en Instructions for use Medi-Test urine test strips

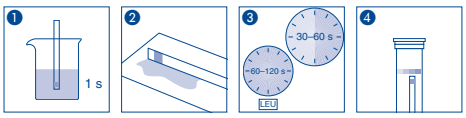
CE IVD

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 colour reaction with the colour 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 point-of-care use outside of a laboratory. They are not suitable for self-testing.

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

Instructions for use



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. In the case of reflectometric analysis, the test strip must be placed according to the instructions for use of the device immediately after excess urine has been dabbed off.
3. Wait for a reaction time of 30 – 60 seconds (leukocyte test field 60 – 120 seconds).
4. Compare reaction colour(s) with the colour scale and read corresponding value(s).

Notes

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

Use only clean containers for urine collection which are free of residues.

Substances which cause abnormal urine colouration 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 colour vision must be assisted by a person with normal colour vision for the colour 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 (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 colour 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 discolourations of the test field. Any green colouration should be interpreted as a positive finding. The colour comparison fields correspond to the following concentrations:

0 (negative) · approx. 5 – 10 · approx. 50 · approx. 250 ery/µL or an amount of haemoglobin from 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. False-positive reactions can be caused by residues of cleaning agents which contain peroxide or other cleaning agents, as well as menstrual blood. In the case of Combi 11, ascorbic acid concentrations > 2.5 mg/dL lead to false-negative results.

In a comparison study with a reference method, a direct correspondence of 88 % was determined.

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 colour 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 colour 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 (> 30 mg/dL). 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. Nitrite concentrations > 2.5 mg/dL lead to lower values/a false-negative reaction.

In a comparison study with a reference method, a direct correspondence of 71 % was determined.

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 colour 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 (> 10 mg/dL) and nitrite (> 2.5 mg/dL). Prolonged exposure of the urine to light can lead to false-negative values. Excreted dyes (e.g. betanin) and medications (e.g. phenazopyridine) can simulate a positive result, as well as urine indican at a concentration of > 10 mg/dL.

In a comparison study with a reference method, a direct correspondence of 94 % was determined.

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 colour 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 discolouration should be interpreted as a positive finding. The colour 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) or disinfectant residues (e.g. benzalkonium chloride > 12.5 mg/dL) in the urine container.

In a comparison study with a reference method, a direct correspondence of 96 % was determined.

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-coloured azo dye. The test detects values starting at 0.025 mg nitrite/dL urine. A pink colour suggests a bacterial urinary tract infection. The colour 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 colour comparison fields correspond to the following evaluations:

negative · positive

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

False-negative results can occur through ascorbic acid concentrations > 10 mg/dL, 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 colour can be caused by dyes (e.g. betanin) excreted in the urine.

In a comparison study with a reference method, a direct correspondence of 98 % was determined.

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 colour 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 colour suggests a positive finding. The colour 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 lead to false-positive results at concentrations > 75 mg/dL.

In a comparison study with a reference method, a direct correspondence of 100 % was determined.

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 test detects values starting from 5 mg ascorbic acid/dL urine.

The detection is based on the decolouration of Tilman's reagent. The presence of ascorbic acid is indicated by a colour change from blue to red. The colour 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 colour 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 colour 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.

In a comparison study with a reference method, a direct correspondence of 92 % was determined.

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 colours (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 colour comparison fields correspond to the following pH values:

5 · 6 · 7 · 8 · 9

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

In a comparison study with a reference method, a direct correspondence of 84 % was determined.

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 with a good correlation to the refractometer method. Detection takes place through an acid ion exchanger and a pH indicator. The colour 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 colour 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.

In a comparison study with a reference method, a correspondence within ±1 scale value of 86 % was determined.

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. Discolourations which can no longer be allocated to the negative comparison field and weak purple discolourations after 120 seconds must be assessed as positive. The colour 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 cephalexin (> 75 mg/dL) or nitrofurantoin (> 2 mg/dL) are taken. Formaldehyde (as a preservative) can lead to a false-positive reaction starting at 30 mg/dL. In the case of specimens from female patients, a false-positive reaction can be simulated by vaginal discharge.

In a comparison study with a reference method, a direct correspondence of 89 % was determined.

* (quantity/cm² after impregnation)

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 in the member state in which the incident occurred. European vigilance contact points: http://ec.europa. eu/growth/sectors/medical-devices/contacts_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, 9th edition, 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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Explanation of symbols

CE Declaration of Conformity

Please read instructions for use!

IVD *In vitro* diagnostic medical device

Manufacturer

REF Item number

Keep away from sunlight

LOT Batch identification

Store in a dry place

Use by

Contains sufficient for <n> tests

Do not reuse

Permitted storage temperature range

Revision: 2022-08

Product overview

The type and combination of the parameters of individual products are listed in the following table.

Name	REF	Contents	BLO	URO	BIL	PRO	NIT	KET	ASC	GLU	pH	SG	LEU
Keton	93005 / 93028	50 / 100						•					
Nitrit	93006 / 93029	50 / 100					•						
Combi 2	93015 / 93037	50 / 100				•				•			
Glucose/Keton	93025 / 93020	50 / 100						•		•			
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 7L	93031	100	•			•	•	•		•	•		•
Combi 8L	93021	100	•			•	•		•	•	•	•	•
Combi 9	930879 / 93023	50 / 100	•	•	•	•	•	•	•	•	•		
Combi 10	93056	100	•	•	•	•	•	•	•	•	•	•	
Combi 10L	93079 / 93058	50 / 100	•	•	•	•	•	•	•	•	•		•
Combi 10SGL	93067	100	•	•	•	•	•	•		•	•	•	•
Combi 11[1) 3)]	93060 / 930871	100 / 125	•	•	•	•	•	•	•	•	•	•	•
URYXXON® Stick 10[2) 3)]	93068 / 930872	100 / 125	•	•	•	•	•	•		•	•	•	•

1) Suitable for analysis on the URYXXON® Relax 2) Suitable for analysis on the URYXXON® 500 and URYXXON® Relax
3) Performance data can be found in the technical manual

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