6 (+) · 1.1 (++) mmol/L

Reactive substances*: 2,6-dichlorophenolindophenol 7 µg.

False-negative results can occur due to oxidising cleaning agents in sample containers.

GLU Glucose

Increased glucose excretion suggests diabetes mellitus.

The detection is based on the glucose oxidase-peroxidase chromogen reaction. Except for glucose, no urine constituent which returns a positive reaction is known. Pathological glucose concentrations are indicated by a color change from green to blue-green. The test detects values starting from 30 mg glucose/dL urine. Yellow to pale green test fields should be evaluated as negative (or normal). The color comparison fields correspond to the following glucose concentrations:

neg. (yellow) · normal (yellow-green) · 50 · 150 · 500 · ≥ 1000 mg/dL or

neg. (yellow) · normal (yellow-green) · 2.8 · 8.3 · 27.8 · ≥ 55.5 mmol/L

Reactive substances*: glucose oxidase 7 U; peroxidase 1 U; tetramethylbenzidine 96 µg.

For URYXXON® Stick 10: glucose oxidase 7 U; peroxidase 1 U; o-tolidine 86 µg.

Normal concentrations of ascorbic acid (≤ 40 mg/dL) do not influence the test result.** False-positive reactions can be caused by oxidising cleaning agents in the sample container.***

pH pH

Large fluctuations in pH may occur in connection with metabolic disorders. Significantly alkaline urine (pH > 8) suggests a urinary tract infection or a delayed urine test with increased microbial growth.

The test paper contains a mixed indicator which shows clearly distinguishable reaction colors (from orange to green to turquoise) in the pH range from 5 to 9. The pH value of urine of a healthy person normally lies between approx. 5 and 7. The color comparison fields correspond to the following pH values:

5 · 6 · 7 · 8 · 9

Reactive substances*: methyl red 3 µg; bromothymol blue 10 µg.

SG Density

In the case of severely restricted fluid intake or significant fluid loss (sweating) the density may increase to over 1.030 g/mL. Low densities (< 1.005 g/mL) may indicate renal failure. The normal value for adults, given normal food and fluid intake, is approximately between 1.005 and 1.030 g/mL.

The test detects the ion concentration of the urine through an acid ion exchanger and a pH indicator. The color changes from blue-green to green to yellow as the ion concentration increases. The test allows determination of urine density between 1.000 and 1.030 g/mL. The color comparison fields correspond to the following density values:

1.000 · 1.005 · 1.010 · 1.015 · 1.020 · 1.025 · 1.030 g/mL

Reactive substances*: bromothymol blue 42 µg; copolymer 1048 µg.

In the case of elevated protein excretion (> 500 mg/dL), the density values determined are too low.

LEU Leukocytes

The increased occurrence of leukocytes in the urine suggests pathological leukocyturia. This is caused, among other factors, by bacterial infections of the kidneys and the urinary tract.

The test is based on the esterase activity of granulocytes. This enzyme splits a carboxylic acid ester. The alcohol component released as a result reacts with a diazonium salt to create a purple dye. The test detects values starting from approx. 10 leukocytes/µL urine. Discolorations which can no longer be allocated to the negative comparison field and weak purple discolorations after 120 seconds must be assessed as positive. The color comparison fields correspond to the following leukocyte concentrations:

negative (normal) · 25 · 75 · 500 leukocytes/µL

Reactive substances*: carboxylic acid ester 16 µg; diazonium salt 14 µg.

An attenuated reaction can be expected if preparations with nitrofurantoin (> 2 mg/dL) or phenazopyridine (> 0.2 mg/dL) are taken.** Formaldehyde (as a preservative, > 20 mg/dL) and dyes (e. g. betanin) can lead to a false-positive reaction. In the case of specimens from female patients, a false-positive reaction can be simulated by vaginal discharge.***

* quantity/cm² after impregnation.

** Interference study with urine with pathological finding (first positive scale value).

*** Interference study with urine without pathological findings.

Shelf life

Protect test strips from sunlight and moisture. Store tin in a cool and dry location (storage temperature 4 – 30 °C). If stored properly, the test strips can be stored until the printed expiry date.

Disposal

Dispose of the used test strips taking applicable safety regulations into account.

Information on reporting obligation if incidents occur

We wish to point out that all serious incidents which occur in connection with the product must be reported to the manufacturer and the competent authority of the European member state or of the state in which the incident occurred. European vigilance contact points:

https://ec.europa.eu/health/md_sector/contact_en.

