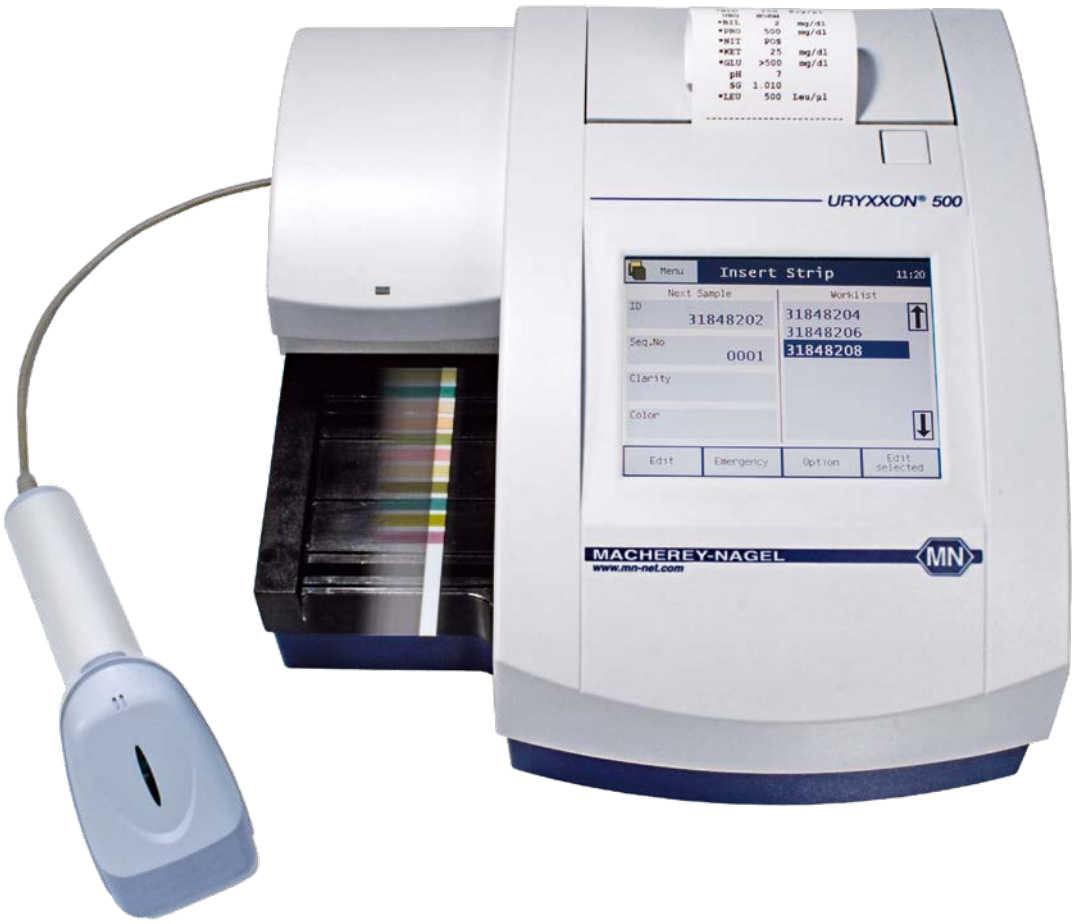
Medi-Test

MACHEREY-NAGEL

Urine analysis



URYXXON® 500

- Quick – Reads 400 strips per hour
- Easy – Touch screen operation
- Hygienic – Automatic strip detection

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Location: Moldova

URYXXON® 500

High performance urine analysis

The URYXXON® 500 is an automatic reader for URYXXON® Stick 10 urine test strips. With a capacity of 400 strips per hour, it is ideal for use in hospitals and practices. The “easy-to-use-features” allow hygienic operation with hardly any training.

The URYXXON® 500 provides dependable urine status results to detect early stages of many diseases such as urinary tract infections, kidney diseases or diabetes. The device eliminates the subjectivity of visual strip evaluation and minimizes risks associated with manual result transcription.

The URYXXON® 500 makes urine analysis quicker, easier and more reliable.

Technical specifications

Instrument memory	500 patient test results including name or patient ID	
Sediment	30 user defined sediment parameters	
Interface	User:	Touchscreen display, alphanumeric input, password protection
	Computer:	1 x USB (type B) and 2 x RS232 interfaces for connection to PC
		PS/2 interface for keyboard / barcode reader
Power requirements	110–240 V AC, automatic	
Dimensions / Weight	240 x 280 mm x 150 mm (D x W x H)	
	3.9 kg (10.5 lb)	
Operation	Temperature range:	5–40 °C (41–104 °F)
	Humidity range:	20–80 % relative humidity, non condensing
	Calibration:	automatic, self calibrating
Capacity	400 strips per hour	
CE	CE labeling according to IVDD 98/79/EC	

URYXXON® 500

Field of application

The URYXXON® 500 is intended for the automatic evaluation of URYXXON® Stick 10 urine test strips. It provides reliable results for the semi-quantitative detection of the following parameters in urine: blood, urobilinogen, bilirubin, protein, nitrite, ketones, glucose, pH, specific gravity and leukocytes. URYXXON® 500 and URYXXON® Stick 10 are CE marked according to the IVD-directive 98/79/EC.

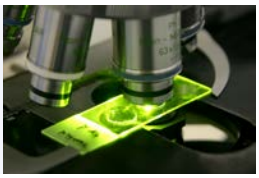
Improvements for your lab

Easy and intuitive

Operating the URYXXON® 500 is easy. Access all functions using the easy-to-follow menu on the touch screen. It nearly eliminates the need for training and makes urine analysis more reliable.

Informative and unique

Add microscopic evidence to the urine chemistry results using the sediment options. Powerful user defined filter functions only admit those samples to sediment analysis that need further diagnostic.



Clean and hygienic

Start the measurement without touching the instrument. Simply place the strip on the transport tray, the detector will recognize it and automatically start the measurement.

Fast and efficient

Once turned on, the URYXXON® 500 is immediately ready for use. It reads up to 400 strips per hour ensuring fast urine chemistry results.

Accurate and convenient

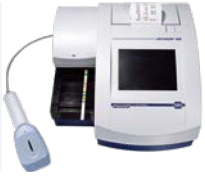
Use a barcode reader to enter patient IDs. Set up lists of samples with ease and convenience and quickly add urine chemistry results to the patient file in your laboratory information system.

Reliable and safe

Use the QC menu to maintain clinical reporting standards with ease and convenience. Medi-Test Control solutions are ideal to ensure correct results at any time.

Small and practical

Free up space with the smallest instrument in its class. With a size of only 28 x 24 cm (11 x 9,4 in) the URYXXON® 500 fits onto every bench. The clear design allows access to all parts and makes cleaning easy.



URYXXON® 500

Medi-Test ordering information

REF 50 strips per pack	REF 100 strips per pack	Type	with test fields for determination of											
			Glucose	Ketones	Ascorbic acid	Protein/ Albumin	Blood	Leukozytes	Nitrite	Density	pH value	Bilirubin	Urobilinogen	Creatinine
93001	930 24	Glucose [1]	■											
93025	930 20	Glucose / Ketone [1]	■	■										
93004	930 27	Protein 2 [1]				■					■			
93005	93028	Ketone [1]		■										
93006	93029	Nitrite [1]							■					
93012	–	Urbi										■	■	
93015	93037	Combi 2 [1]	■			■								
93007	93030	Combi 3 A®	■		■	■					■			
93009	93032	Combi 5	■		■	■	■				■			
93035	93036	Combi 5 N®	■		■	■	■		■		■			
93055	–	Combi 5 S	■	■		■	■				■			
93018	93078	Combi 6	■			■	■	■	■				■	
93013	93034	Combi 6 A	■	■	■	■	■				■	■		
93010	93022	Combi 7	■	■	■	■	■		■		■			
–	93021	Combi 8 L	■		■	■	■	■	■	■	■			
93011	93023	Combi 9®	■	■	■	■	■		■		■	■	■	
–	93056	Combi 10®	■	■	■	■	■		■	■	■	■	■	
93079	93058	Combi 10® L	■	■	■	■	■	■	■		■	■	■	
–	93060	Combi 11	■	■	■	■	■	■	■	■	■	■	■	
93077	93067	Combi 10® SGL	■	■		■	■	■	■	■	■	■	■	
–	93068	URYXXON® Stick 10 [2] [3]	■	■		■	■	■	■	■	■	■	■	
930874	–	Microalbumin [3] [5]				■								■

