en Instructions for use Medi-Test urine test strips

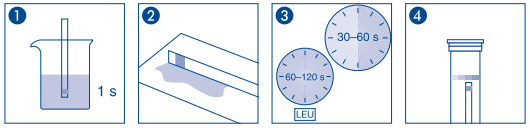
Intended purpose

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 disorders.

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)