Literature

Urinlabor, M. Zimmermann-Spinnler, Medical Laboratory Consulting, 1991.

Labor und Diagnose 2020, L. Thomas, Online Edition, 2020.

K. P. Kohse, Klinische Chemie und Hämatologie, 9. Auflage, Georg Thieme Verlag KG, 2019.

Technical service

If you still have questions after reading the instructions or need technical assistance, please contact

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Revision:

04/2024

Reason of revision:

Correction of the ketone concentration (es)

Leistungsdaten / Performance data / données de performance / dati di performance / datos de rendimiento / prestatiegegevens / teljesítményadatok

	BLO	URO	BIL	PRO	NIT	KET	ASC	GLU	pH	SG	LEU
Comparison with reference method (visual evaluation with competitor test strips)[1], N= 125, [%]	94	96	99	96	99	100	100*	98	85	99**	97
Diagnostic specificity / sensitivity[2], N= 125, [%]	100/91	97/100	99/100	97/100	99/100	100/100	100/100	100/100	n/a	n/a	99/100
NPV/PPV***, N= 125 [%]	98/100	100/69	100/92	100/92	100/93	100/100	100/100	100/100	n/a	n/a	100/97
Batch to batch repeatability[3], N= 120, [%]	100	100	100	100	100	100	100	100	100	100	100
Repeatability within series[4], [%]	100 (N= 80)	100 (N= 100)	100 (N= 80)	100 (N= 80)	100 (N= 40)	100 (N= 80)	100 (N= 60)	100 (N= 120)	100 (N= 100)	100 (N= 140)	100 (N= 80)
Reproducibility[5], N= 120, [%]	100	100	100	100	100	100	100	100	100	100	100

Likelihood ratios for all parameters were calculated as LR+ > 10 and LR- < 0,1, which demonstrates convincing diagnostic evidence; die Likelihood Ratios für alle Parameter wurden mit LR+ > 10 und LR- < 0,1 berechnet, was einen überzeugenden diagnostischen Beweis darstellt; les rapports de vraisemblance pour tous les paramètres ont été calculés comme LR+ > 10 et LR- < 0,1, ce qui démontre une preuve diagnostique convaincante ; i rapporti di probabilità per tutti i parametri sono stati calcolati come LR+ > 10 e LR- < 0,1, il che dimostra un'evidenza diagnostica convincente; los cocientes de probabilidad para todos los parámetros se calcularon como LR+ > 10 y LR- < 0,1, lo que demuestra una evidencia diagnóstica convincente; de likelihood ratio's voor alle parameters werden berekend als LR+ > 10 en LR- < 0,1, hetgeen overtuigend diagnostisch bewijs aantoont; az összes paraméterre vonatkozó valószínűségi arányokat LR+ > 10 és LR- < 0,1, ami meggyőző diagnosztikai bizonyítékot mutat.

[1] Vergleich mit einer Referenzmethode (visuelle Auswertung mit Mitbewerberteststreifen); Comparaison avec la méthode de référence (évaluation visuelle avec des bandes de test concurrentes) ; Confronto con il metodo di riferimento (valutazione visiva con strisce di test concorrenti); Comparación con el método de referencia (evaluación visual con tiras reactivas de la competencia); Vergelijking met referentiemethode (visuele evaluatie met teststrookjes van concurrenten); Összehasonlítás a referenciamódszerrel (vizuális értékelés a versenytárs tesztcsíkokkal)

[2] diagnostische Spezifität / Sensitivität; spécificité / sensibilité diagnostique ; specificità / sensibilità diagnostica; especificidad / sensibilidad diagnóstica; diagnostische specificiteit/gevoeligheid; diagnosztikai specificitást / érzékenységet

[3] Charge zu Charge Wiederholbarkeit; la précision du LOT au LOT ; Ripetibilità da lotto a lotto; Repetibilidad entre lotes; LOT tot LOT precisie; Tételenkénti ismételhetőség

[4] Wiederholbarkeit in einer Reihe; Répétabilité d'une série ; Ripetibilità in serie; Repetibilidad en una serie; Herhaalbaarheid in een serie; Ismételhetőség sorozatban

[5] Reproduzierbarkeit; reproductibilité ; riproducibilità; Reproducibilidad; reproduceerbaarheid; reprodukálhatóság