Further Medi-Test urine test strips

Test strips for veterinary applications			
–	930870	Combi 10® VET [4]	■ ■ ■ ■ ■ ■ ■ ■ ■ ■
Test strips for detection of urine adulteration			
93019	–	Medi-Test Adulteration Stick [4]	for the detection of urine adulteration prior to drugs-of-abuse tests with test fields for Creatinine, Glutaraldehyde, Nitrite, pH, Oxidants and Density

All products (except 4) are CE-marked according to the directive 98/79/EC
[1] suitable for patient self-testing [2] for evaluation with reflectometer URYXXON® 500 [3] for evaluation with reflectometer URYXXON® Relax [4] not an IVD product (no CE-mark) [5] pack of 24 test strips

Instruments for evaluation of urine test strips URYXXON® Stick 10	
93088	URYXXON® Relax, suitable for the evaluation of MT URYXXON® Stick 10
930080	URYXXON® 500, suitable for the evaluation of MT URYXXON® Stick 10
Accessories and spare parts	
93038	Medi-Test Control, solution to check Medi-Test urine test strips and URYXXON® instruments
93071	Printer paper for URYXXON® 300 and URYXXON® 500, pack of 5 rolls
93074	Barcode scanner for URYXXON® instruments

www.mn-net.com

MACHEREY-NAGEL

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Medi-Test

MACHEREY-NAGEL

Medi-Test urine analysis

Easy urine analysis

- Urine analysis with test strips
- URYXXON® Relax
  Automated urine analysis at the point of care
- URYXXON® 500
  High performance urine analysis

The company

Welcome to MACHEREY-NAGEL

We are pleased that you are interested in our high-quality medical test strips. This brochure gives you an overview over our different products and applications in the field of urine analysis.

Since its foundation in 1911, the roots of MACHEREY-NAGEL are the production of high-quality filter papers. Since the fifties, we have developed filter papers into top quality test papers for laboratory use. Today, we offer the world's largest selection of different test papers. Additionally, we offer a versatile program of special products for analytical chemistry including Chromatography, Water Analysis and Bioanalysis.

The production facilities of our test strips, as well as our company headquarter, are located in Düren (Germany). Local sales offices for test strips are found in Switzerland, France and the US.

Medical test strips

In the late seventies, MACHEREY-NAGEL started producing high-quality test strips for urine analysis. At that time, we were one of the first manufacturers of such test strips world-wide. Since then we have continuously developed the chemistry of our test strips. We are proud that today customers in more than 70 countries trust the outstanding quality of our medical test strips.

In addition, many pharmaceutical companies rely on MACHEREY-NAGEL. pH test strips manufactured by MN are used to monitor the dosing of different medications. They are CE-marked according to the IVD Directive 98/79/EC.

- Urine analysis for more than 40 years
- Special pH papers for the pharmaceutical industry

Certified quality

Already since 1996, MACHEREY-NAGEL is certified according to ISO 9001. Obviously, we are also certified according to EN ISO 13485 and fulfill the requirements of the European Medical Device and IVD Directives. Today, we are among the few manufacturers who can offer urine test strips with CE certification not only for professionals, but also for patient self-testing.

Good to know

Certified

We have been certified according to the international standards ISO 9001 and EN ISO 13485 since 1996.

MACHEREY-NAGEL meets your needs

If you have any questions concerning the Medi-Test products in this catalog please feel free to contact us:

Technical support and customer service:

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Please visit our Medi-Test pages: *www.mn-net.com*

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Urine analysis

Urine analysis with test strips

- Urine test strips offer a rapid survey of a patient's health status
- Urine chemistry – rapid and reliable
- Flexible strip design for small volume urine samples

The use of urine test strips is acknowledged as a modern screening method in medical practice. With these non-invasive tests important information on the health status of patients is rapidly obtained. The urine sample is easily drawn and can be investigated immediately with a test strip. Thus one obtains results within minutes, which facilitates the decision on further diagnostic and therapeutic action.

This saves considerable costs for the healthcare system and avoids unnecessary examinations for the patient.

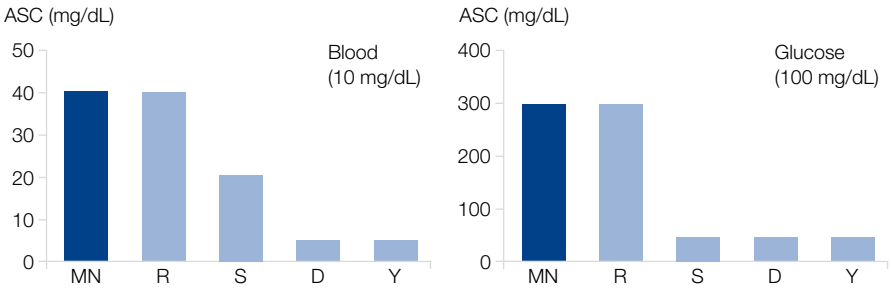
Urine test strips from MACHEREY-NAGEL are especially user-friendly. Due to the high resistance towards ascorbic acid interferences a second testing for sensitive parameters such as blood or glucose is unnecessary in most cases. The optimized, flexible shape of the test strips also allows the examination of very small amounts of urine. This makes urine analysis reliable and easy.

Best available vitamin C protection

The test pads for glucose and blood have the best available protection against interferences caused by vitamin C (ascorbic acid). This ensures correct results even when fruit juice or vitamin tablets are consumed. Eating restrictions do not apply.

The excretion of vitamin C is harmless in itself. However, vitamin C interferes with important oxidation reactions. With many test strips this leads to false negative readings for blood and glucose.

The Medi-Test technology overcomes the influence of vitamin C. This ensures optimal and safe results for all important urine parameters.



Concentration of vitamin C in the sample, with no effect on the results for blood and glucose in urine (mg/dL)

Safe and easy quality control – Medi-Test Control

In professional use it is recommended to confirm the performance of test strips by use of positive and negative control solutions. Positive and negative controls should be analyzed whenever a new lot of strips is started, and every 30 days to check storage conditions. Each laboratory should establish its own goals for adequate standards of performance, and should question handling and testing procedures if these standards are not met. Medi-Test Control are specially formulated control reagents to ensure optimal and convenient quality control for Medi-Test urine test strips and URYXXON® strip readers.

The reagents can be used immediately without any further preparation and the large reagent tubes make working with Medi-Test Control particularly easy.

Medi-Test Control

URYXXON® Relax

Automated urine analysis at the point of care

The URYXXON® Relax device provides dependable urine status results to detect early stages of many diseases such as diabetes, kidney disease and urinary tract infections. Instrument-read results have long proven to be advantageous for both busy health care professionals and patients. URYXXON® Relax readings eliminate the subjectivity of visual color interpretation. The comprehensive interface options and the optimized printouts minimize risks associated with manual transcriptions. Reliable results can be obtained immediately at the point of care.

The URYXXON® Relax makes urine analysis easier and more reliable.

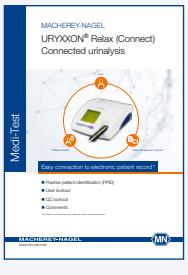
- 50 measurements/h
- Autostart
- High precision optics

Technical specifications

Instrument memory	200 patient test results including name or patient ID	
Interface	User:	Touchscreen display, alphanumeric input, password protection
	Computer:	USB interface for connection to PC alternatively RS232 interface for connection to PC
		USB A interface for connection of keyboard and / or barcode reader
Power requirements	110–240 V AC, automatic	
	Battery powered operation (optional) with 6 AA batteries	
Dimensions / Weight	Depth: 20 cm (7.9 inches)	
	Width: 16 cm (6.3 inches)	
	Height: 7.5 cm (3.0 inches)	
	Weight: 710 g (1.90 lb) (without batteries and power supply)	
Operation	Temperature range: 10 — 40 °C (50–104 °F)	
	Humidity range:	20–80 % relative humidity, non condensing
	Calibration:	automatic, self calibrating
Capacity	50 strips per hour	
CE	CE labeling according to Conformity with the European IVD Regulation 2017/746	

Medi-Test URYXXON® Stick 10

Good to know



For advanced connection options please contact MACHEREY-NAGEL. We keep you informed about our URYXXON® Relax Connect.

URYXXON® 500

High performance urine analysis

The URYXXON® 500 is an automatic reader for URYXXON® Stick 10 urine test strips. With a capacity of 400 strips per hour, it is ideal for use in hospitals and practices. The “easy-to-use-features” allow hygienic operation with hardly any training.

The URYXXON® 500 provides dependable urine status results to detect early stages of many diseases such as urinary tract infection, kidney diseases or diabetes. The device eliminates the subjectivity of visual strip evaluation and minimizes risks associated with manual result transcription.

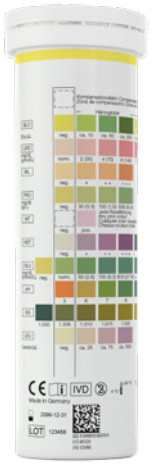
The URYXXON® 500 makes urine analysis quicker, easier and more reliable.

Perfect workflow usability

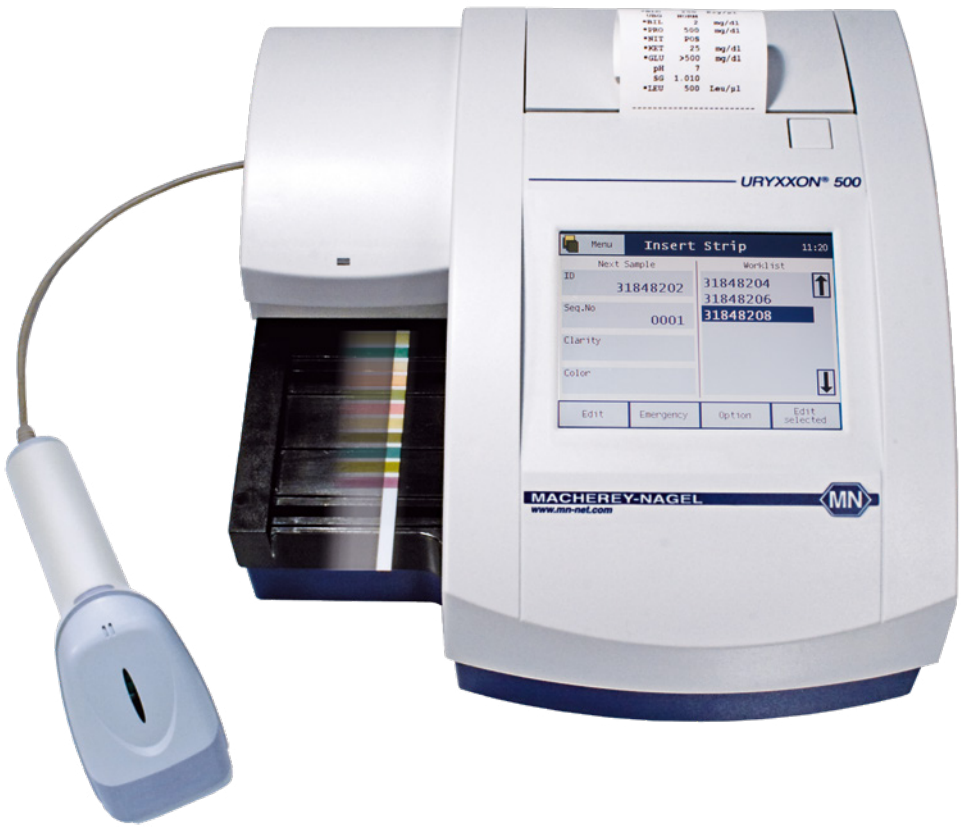
- 400 measurements/h
- Easy to use
- Compact design

Technical specifications

Instrument memory	500 patient test results including name or patient ID	
Sediment	30 user defined sediment parameters	
Interface	User:	Touchscreen display, alphanumeric input, password protection
	Computer:	1 x USB (type B) and 2 x RS232 interfaces for connection to PC
		PS/2 interface for keyboard / barcode reader
Power requirements	110–250 V AC, automatic	
Dimensions / Weight	240 x 280 mm x 150 mm (D x W x H)	
	3.9 kg (10.5 lb)	
Operation	Temperature range: 4–30 °C (39.2–86 °F)	
	Humidity range:	max. 80 % relative humidity, non condensing
	Calibration:	automatic, self calibrating
Capacity	360 strips per hour	
CE	CE labeling according to Conformity with the European IVD Regulation 2017/746	



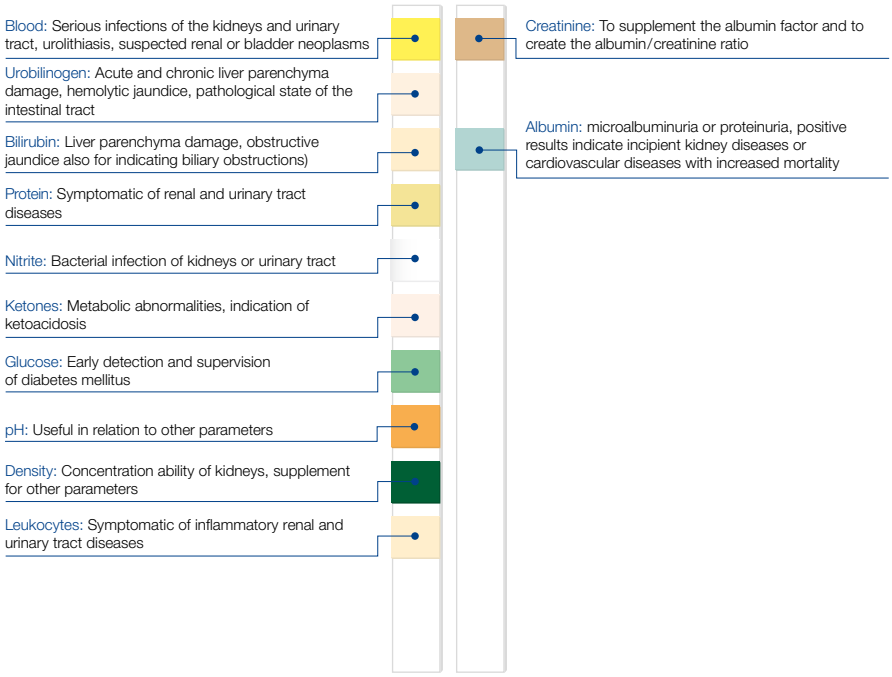
Medi-Test URYXXON® Stick 10



Significance of the parameters

The medical context of urine parameters

Urine test strips are indispensable tools in medical diagnostics to gain a rapid survey of the state of health of a patient.



Urine test strips for animals – Combi 10® VET

The examination of the urine of small animals (dogs, cats, rabbits, guinea pigs etc.) provides valuable information for the diagnosis of urinary tract disorders and diseases. Ideally, a urine sample should be obtained through cystocentesis. However, the examination of spontaneous urine is often adequate for an initial diagnosis. First, all urine samples undergo a macroscopic examination. The urine volume, color, transparency and smell are evaluated.

Using Medi-Test Combi 10® VET the urine status can easily be evaluated. The leaflet describes characteristics of the individual tests for the different species. This makes urine analysis of small animals safe and easy. Medi-Test Reflection photometer URYXXON® Relax is suitable for the instrumental evaluation of Medi-Test Combi 10® VET urine test strips.

Urine test for animals: rapid and easy

Medi-Test strips Mikroalbumin

Medi-Test Mikroalbumin urine test strips are for the rapid and reliable screening for early stages of microalbuminuria. Consequently, they allow for early intervention with the goal to prevent or delay nephropathy. Tests for microalbuminuria are regularly used for risk group patients like diabetics or patients with hypertension.

The easy test strips have two different test pads. One test pad is for creatinine and gives a measure of how concentrated the urine is, the other test detects albumin. The combination of both test pads allows the conclusion whether the results are normal or pathologic. The tests can easily be read using the evaluation chart in the picture that is also on the tube. Alternatively these test strips can be evaluated with the reflection photometer URYXXON® Relax.

Medi-Test Mikroalbumin

Medical parameters – Principle, evaluation, sources of error, diagnosis

Mikroalbumin:

Principle: The test is based on the principle of the “protein error” of indicators, i. e. at a constantly buffered pH, albumin reacts with a tetrabromophenol sulphonephthalein derivative resulting in a color change from yellow-green to green-blue.