* reference method: instrumental evaluation of semi-quantitative test strips; Referenzmethode: instrumentelle Auswertung von semi-quantitativen Teststreifen; méthode de reference : évaluation instrumentale des languettes de test semi-quantitatives; metodo di referenza: valutazione strumentale di strisce di test semi-quantitativi; método de referencia: evaluación instrumental de las tiras reactivas semicuantitativas; referentiemethode: instrumentele evaluatie van semi-kwantitatieve teststrips; referenciamódszerrel: szemikvantitatív tesztcsíkok instrumentális kiértékelése

** reference method (urine density refractometer), correspondence within ± 1 scale value; Vergleichsmethode (Urindichte-Refraktometer), Übereinstimmung ± 1 Skalenwert; méthode de référence (réfractomètre de densité urinaire), concordance ± 1 valeur de l'échelle ; metodo di confronto (rifrattometro per la densità dell'urina), accordo ± 1 valore di scala; método de refencia (refractómetro de densidad de la orina), concordancia dentro de ± 1 valor de la escala; referentiemethode (urindichtheid refractometer), overeenkomst binnen ± 1 schaalwaarde; referenciamódszerrel (refraktométeres vizsleltfajsúly-vizsgálat), Konkordancia ± 1 Skálaérték

*** negative/positive predictive value; negativ/positiv prädiktiver Wert; valeur prédictive negative/positive ; valore predittivo negativo/positivo; valor predictivo negativo/positivo; negatief/positief voorspellende waarde; negatív/pozitív prediktív érték

Produktübersicht / Product overview / Aperçu des produits / Prospetto dei prodotti / Resumen de productos / Productoverzicht / Termékáttekintés

Die Art und Kombination der Parameter einzelner Produkte ist in folgender Tabelle aufgeführt. / The type and combination of the parameters of individual products are listed in the following table. / Le type et la combinaison des paramètres des produits sont indiqués dans le tableau suivant. / Il tipo e la combinazione dei parametri dei singoli prodotti sono riportati nella seguente tabella. / El tipo y la combinación de los parámetros de cada uno de los productos se indica en la tabla siguiente. / De volgende tabel geeft een overzicht van het type en de combinatie van parameters van afzonderlijke producten. / Az egyes termékek paramétereinek típusát és kombinációját a következő táblázat tartalmazza.

Name / Nom / Nome / Nombre / Naam / Név	REF	Σ	BLO	URO	BIL	PRO	NIT	KET	ASC	GLU	pH	SG	LEU
Glucose	93001 / 93024	50 / 100								•			
Keton	93005 / 93028	50 / 100						•					
Nitrit	93006 / 93029	50 / 100					•						
Combi 2	93015 / 93037	50 / 100				•				•			
Glucose/Keton	93025	50						•		•			
Protein 2	93004 / 93027	50 / 100				•					•		
Combi 3A®	93007 / 93030	50 / 100				•			•	•	•		
Combi 5	93009 / 93032	50 / 100	•			•			•	•	•		
Combi 5S	93055	50	•			•		•		•	•		
Combi 5N®	93035 / 93036	50 / 100	•			•	•		•	•	•		
Combi 6A	93034	100	•		•	•		•	•	•	•		
Combi 7	93022	100	•			•	•	•	•	•	•		
Combi 7 L[1)]	93031	100	•			•	•	•		•	•		•
Combi 8 L	93021	100	•			•	•		•	•	•	•	•
Combi 9®	930879 / 93023	50 / 100	•	•	•	•	•	•	•	•	•		
Combi 10® L	93079 / 93058	50 / 100	•	•	•	•	•	•	•	•	•		•
Combi 10® SGL	93067	100	•	•	•	•	•	•		•	•	•	•
Combi 11[1) 3)]	93060 / 930871	100 / 125	•	•	•	•	•	•	•	•	•	•	•
URYXXON® Stick 10[2) 3)]	93068 / 930872	100 / 125	•	•	•	•	•	•		•	•	•	•

[1)] Geeignet zur Auswertung auf dem URYXXON® Relax / Suitable for analysis on the URYXXON® Relax / Peut être utilisé pour l'analyse sur l'URYXXON® Relax / Idoneo per analisi con URYXXON® Relax / Apto para la evaluación en URYXXON® Relax / Geschikt voor beoordeling op de URYXXON® Relax / Alkalmas a URYXXON® Relax készülékkel történő kiértékelésre