Evaluation: The color fields correspond to the following concentrations of Albumin:

10, 30, 80 and 150 mg/L albumin

Diagnosis: In combination with the test for creatinine, this test allows the calculation of the albumin / creatinine ratio using the interpretation table printed on the container. The albumin / creatinine ratios classified in the table are based on the following value ranges (mg albumin/g creatinine):[1)]

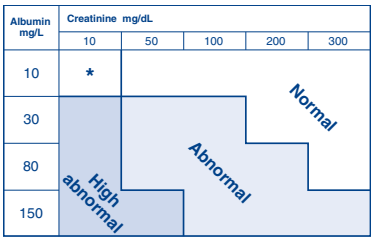
Normal: < 30 mg/g

Abnormal: 30–299 mg/g (microalbuminuria)

High abnormal: ≥ 300 mg/g (macroalbuminuria or proteinuria)

[1)] Position Statement: Diabetic Nephropathy. Diabetes Care. 27. S 79-S 83 (Supplement 1), 2004

Creatinine:



Principle: The detection is based on the reaction of creatinine with dinitrobenzoic acid. The resulting coloration ranges, depending on concentration, from yellow-brown to blue-black.

Evaluation: The color fields correspond to the following concentrations of Creatinine:

10–50–100–200–300 mg/dL Creatinine

Diagnosis: In combination with the test for creatinine, this test allows the calculation of the albumin / creatinine ratio using the interpretation table printed on the container. The albumin / creatinine ratios classified in the table are based on the following value ranges (mg albumin/g creatinine):[1)]

Normal: < 30 mg/g

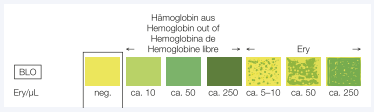
Abnormal: 30–299 mg/g (microalbuminuria)

High abnormal: ≥ 300 mg/g (macroalbuminuria or proteinuria)

[1)] Position Statement: Diabetic Nephropathy. Diabetes Care. 27. S 79-S 83 (Supplement 1), 2004

Blood

Principle: The detection is based on the pseudoperoxidative activity of hemoglobin and myoglobin, which catalyze the oxidation of an indicator by an organic hydroperoxide, producing a green color.



- Indicator for several serious diseases

Evaluation: The minimum sensitivity of the test strip is 4 erythrocytes/µL urine corresponding to approx. 0.012 mg hemoglobin or myoglobin/dL urine. Intact erythrocytes are indicated by flecked discolourations of the test field. The color fields correspond to the following values:

0 (negative), ca. 5–10, ca. 50, ca. 250 Ery/µL, or
a hemoglobin concentration out of ca. 10, ca. 50, ca. 250 Ery/µL.

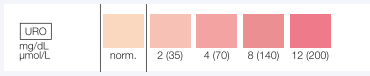
The blood test on Medi-Test urine test strips is optimally protected against interferences by ascorbic acid. Normal concentrations of vitamin C (< 40 mg/dL) do not influence the test result. However gentisic acid still shows an inhibitory effect. Falsely positive reactions can be produced by a residue of peroxide-containing cleansing agents.

Diagnosis: Every positive reaction should be taken as a pathological finding requiring further diagnostic examinations. Hematuria (hemolysis of intact erythrocytes occurs on the test field), hemoglobinuria or myoglobinuria are frequently caused by:

Serious infections of the kidneys and urinary tract, kidney and bladder calculi, serious poisonings (e.g. benzene and aniline derivatives, chlorate, bacteria toxins, poisonous mushrooms and snake poison), heart attack, hemolysis after transfusion incident, cold hemoglobinuria or march hemoglobinuria (after strong physical exertion), different paroxysmal hemoglobinurias and serious hemolytic anemias.

Medical parameters – Principle, evaluation, sources of error, diagnosis

Urobilinogen



- Detection of liver diseases
- In combination with bilirubin differentiation between different forms of jaundice

Principle: The test paper contains a stable diazonium salt producing a reddish azo compound with urobilinogen.

Evaluation: Depending on the urine color concentrations from 1 mg urobilinogen/dL urine are indicated. 1 mg/dL is considered to be the normal excretion rate. Higher values are pathological. A complete absence of urobilinogen in the urine, which is likewise pathological, cannot be detected with the strips. The color fields correspond to the following urobilinogen concentrations:

normal (0–1), 2, 4, 8, 12 mg/dL or
normal (0–17), 34, 70, 140, 200 µmol/L.

The test is inhibited by higher concentrations of formaldehyde. Longer exposure of the urine to light leads to lowered or falsely negative results. Higher, or falsely positive results, can be caused by the presence of diagnostic or therapeutic dyes in the urine. Larger amounts of bilirubin produce a yellow coloration.

Diagnosis: An increased urobilinogen concentration in urine is a sensitive index of liver dysfunction or hemolytic diseases. Urobilinogen uria is caused by e.g. virus hepatitis, chronic hepatitis, liver cirrhosis, infections, poisonings, congestion or carcinoma of liver, hemolytic, and pernicious anemina, polycythemia and pathological state of the intestinal tract with an increased resorbence.

Bilirubin

- Detection of liver diseases
- In combination with urobilinogen differentiation between different forms of jaundice

Principle: A red azo compound is obtained in the presence of acid by the coupling of bilirubin with a diazonium salt.

Evaluation: Values starting at 1.0 mg bilirubin/dL urine are indicated and should be interpreted as a positive finding. The color fields correspond to the following values:

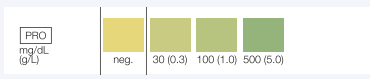
0 (negative), 1 (+), 2 (++), 4 (+++) mg/dL or
0 (negative), 17 (+), 35 (++), 70 (+++) µmol/L.

Some urine components can produce a yellow coloration of the test strip. Ascorbic acid and nitrite in higher concentrations inhibit the test. Longer exposure of the urine to light leads to lowered, or falsely negative results. Higher, or falsely positive results can be caused by the presence of diagnostic or therapeutic dyes in the urine.

Diagnosis: Only conjugated (water soluble) bilirubin is excreted by the kidneys. Normally bilirubin is undetectable in urine. Bilirubinuria generally indicates liver parenchyma damage (e.g. acute virus hepatitis and other forms of hepatitis, liver cirrhosis, toxic liver cell damage) or biliary obstructions (e.g. cholangitis, obstructive jaundice).

Unconjugated bilirubin, which is detectable in serum, indicating hemolytic jaundice is not excreted by the kidneys and is absent from urine.

Protein



- Symptomatic of renal and urinary tract diseases

Principle: The test is based on the “protein error” principle of indicators. The test zone is buffered to a constant pH value and changes color from yellow to greenish blue in the presence of albumin. Other proteins are indicated with less sensitivity.

Evaluation: The test strip detects values above 10 mg protein/dL urine. The color fields correspond to the following ranges of albumin concentrations:

negative, 30, 100 and 500 mg/dL or negative, 0.3, 1.0, and 5.0 g/L.

Falsely positive results are possible in strongly alkaline urine samples (pH > 9), after infusions with polyvinylpyrrolidone (blood substitute), after intake of medicaments containing quinine, and also by disinfectant residues in the urine sampling vessel. The protein coloration may be masked by the presence of medical dyes (e.g. methylene blue) or beetroot pigments.

Diagnosis: The limit of a physiological proteinuria lies between 10 and 30 mg/dL. It differentiates between:

1) Benign proteinuria is observed after physical strain, orthostatic proteinuria, with fever and during pregnancy. In such cases the protein excretion rate is usually normal in the first morning urine, however in the course of the day values can vary greatly.
2) Extrarenal proteinuria frequently appears with acute diseases like heart insufficiency, colics, liver cirrhosis, plasmocytoma, and carcinomas.

3) Renal proteinuria is caused by increased permeability of the glomerular filter and may indicate pyelonephritis, glomerulonephritis, tuberculosis of the kidneys, kidneys participation at infections and poisonings, cystic kidneys, gouty kidney. Every positive test reaction requires further diagnostic examinations.

Nitrite

- Bacterial infection of the kidneys or urinary tract

Principle: Microorganisms, which are able to reduce nitrate to nitrite, are indicated indirectly with this test, which is based on the principle of Griess reagent. The test paper contains an amine and a coupling component. Diazotization and subsequent coupling result in a red colored azo compound. Only nitrite can produce a diazonium salt for coupling reaction, therefore falsely positive results are virtually impossible in this case.

Evaluation: The test detects concentrations from 0.025 mg nitrite/dL urine. A pink color indicates a bacterial infection of the urinary tract. The color intensity only shows the nitrite concentration, and does therefore not provide information about the extent of the infection. A negative result does not preclude an infection of the urinary tract, if bacteria, which cannot produce nitrite are present. Falsely negative results can be produced by high doses of ascorbic acid, by antibiotics therapy, and by very low nitrate concentrations in urine as the result of low nitrate diet or strong dilution (diuresis). Falsely positive results can be caused by the presence of diagnostic or therapeutic dyes in the urine.

Diagnosis: Bacteria, which cause infections, and can produce nitrite in the urine are e.g. *E. coli* (bacteria which causes most frequently infections), Aerobic Bacteria, Citrobacteria, Klebsiella, Proteus, Salmonellae and in part Enterococci, Pseudomonas and Staphylococci. If the test is positive a microscopic examination and determination of susceptibility of pathogenic bacteria to chemotherapeutic agents should follow.

Ketones

- Early detection of ketosis /acidosis
- Control-parameter for diabetes mellitus

Principle: The test is based on the principle of Legal's test. Acetoacetic acid and acetone form a violet colored complex with sodium nitroprusside in alkaline medium.

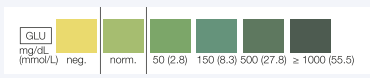
Evaluation: Acetoacetic acid reacts more sensitively than acetone. Values of 4 mg/dL of acetoacetic acid or 50 mg/dL acetone are indicated. The color fields correspond to the following acetoacetic acid values:

0 (negative), 25 (+), 100 (++), and 300 (+++) mg/dL or
0 (negative), 2.5 (+), 10 (++), and 30 (+++) mmol/L.

Phenylketones in higher concentrations interfere with the test, and will produce deviating colors. ß-hydroxybutyric acid (not a ketone) is not detected. Phthalein compounds interfere by producing a red coloration.

Diagnosis: Ketone bodies including acetoacetic acid, acetone, and ß-hydroxybutyric acid are only produced in the liver. Ketones in the urine are caused by an abnormal carbohydrate metabolism. Frequently, ketonuria is a sign of diabetic ketosis, which in connection with other metabolic abnormalities may cause diabetic coma. Ketonuria may also be noted in case of insulin overdoses, starvation (e.g. slimming diet, calorie free diet), dangerous metabolic abnormalities during pregnancy (hyperemesis gravidarum), acetonemic vomiting of infants and fever caused especially by infections.

Glucose



- Early detection of diabetes mellitus
- Supervision of type-II-diabetes

Principle: The detection is based on the glucose oxidase-peroxidase-chromogen reaction. The oxidation of glucose by atmospheric oxygen is catalyzed by glucose oxidase to form gluconic acid lactone and hydrogen peroxide. Peroxidase catalyzes the reaction of hydrogen peroxide with the chromogen. Apart from glucose, no other compound in urine is known to give a positive reaction.

Evaluation: Pathological glucose concentrations are indicated by a color change from green to bluish green. Yellow or greenish test fields should be considered negative or normal. All test fields which have an intensity greater than the greenish negative color field must be considered positive. The color fields correspond to the following ranges of glucose concentrations:

negative (yellow), neg. or normal (greenish), 50, 150, 500, and ≥ 1000 mg/dL or
negative (yellow), neg. or normal (greenish), 2.8, 8.3, 27.8, and ≥ 55.5 mmol/L.

An inhibitory effect is produced by gentisic acid. Falsely positive reactions can also be produced by a residue of peroxide-containing cleansing agents. The test is not influenced by vitamin C.

Diagnosis: Because of the clear distinction between physiological and pathological glucosuria, the test is especially suitable for the detection of diabetes mellitus and for supervising (and self-supervising) of diabetes. Apart from diabetes mellitus, renal glucosuria with increased glucose concentrations may be noted during pregnancy, and after a meal with excessive carbohydrates. Every positive test reaction requires further diagnosis.

pH value

Principle: The test paper contains indicators, which clearly change color between pH 5 and pH 9 (from orange to green to turquoise).

Evaluation: The pH value of fresh urine from healthy people varies between pH 5 and pH 7. The color scale gives a clear distinction of pH value between pH 5 and pH 9. The pH should always be measured in fresh urine, since bacterial decomposition may increase the pH of the urine to values > 9.

Diagnosis: The pH value is only of significance in relation to other parameters. More acid urine (lower pH values) is found in case of an increased protein metabolism, high fever, serious diarrhoea and metabolic acidosis (serious form of diabetes mellitus). Alkalinity (increased pH value) may be noted in urinary tract infections, respiratory or metabolic alkalosis.

- Diseases of the urogenital tract
- Supplement for other parameters
- Backup for microscopic results

Density

Principle: The test indicates the ion concentration of urine with good correlation to the refractometric method. Increasing ion concentrations cause a color change from blue-green via green to yellow.

Evaluation: The test allows determination of the urine density between 1.000 and 1.030 with the following values:

1.000, 1.005, 1,010, 1.015, 1.020, 1.025, 1.030.

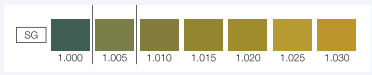
The normal value for adults with normal intake of food and liquid is from about 1.015 to 1.025; however, it can vary between 1.000 after extreme liquid intake, and 1.040 after a longer period of thirst. The density measured with test strips can vary slightly from value determined with other methods, since density increases due to glucose concentrations > 1000 mg/dL (> 56 mmol/L) are not covered. Increased protein excretion can result in density values, which are too high. Alkaline urines, with high contents of buffer substances, often show results, which are too low.

Diagnosis: In kidney diagnostics determination of the urine concentration is important for checking the function of the kidney parenchyma. If high liquid intake is excluded, a very dilute urine can indicate a substantial insufficiency of the kidneys, and also a lowered ability of the kidneys to concentrate the urine, which may result from diabetes mellitus, diabetes insipidus, hyperaldosteronism or influence of diuretic drugs.

The density of the urine yields valuable supplementary information for the evaluation of other test strip parameters, and thus helps to avoid misinterpretations, especially:

- During lysis of leukocytes and erythrocytes for interpreting possible differences with the sedimentation results
- For evaluation of the test fields for nitrite, protein and glucose

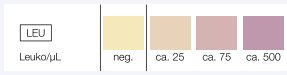
Especially in the intermediate range, between physiological and pathological results, the urine density can have a decisive role.



- Indication of the status of the kidney
- Information about the state of hydration

Medical parameters – Principle, evaluation, sources of error, diagnosis

Leukocytes



- Symptomatic of renal and urinary tract diseases

Principle: The test is based on the esterase activity of granulocytes. This enzyme splits a carboxylic acid ester. The alcohol component formed during this step reacts with a diazonium salt to form a violet dye.

Evaluation: The test detects values from about 10 leukocytes/µL urine. Discolorations, which can no longer be correlated to the negative test field, and weakly violet discolorations after 120 seconds are to be considered positive. The color fields correspond to the following leukocyte concentrations:

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

A diminished reaction can result for protein excretion above 500 mg/dL, and a glucose concentration above 2 g/dL as well as during therapy with preparations containing cephalexin or gentamycin. Bacteria, trichomonades and erythrocytes do not give a positive reaction with this test. Formaldehyde (a preservative) can cause falsely positive reactions.

Excretion of bilirubin, nitrofurantoin, or other strongly colored compounds can cover the reaction color. For samples from female patients vaginal secretion can simulate a falsely positive reaction. In order to avoid falsely positive results, the urine should only be sampled after thorough cleaning of the genitals.

Diagnosis: An increased excretion of leukocytes in urine (leukocyturia) is an important symptom for infectious diseases of the kidneys and/or urinary tract (incl. the prostate).

Leukocyturia is especially important for diagnosis of chronic pyelonephritis. Often it is the only symptom between acute attacks. Other causes for leukocyturia may be: analgetic nephropathia, glomerulopathia and intoxications, cystitis, urethritis, kidney or urogenital tuberculosis, fungus and trichomonade infections, gonorrhoea, urolithiasis, tumors with obstructions.

Ascorbic acid (Vitamin C)

- High concentrations may disturb other test fields

Modern Medi-Test urine test strips have the best available protection against influences of ascorbic acid (vitamin C) in the sample. For historic reasons, many test strips still feature a test pad for ascorbic acid.

Principle: The detection is based on the de-coloration of Tillman‘s reagent. The blue colored 2,6-dichlorophenol indophenol sodium salt is reduced to the colorless leuco form by ascorbic acid. In the presence of ascorbic acid a color change takes place from blue to red.