[2)] Geeignet zur Auswertung auf dem URYXXON® 500 und URYXXON® Relax / Suitable for analysis on the URYXXON® 500 and URYXXON® Relax / Peut être utilisé pour l'analyse sur l'URYXXON® 500 et URYXXON® Relax / Idoneo per analisi con URYXXON® 500 e URYXXON® Relax / Apto para la evaluación en URYXXON® 500 y URYXXON® Relax / Geschikt voor beoordeling op de URYXXON® 500 en URYXXON® Relax / Alkalmas a URYXXON® 500-on és a URYXXON® Relax készülékkel történő kiértékelésre

[3)] Leistungsdaten für die reflektometrische Auswertung befinden sich im Gerätehandbuch / Performance data for the reflectometric evaluation can be found in the manual of the corresponding devices / Les caractéristiques de performance pour l'analyse par réflectométrie figurent dans le manuel de l'appareil / I dati delle prestazioni per la valutazione riflessometrica sono riportati nel manuale del dispositivo / Los datos de rendimiento para la evaluación reflectométrica figuran en el manual del aparato / Raadpleeg de handleiding bij de apparatuur voor prestatiegegevens voor de reflectometrische beoordeling / A reflektometriás kiértékelésre vonatkozó teljesítményadatok a készülék kézikönyvében találhatók.

Erklärung der angewendeten Symbole / Explanation of applicable symbols / Explication des symboles applicables / Spiegazione dei simboli utilizzati / Explicación de los símbolos aplicables / Verklaring van de toepassellijke symbolen / Jelmagyarázat

CE
Konformitätserklärung
Declaration of Conformity
Déclaration de conformité
Dichiarazione di conformità
Declaración de Conformidad
Conformiteitsverklaring
Megfelelőségi nyilatkozat

IVD
In-vitro-Diagnostikum
In vitro diagnostic medical device
Médicaux de diagnostic *in vitro*
Presidio diagnostico *in vitro*
Diagnóstico *in vitro*
In-vitrodiagnostiek
In vitro diagnosztikai használatra

Gebrauchsanweisung beachten
Please read instructions for use
Respecter les instructions d'utilisation
Seguire le istruzioni per l'uso
Obsérvense las instrucciones de uso
Gebruiksaanwijzing raadplegen
Olvassa el az útmutatót

REF
Artikelnummer
Item number
Référence produit
Codice articolo
Referencia
Artikelnummer
Rendelési szám

LOT
Chargencode
Batch identification
Numéro de lot
Codice lotto
Código de lote
Partijcode
Gyártási szám

Nicht wiederverwenden
Do not reuse
Ne pas réutiliser
Non riutilizzare
Producto de un solo uso
Niet opnieuw gebruiken
Csak egyszer használja!

Verwendbar bis
Use by
À utiliser avant
Utilizzare entro il
Fecha de caducidad
Uiterste gebruiksdatum
Felhasználható

Hersteller
Manufacturer
Fabricant
Produttore
Fabricante
Fabrikant
Gyártó

Vor Sonnenlicht schützen
Keep away from sunlight
Tenir à l'écart des rayons du soleil
Proteggere dalla luce solare
Mantener alejado de la luz solar
Beschermen tegen zonlicht
Napfénytől távol tartandó

Ausreichend für <n> Prüfungen
Contains sufficient for <n> tests
Contenu suffisant pour <n> tests
Sufficienti per <n> test
Contenido suficiente para <n> tests
Voldoende voor <n> tests
<N> db vizsgálathoz elegendő

Trocken aufbewahren
Store in a dry place
Conserver au sec
Conservare in luogo asciutto
Mantener seco
Droog bewaren
Száraz helyen tartandó

Temperaturbegrenzung
Permitted storage temperature range
Limites de température
Limiti di temperatura
Límites de temperatura
Temperatuurlimiet
Tárolási hőmérséklet

Produkt nicht zur Eigenanwendung
Device not for self-testing
Dispositif non destiné à l'autodiagnostic
Dispositivo non destinato a test autodiagnostico
No destinado para el autodiagnóstico
Geen hulpmiddel voor zelftesten
Nem önellenőrzésre szolgáló eszköz

Produkt für patientennahe Tests
Device for near-patient testing
Dispositif de diagnostic près du patient
Dispositivo per analisi decentrate (near-patient testing)
Prueba diagnóstica en el lugar de asistencia al paciente
Hulpmiddel voor patiëntnabije tests (hulpmiddel voor near-patient testing)
Betegközeli laboratóriumi diagnosztikára használt eszköz

CE 0197 IVD
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A070900/xxxx

Medi-Test Control

ro | REF **93038** | **CONTROL** | IVD

Soluții de control negative și pozitive pentru bandeletele de testare a urinei Medi-Test