Evaluation: The color fields correspond to the following values:

0 (negative), 10 (+), and 20 (++) mg/dL or
0 (negative), 0.6 (+), and 1.1 (++) mmol/L.

Diagnosis: The wide spread intake of ascorbic acid (e.g. in vitamin C therapy, as a therapeutical ingredient and stabilizer of numerous medicaments, oxidation inhibitors and preservatives in food industry) causes a rapid saturation of the organism, and a renal excretion of the excess. Interfering ascorbic acid concentrations may be reached after the ingestion of fruit juice or plenty of fruit. Therefore, the ascorbic acid test zone minimizes falsely negative results. As with glucose detection, blood detection is also disturbed by low concentrations of ascorbic acid, whereas high ascorbic acid concentrations interfere with the nitrite and bilirubin test zones.

Medi-Test ordering information

Medi-Test ordering information

REF 50 strips per pack	REF 100 strips per pack	Type	with test fields for determination of											
			Glucose	Ketones	Ascorbic acid	Protein/ Albumin	Blood	Leukozytes	Nitrite	Density	pH value	Bilirubin	Urobilinogen	Creatinine
93001	93024	Glucose	■											
93025	93020	Glucose / Ketone	■	■										
93004	93027	Protein 2				■					■			
93005	93028	Ketone		■										
93006	93029	Nitrite							■					
93015	93037	Combi 2	■			■								
93007	93030	Combi 3 A®	■		■	■					■			
93009	93032	Combi 5	■		■	■	■				■			
93035	93036	Combi 5 N®	■		■	■	■		■		■			
93055	–	Combi 5 S	■	■		■	■				■			
93018	93078	Combi 6	■			■	■	■	■				■	
–	93034	Combi 6 A	■	■	■	■	■				■	■		
–	93022	Combi 7	■	■	■	■	■		■		■			
–	93021	Combi 8 L	■		■	■	■	■	■	■	■			
930879	93023	Combi 9®	■	■	■	■	■		■		■	■	■	
93079	93058	Combi 10® L	■	■	■	■	■	■	■		■	■	■	
–	93067	Combi 10® SGL	■	■		■	■	■	■	■	■	■	■	
–	93068	URYXXON® Stick 10 [1) 2)]	■	■		■	■	■	■	■	■	■	■	
930874	–	Microalbumin [2) 3)]				■								■

Further Medi-Test urine test strips

Test strips for veterinary applications													
–	930870	Combi 10® VET [4)]	■	■		■	■	■	■	■	■	■	■	

All products are CE-marked according to the directive 98/79/EC
[1)] for evaluation with reflectometer URYXXON® 500 [2)] for evaluation with reflectometer URYXXON® Relax [3)] pack of 24 test strips [4)] not an IVD product (no CE-mark)

Instruments for evaluation of urine test strips URYXXON® Stick 10	
93088	URYXXON® Relax, fast, standardized urine analysis
930080	URYXXON® 500, automated urine analysis for medium to large sample volumes
Accessories	
93038	Medi-Test Control, solution to check Medi-Test urine test strips and URYXXON® instruments
93071	Printer paper for URYXXON® 500, pack of 5 rolls
93074	Barcode scanner for URYXXON® instruments

KATEN100017 Medi-Test Broschüre en19

www.mn-net.com

MACHEREY-NAGEL

Management System EN ISO 13485:2016 ISO 9001:2015 TÜVRheinland CERTIFIED www.tuv.com ID 9000008338

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

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CH Tel.: +41 62 388 55 00 sales-ch@mn-net.com
FR Tel.: +33 388 68 22 68 sales-fr@mn-net.com
US Tel.: +1 888 321 62 24 sales-us@mn-net.com

EC Declaration of Conformity for In-vitro-diagnostics

according to directive 98/79/EC

The procedure for EC declaration established a quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2003+AC:2009.

CE

We

Name of manufacturer:	MACHEREY-NAGEL GmbH & Co. KG
Address:	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Strasse 6-8 D - 52355 Dueren Germany

confirm that the following reflectometer for professional use

Name of product	**Reference numbers**
URYXXON® 500	930 080

Type:	URINE MULTI-CONSTITUENT TEST STRIPS EDMS 11-70-02-02-00
Registration number:	DE/CA21/MACHEREY/2003/11/IVD/0005

is manufactured in compliance with the European Directive 98/79/EC.

Dueren, 2013-07-30

Dietmas Czyron

i.A. D. Czyron (QA Manager)

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, 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 2020-05-29 until 2023-05-28.

2022-05-03 (Change)

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

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

TÜVRheinland®
Precisely Right.

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, water analysis, 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 chromatography and bioanalysis
/03	c/o MACHEREY-NAGEL GmbH & Co. KG Papiermühle 50 52349 Düren Germany	Waste disposal
/04	c/o MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Storage
/05	c/o MACHEREY-NAGEL GmbH & Co. KG Monschauer Str. 64 52355 Düren Germany	Production

2022-05-03

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

TÜVRheinland®
Precisely Right.

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, gastric and vaginal 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.: 1094054 -20
Effective date: 2020-05-29
Expiry date: 2023-05-28
Issue date: 2022-02-16

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

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 also covers the following:

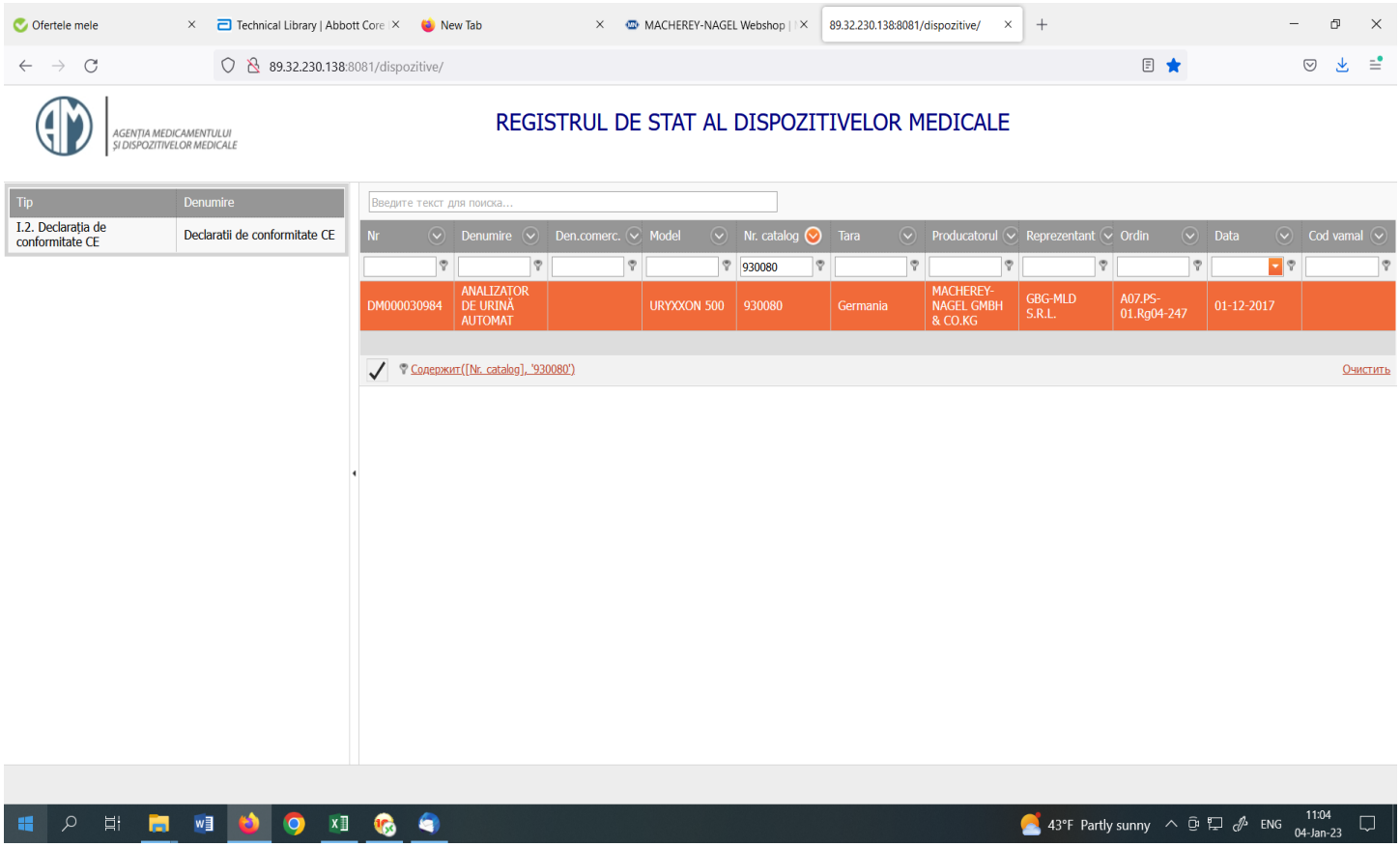
No.	Facility	Scope
/01	c/o MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany	Design and development, manufacture and distribution of in vitro diagnostic test strips including self-testing devices and reflectometers used in the field of urine, gastric and vaginal fluid analysis, as 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.: 1094054 -20
Effective date: 2020-05-29
Expiry date: 2023-05-28
Issue date: 2022-02-16

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02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MACHEREY-NAGEL Webshop
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04-Jan-23

EC Certificate

TÜVRheinland®

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

Registration No.: HL 1038121-1

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

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

Replaces Certificate, Registration No.: HL 60119814 0001

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

Report No.: 1106581-20

Effective date: 2022-02-16

Expiry date: 2025-05-26

Issue date: 2022-02-16

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

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

EC Certificate

TÜVRheinland®

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

Registration No.: HL 1038121-1

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

The scope of certification includes the following manufacturing sites:

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

Report No.: 1106581-20

Effective date: 2022-02-16

Expiry date: 2025-05-26

Issue date: 2022-02-16

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. Sven Hoffmann
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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.

Certificate of Completion

this is to certify

Mr. Alexei Legun

has successfully completed

The technical maintenance training course

On

Urine Analysis

URYXXON 200;
URYXXON RELAX;
URYXXON 500;

Mars, 2006

President
MACHEREY-NAGEL GMBH & CO.KG

Medi-Test Control

fr

Solutions de contrôle négatif et positif pour bandelettes réactives urinaires Medi-Test

LOT 25064 REF 930 38 2015-07 CONTROL IVD CE

Généralités :
Les solutions de contrôle Medi-Test Control sont destinées à la vérification du bon fonctionnement des bandelettes réactives urinaires Medi-Test et des réflectomètres pour l'analyse d'urine URYXXON® par comparaison avec les valeurs de référence (voir tableau).
Utilisation réservée au personnel compétent.

Réactifs :
Chaque emballage contient :
- 1 éprouvette contenant 15 ml de réactif Medi-Test Control N
- 1 éprouvette contenant 15 ml de réactif Medi-Test Control P

Les réactifs sont des solutions de contrôle prêtes à l'emploi de composition purement chimique. La solution N simule ici un échantillon d'urine dont les concentrations sont situées dans la plage négative ou normale. La solution P induit une réaction colorée positive (concentrations pathologiques) avec les bandelettes urinaires Medi-Test pour les paramètres suivants : sang, urobilinogène, bilirubine, protéines, nitrite, corps cétoniques, glucose et leucocytes.

Conservation et stabilité :
Les réactifs Medi-Test Control N et P non entamés doivent être conservés à l'abri de la lumière, entre 2 et 8 °C. Ne les congeler en aucun cas.
Dans la mesure où les consignes énoncées sont respectées, ils se conservent jusqu'à la date de péremption imprimée sur l'emballage. Après ouverture, chaque réactif est utilisable pendant 3 mois mais tout au plus pour 20 contrôles de bandelettes.
D'éventuelles précipitations dans les réactifs n'influencent pas le résultat des mesures. Si les solutions ont été contaminées de quelque manière que ce soit, ne plus les utiliser. Les solutions peuvent être jetées dans les canalisations en veillant à laisser couler beaucoup d'eau du robinet.

Mode d'emploi :
Retirer les éprouvettes contenant les solutions Medi-Test Control P et N du réfrigérateur et attendre qu'elles aient pris la température de la pièce. Les agiter bien à obtenir un mélange homogène, en évitant toutefois la formation de mousse.
Oter ensuite le bouchon des éprouvettes. Ne versez pas les solutions dans un autre récipient. Effectuer des mesures directement dans le éprouvette. Prélever le nombre de bandelettes réactives urinaires nécessaire de la boîte. Refermer la boîte immédiatement après. Eviter de toucher les zones de test avec les doigts.
Plonger la bandelette réactive pendant env. 1 seconde dans la solution respective en veillant à ce que toutes les zones de test soient dans le liquide. Eliminer l'excédent de liquide en tamponnant brièvement la tranche de la bandelette réactive sur du papier absorbant. Introduire la languette réactive dans l'appareil conformément au mode d'emploi des réflectomètres URYXXON® 300/500 et URYXXON® Relax. Attendre l'achèvement de l'évaluation et l'impression des résultats.
En cas d'évaluation visuelle, comparer les couleurs de réaction avec l'échelle colorimétrique après 30-60 secondes (1-2 minutes pour les leucocytes). Le temps de lecture idéal du résultat est après 1 minute. Les changements de couleur qui se produisent au-delà de 2 minutes sont sans importance.
L'évaluation visuelle des bandelettes réactives urinaires doit s'effectuer à la lumière du jour, en évitant l'exposition directe au soleil.
La zone réactive correspondant à l'urobilinogène est susceptible de prendre une teinte plus rouge orangé que l'échelle colorimétrique.
Refermer immédiatement les réactifs après l'achèvement des contrôles et lorsqu'ils ne sont pas utilisés. Les conserver entre 2 et 8 °C.

Remarques :
Se référer également au mode d'emploi des réflectomètres URYXXON®. Ne pas avaler ! Eviter tout contact avec la peau et les yeux !
Conserver hors de la portée des enfants.

Rev. 2014-05

Symboles :

LOT		REF	2°C 8°C	IVD	CE	
Numéro de lot	Date de péremption	Référence	Température de conservation (2 à 8 °C)	Diagnostic *in vitro*	Déclaration de conformité (produit conforme à la directive 98/79/CEE – dispositifs de DIV)	Lire le mode d'emploi

Valeurs de référence :
Les plages figurant dans le tableau suivant ont été déterminées avec plusieurs lots de bandelettes réactives Medi-Test Combi 10® SGL et URYXXON® Stick 10, et avec différents réflectomètres URYXXON®. Il est recommandé à chaque laboratoire de n'utiliser les valeurs fournies qu'à titre indicatif et d'établir ses propres paramètres de précision.

Analyte	Medi-Test Combi 10® SGL, visuel		URYXXON® Stick 10 avec URYXXON® 300 / URYXXON® 500 / URYXXON® Relax	
	Control N	Control P	Control N	Control P
Sang	Négatif	10-250 hématies/µl	Négatif	10-250 Ery/µl
Urobilinogène	Normal	Normal (0.2) - 12 mg/dL[1] (norm-200 µmol/L)	Normal (0.2 mg/dL)	Normal (0.2) -12 mg/dL[1] (norm-200 µmol/L)
Bilirubine	Négatif	1-4 mg/dl (1+-3+)	Négatif	1-6 mg/dL (1+-3+)
Protéines	Négatif	100-500 mg/dL	Négatif	25-500 mg/dL
Nitrite	Négatif	Positif	Négatif	Positif
Corps cétoniques	Négatif	25-300 mg/dL (1+-3+) (2.5-30 mmol/L)	Négatif	5-300 mg/dL (1+-3+) (0.5-30 mmol/L)
Glucose	Négatif-normal	500-≥1000 mg/dL (27.8-55.5 mmol/L)	Négatif-normal	50-1000 mg/dL (2.8-60 mmol/L)
pH	5-7	6-9	5-7	6-9
Densité	1.010-1.030	1.005-1.025	1.010-1.030	1.005-1.025
Leucocytes	Négatif	25-500 leucocytes/µl	Négatif	15-500 leucocytes/µl

[1] La zone réactive correspondant à l'urobilinogène vire plus au brun par rapport à l'échelle colorimétrique.