Destinația de utilizare:
Medi-Test Control este o soluție de control pentru controlul funcționalității bandeletelor de testare a urinei Medi-Test și a dispozitivelor URYXXON® ® Relax și URYXXON® 500.
Soluția N simulează o probă de urină cu toate valorile în intervalul negativ sau normal. Soluția P produce o reacție colorată pozitivă cu bandeletele de testare a urinei Medi-Test. După imersia în soluțiile de control, bandeletele de testare a urinei pot fi evaluate vizual cu ajutorul scalei de culori sau pot fi citite cu ajutorul dispozitivelor URYXXON® Relax și URYXXON® 500. Rezultatele parametrilor urinari, sânge, urobilinogen, bilirubină, proteine, nitriți, corpi cetonici, glucoză, pH, densitate și leucocite, sunt comparate cu valorile țintă prezentate în tabelul furnizat în IDU. Soluțiile Medi-Test Control sunt destinate utilizării exclusiv de către profesioniști. Medi-Test Control nu este destinat autotestării și nici testării în proximitatea pacientului.

Reactivi:
Fiecare pachet conține:
• 1 eprubetă cu 15 mL soluție de reactiv Medi-Test Control N
• 1 eprubetă cu 15 mL soluție de reactiv Medi-Test Control P

Precauții de siguranță:

Soluțiile de reactivi Medi-Test Control conțin clorometilizotiazolinonă 0,0015 – 0,06 %, CAS 26172-55-4. AVERTISMENT H317 Poate provoca o reacție alergică a pielii. P280 Purtați mănuși de protecție/ echipament de protecție a ochilor. P302+352 ÎN CAZ DE CONTACT CU PIELEA: spălați cu multă apă. P333+313 În caz de iritare a pielii sau de erupție cutanată: consultați medicul. Pentru informații suplimentare, vă rugăm să solicitați fișa cu date de securitate *(consultați www.mn-net.com/MSDS)*.

Depozitare și perioadă de valabilitate:
Atunci când nu sunt utilizate, se recomandă ca soluțiile de reactivi Medi-Test Control N și P să fie depozitate într-un loc întunecos, la temperaturi de 2 – 8 °C. Nu congelați sub nicio formă soluțiile.
Dacă sunt depozitate corect, soluțiile de reactivi pot fi folosite până la data limită de utilizare imprimată pe ambalaj. După prima utilizare, fiecare soluție de reactiv poate fi folosită timp de până la trei luni sau pentru scufundarea bandeletei de test de până la 20 de ori, oricare dintre aceste situații survine mai întâi.
Precipitările din soluțiile de reactivi nu au niciun efect asupra rezultatului măsurătorii. Dacă soluțiile prezintă alte urme de contaminare, nu mai trebuie utilizate. Soluțiile pot fi eliminate cu multă apă de la robinet în sistemul de canalizare al stației locale de tratare a apelor reziduale.

Procedură de testare:
Scoateți din frigider eprubetele cu soluțiile Medi-Test Control P și N, lăsați-le să se încălzească la temperatura camerei și agitați-le bine astfel încât soluțiile să se poată omogeniza. Evitați formarea spumei.
Deschideți capacele eprubetelor. Nu turnați soluțiile într-un alt vas. Efectuați măsurătorile direct în eprubetă. Dacă este necesar, scoateți o bandeletă de testare dintr-un recipient cu bandelete de testare. După ce ați scos o bandeletă, închideți imediat recipientul la loc. Nu atingeți câmpurile de testare cu degetele.
Pentru controlul timpului de scufundare și de reacție, utilizați un cronometru cu precizie de o secundă. Scufundați bandeleta de testare cu toate câmpurile de testare în soluția de reactiv respectivă timp de aproximativ 1 secundă. După ce ați scos bandeleta de testare din soluție, tamponați pentru scurt timp marginea de-a lungul unei părți pe un prosop absorbant din hârtie. Pentru evaluarea instrumentarului, introduceți bandeleta de testare în dispozitiv conform instrucțiunilor fotometrelor cu reflexie URYXXON® 500 și URYXXON® Relax. Câmpurile de testare sunt analizate, iar apoi rezultatele sunt tipărite.
Când evaluați vizual culorile reacției din câmpurile de testare, comparați aceste câmpuri cu scala colorimetrică după aproximativ 30 – 60 de secunde (comparați câmpul de testare a leucocitelor după 60 – 120 de secunde). Cel mai oportun moment de citire este după 30 de secunde. Orice modificări de culoare care apar după mai mult de 2 minute nu prezintă semnificație.
Orice evaluare vizuală a bandeletelor de testare a urinei trebuie efectuată la lumina zilei. Totuși, trebuie evitată lumina directă a soarelui.
Câmpul de testare a urobilinogenului poate afișa o culoare roșie-portocalie puțin mai intensă în comparație cu scala colorimetrică.
Atunci când nu utilizați eprubetele și după ce încheiați procedurile de control, așezați la loc capacele pe eprubetele cu soluțiile de reactivi și depozitați-le la 2 – 8 °C.