MACHEREY-NAGEL GmbH & Co. KG · Neumann-Neander-Str. 6-8 · 52355 Düren (Allemagne) · Tél. +49 (0) 24 21 96 90 · Fax +49 (0) 24 21 96 91 99
E-mail : sales-de@mn-net.com · www.mn-net.com

Certificate

Specialized Waste Management Company

Certificate Registration No.: 01 400 0114 (Certificate for Decoration)

On 2022-03-11 TÜV Rheinland Cert GmbH carried out a voluntary inspection on the premises of

MACHEREY-NAGEL
GmbH & Co. KG
Valencienner Straße 11
D- 52355 Düren

as part of a repeat audit with regard to the criteria contained in the Ordinance on Specialized Waste Management Companies (EfbV) on the basis of Art. 56 and 57 KrWG.

This Certificate is valid for

Site
Papiermühle 50 ♦ D- 52349 Düren
(Waste producer number: **E35828749**, waste management number: **E35837000**)

and covers the storage, treatment and disposal of waste Code no. 16 05 06*, 16 05 07* and 16 05 08* as stated in annex 1 of the official certificate according to annex 3 of EfbV.

Evidence was provided in Audit Report No. 37189536 that the above conditions have been met.

According to Art. 22 EfbV this Certificate **is valid until 2023-08-31**. The next audit (at least one audit per year as specified in Art. 22 EfbV) **will be conducted until 2023-02-28. This Certificate is valid only in connection with the official certificate dated from 2022-07-13 according to annex 3 of EfbV.**

Cologne, 2022-07-13

TÜV Rheinland Cert GmbH
EfbV- Certification Body
Christoph Schmieder

EfbV- Expert
Thomas Nitsche

www.tuv.com

TÜVRheinland®
Precisely Right.

EC Declaration of Conformity

EC Declaration of Conformity for In-vitro Diagnostic Products

The procedure for EC declaration of conformity was established on the basis of a full quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2012+AC:2012 according to the IVD directive 98/79/EC Annex IV, except chapters 4 and 6.

CE

We

Name of manufacturer	MACHEREY-NAGEL GmbH & Co. KG
Address:	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Strasse 6-8 D - 52355 Dueren Germany

confirm that the following test strips for professional use

Name of product	**Reference numbers**
Medi-Test Glucose PN	93017; 930965
Medi-Test Glucose	93001; 93024
Medi-Test Glucose 3	93003; 93026
Medi-Test Glucose/Keton	93020; 93025
Medi-Test Protein 2	93004; 93027
Medi-Test Keton	93005; 93028
Medi-Test Nitrit	93006; 93029
Medi-Test Combi 2	93015; 93037
Medi-Test Urbi	93012
Medi-Test Combi 3	93050
Medi-Test Combi 3A	93007; 93030
Medi-Test Combi 5	93009; 93032
Medi-Test Combi 5N	93035; 93036
Medi-Test Combi 5S	93055
Medi-Test Combi 6	93018; 93078
Medi-Test Combi 6A	93013; 93034
Medi-Test Combi 7	93010; 93022
Medi-Test Combi 7L	93031
Medi-Test Combi 8L	93021
Medi-Test Combi 9	93011; 93023
Medi-Test Combi 10	93056
Medi-Test Combi 10L	93058; 93079
Medi-Test Combi 10 SGL	93067; 93077
Medi-Test URYXXON Stick 10	93068; 930872
Medi-Test Combi 11	93060; 930871
Medi-Test Mikroalbumin	930874

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Tel.: +33 388 68 22 68
Fax: +33 388 51 76 88
E-mail: sales-fr@mn-net.com

US:
Tel.: +1 484 821 0984
Fax: +1 484 821 1272
E-mail: sales-us@mn-net.com

Type:	Urine Multi-constituent Test Strips EDMS 11-70-02-02-00
Registration number:	DE/CA21/MACHEREY/2002/06/IVD/0001
Notified body:	TÜV Rheinland LGA Products GmbH Tillystr. 2, 90431 Nürnberg

are manufactured in compliance with the European Directive 98/79/EC. The manufacturer is exclusively responsibility for the declaration of conformity.

Düren, 22.09.2017

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

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Fax: +1 484 821 1272
E-mail: sales-us@mn-net.com

EC Declaration of Conformity

The procedure for EC declaration was established according to the IVD directive 98/79/EC on the basis of a full quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2012+AC:2012.

CE

We

Name of manufacturer	MACHEREY-NAGEL GmbH & Co. KG
Address:	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Strasse 6-8 D - 52355 Dueren Germany

confirm that the following product for professional use

Name of product	Medi-Test Control
Reference number, REF	930 38
Type:	Other calibrators and standards (CC) EDMS 11-50-03-90-00
Registration number:	DE/CA21/MACHEREY/2002/11/IVD/0007

is manufactured in compliance with the European Directive 98/79/EC.

Dueren, 12.02.2014

i.A. Markus Meusel (QA Manager)

MACHEREY-NAGEL

EC DECLARATION OF CONFORMITY

according to Annex III of the IVD Directive 98/79/EC

EG Konformitätserklärung

gemäß Anhang III der IVD Richtlinie 98/79/EG

We hereby declare that the in vitro diagnostic medical device (IVD)

Hiermit erklären wir, dass das In-vitro-Diagnostikum (IVD)

URYXXON® 500
REF 930 080

URYXXON® 500
REF 930 080

GMDN Code: CT943 Instrument/analyser IVDs
EDMA IVD Classification: 21 05 Urine Analyser

GMDN Code: CT943 Instrumente/Analysatoren, IVD
EDMA IVD Klassifizierung: 21 05 Urin Analysegerät

is classified as ***all other IVD*** according to Annex II of the European directive 98/79/EC on in vitro diagnostic medical devices (IVDD)

gemäß Anhang II der Europäischen Richtlinie 98/79/EG über In-vitro-Diagnostika als ***sonstiges IVD*** klassifiziert ist

and complies with the essential requirements (Annex I) of the IVD Directive 98/79/EC.

und die Grundlegenden Anforderungen (Anhang I) der IVD Richtlinie 98/79/EG erfüllt.

In addition, it meets the requirements according to the following directive

Darüberhinaus erfüllt es die Anforderungen gemäß der folgenden Richtlinie

European directive 2011/65/EU on the restriction of the use of certain hazardous sub-stances in electrical and electronic equipment (RoHS 2)

Europäische Richtlinie 2011/65/EU zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (RoHS 2)

applied harmonized standards

angewandte Harmonisierte Normen

DIN EN ISO 9001:2008
DIN EN ISO 13485:2012 + AC:2012
DIN EN ISO 14971:2012

DIN EN ISO 18113-1:2010
DIN EN ISO 18113-3:2010
DIN EN 13612:2002
DIN EN 980:2008

DIN EN ISO 15223-1:2013
DIN EN 62366:2008
DIN EN 62304:2006

DIN EN 61010-1:2010

DIN EN 61010-2-101:2003-09

DIN EN 61326-1:2013

Düren, 12 September 2016

ppa.

Quality-management representative (authorized representative)

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MACHEREY-NAGEL

EC DECLARATION OF CONFORMITY

according to Annex III of the IVD Directive 98/79/EC

EG Konformitätserklärung

gemäß Anhang III der IVD Richtlinie 98/79/EG

We hereby declare that the in vitro diagnostic medical device (IVD)

URYXXON® Relax
REF 930 88

GMDN Code: CT943 Instrument/analyser IVDs
EDMA IVD Classification: 21 05 Urine Analyser

is classified as ***all other IVD*** according to Annex II of the European directive 98/79/EC on in vitro diagnostic medical devices (IVDD)

and complies with the essential requirements (Annex I) of the IVD Directive 98/79/EC.

In addition, it meets the requirements according to the following directive

European directive 2011/65/EU on the restriction of the use of certain hazardous sub-stances in electrical and electronic equipment (RoHS 2)

Hiermit erklären wir, dass das In-vitro-Diagnostikum (IVD)

URYXXON® Relax
REF 930 88

GMDN Code: CT943 Instrumente/Analysatoren, IVD
EDMA IVD Klassifizierung: 21 05 Urin Analysegerät

gemäß Anhang II der Europäischen Richtlinie 98/79/EG über In-vitro-Diagnostika als ***sonstiges IVD*** klassifiziert ist

und die Grundlegenden Anforderungen (Anhang I) der IVD Richtlinie 98/79/EG erfüllt.

Darüberhinaus erfüllt es die Anforderungen gemäß der folgenden Richtlinie

Europäische Richtlinie 2011/65/EU zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (RoHS 2)

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DIN EN 61010-1:2010

DIN EN 61010-2-101:2003-09

DIN EN 61326-1:2013

Düren, 12 September 2016

Quality management representative (authorized representative)

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