Date despre performanță:
Precizia în cadrul măsurătorilor repetate (N = 20) și precizia între loturi (N = 3 × 20) au fost de 100 % pentru toți parametrii soluțiilor de control N și P.

Note:
De asemenea, vă rugăm să țineți cont de instrucțiunile pentru fotometrele cu reflexie URYXXON®.

Nu ingerați soluțiile! Evitați orice contact cu pielea sau ochii! Depozitați soluțiile de reactivi într-un loc sigur, inaccesibil copiilor!

Informații privind obligația de raportare în cazul în care se produc incidente:
Dorim să subliniem faptul că toate incidentele grave care se produc în legătură cu produsul trebuie raportate producătorului și autorității competente din statul membru european sau din statul în care s-a produs incidentul. Puncte de contact europene pentru vigilență: *https://ec.europa.eu/health/md_sector/contact_en*

Literatură de specialitate:
J. Penders, T. Fiers, J. R. Delanghe, Clinical Chemistry (Biochimie clinică) 2002, 48, 2236 – 2241.

Explicația simbolurilor

CE	Declarație de conformitate
	Respectați instrucțiunile de utilizare
	Limite de temperatură
	Valabil până la
LOT	Cod de lot
REF	Număr articol
	Producător
	Да се пази от пряка слънчева светлина
IVD	Dispozitiv medical de diagnostic *in vitro*
CONTROL	Control
CONTROL –	Control, negativ
CONTROL +	Control, pozitiv

Motivul revizuirii: Includerea simbolului „A se feri de lumina soarelui" și a simbolului de avertizare GHS. Corecția valorilor așteptate pentru Control P.

Valori preconizate:
Intervalele identificate în tabel au fost stabilite utilizându-se mai multe loturi diferite de Medi-Test Combi 10® SGL și URYXXON® Stick 10 și au fost verificate cu ajutorul unei serii variate de dispozitive URYXXON®. Fiecare laborator trebuie să utilizeze rezultatele furnizate numai ca referință și să își stabilească parametri de precizie proprii.

Analiți	Medi-Test Combi 10® SGL vizual		URYXXON® Stick 10 cu URYXXON® 500/URYXXON® Relax	
	Control N	Control P	Control N	Control P
Sânge	Negativ	10 – 250 eritrocite/µL	Negativ	10 – 250 eritrocite/µL
Urobilinogen	Normal	2 – 12 mg/dL[1)] (35 – 200 µmol/L)	Normal	2 – 12 mg/dL[1)] (35 – 200 µmol/L)
Bilirubină	Negativ	1 – 4 mg/dL (1+ – 3+)	Negativ	1 – 4 mg/dL (1+ – 3+)
Proteine	Negativ	30 – 500 mg/dL	Negativ	30 – 500 mg/dL
Nitriți	Negativ	Pozitiv	Negativ	Pozitiv
Cetone	Negativ	25 – 300 mg/dL (1+ – 3+) (2,5 – 30 mmo/L)	Negativ	25 – 300 mg/dL (1+ – 3+) (2,5 – 30 mmol/L)
Glucoză	Negativ–Normal	50 – ≥ 1000 mg/dL (2,8 – 55,5 mmol/L)	Negativ–Normal	50 – ≥ 500 mg/dL (2,8 – ≥ 27,8 mmol/L)
Valoare a pH-ului	5 – 7	7 – 9	5 – 7	7 – 9
Greutate specifică (densitate)	1,010 – 1,030	1,005 – 1,025	1,010 – 1,030	1,005 – 1,025
Leucocite	Negativ	25 – 500 leucocite/µL	Negativ	25 – 500 leucocite/µL

[1)] Câmpul de testare a urobilinogenului are o culoare roșie-portocalie în comparație cu scala colorimetrică.

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