

Test strips for rapid determination of blood, urobilinogen, bilirubin, protein, nitrite, ketones, glucose, pH-value, density and leukocytes in urine

Use

Screening test for detection of diabetes, metabolic abnormalities, liver diseases, biliary and hepatic obstructions, hemolytic diseases and diseases of kidney and urinary tract. Only for use by qualified personnel.

Instructions for use

Dip the test strip for approximately 1 second into the fresh urine. Draw it across the rim of the container to remove excess urine. After 30 to 60 seconds (leukocyte test field after 60–120 seconds) compare the test strip with the color scale. The best time for comparison is after 30 seconds. Color changes that take place after more than 2 minutes are of no significance. When tested the urine should not be older than 2 hours.

Principle

Blood: 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.

Urobilinogen: The test paper contains a stable diazonium salt forming a reddish azo compound with urobilinogen.

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

Protein: 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.

Nitrite: Microorganisms, which are able to reduce nitrate to nitrite, are indicated indirectly by this test. The principle of Griess reagent is the basis of this test. The test paper contains an amine and a coupling component. A red colored azo compound is formed by diazotisation and subsequent coupling.

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

Glucose: The detection is based on the glucoseoxidase-peroxidase-chromogen reaction. Apart from glucose, no other compound in urine is known to give a positive reaction.

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

Density: The test determines the concentration of ions in urine and shows a good correlation to the refractometrical method. The color of the test strip changes from deep blue in urine with low ionic concentration through green to yellow in urines with high ionic concentrations.

Leukocytes: The test is based on the esterase activity of granulocytes. This enzyme splits carboxylic acid ester. The alcohol constituent released reacts with a diazo salt producing a violet color.

Evaluation – Sources of Error

Blood: The minimum sensitivity of the test strip is 5 erythrocytes/μL urine corresponding to approx. 0.015 mg hemoglobin/dL urine. Intact erythrocytes are indicated by flecky discolorations of the test field. The color fields correspond to the following values:

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

Normal concentrations of ascorbic acid (< 40 mg/dL) do not influence the test results. Falsely positive reactions can be produced by a residue of peroxide containing cleansing agents.

Urobilinogen: In dependence upon the urine color 0.5 to 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 indicated by the strips. The color fields correspond to the following urobilinogen concentrations:

norm. (normal), 2, 4, 8, 12 mg/dL or norm. (normal), 35, 70, 140, 200 μmol/L

The test will be inhibited by higher concentrations of formaldehyde. Exposure of the urine to light for a longer period of time may lead to lowered or falsely negative results. Too high 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.

Bilirubin: The minimum sensitivity of the test strip is 0.5 to 0.75 mg bilirubin/dL urine. 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 contents can produce a yellow coloration of the test strip. Ascorbic acid and nitrite in higher concentrations inhibit the test. Exposure of the urine to light for a longer period of time may lead to lowered or falsely negative results. Too high or falsely positive results can be caused by the presence of diagnostic or therapeutic dyes in the urine.

Protein: The minimum sensitivity of the test strip is 10 mg protein/dL urine. The color fields correspond to the following ranges of albumin concentrations:

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

Falsely positive results are possible in 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.

Nitrite: The test detects concentrations from 0.05 mg nitrite/dL urine. Every pink color indicates a bacterial infection of the urinary tract. The color intensity depends only on the nitrite concentration, but does 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.

Ketones: The test is more sensitive to acetoacetic acid than to acetone. Values of 5 mg/dL acetoacetic acid or 50 mg/dL acetone are indicated. The color fields correspond to the following acetoacetic acid values:

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

Phenylketones in higher concentrations interfere with the test, and will produce variable colors.

β-Hydroxybutyric acid is not detected. Phthalein compounds interfere by producing a red coloration.

Glucose: 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. The color fields correspond to the following ranges of glucose concentrations:

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

The influence of ascorbic acid (vitamin C) has been largely eliminated. An inhibitory effect is produced by gentisic acid. Falsely positive reactions can be produced by a residue of peroxide containing cleansing agents.

pH: The pH value of fresh urine of healthy people varies between pH 5 and pH 6. The color scale gives a clear distinction of pH value between pH 5 and pH 9.

Density: The test permits the determination of urine density between 1.000 and 1.030. Urines from adults with normal diets and normal fluid intake will have a density of 1.015–1.025.

The chemical nature of the test strip may cause slightly different results from those obtained with other methods when elevated amounts of certain urine constituents are present, e.g. the increase of urine density in dependence on glucose concentrations of > 1000 mg/dL (> 56 mmol/L) cannot be demonstrated by the strips. Elevated density readings may be obtained in the presence of moderate quantities of protein. Highly buffered alkaline urines may cause low readings.

Leukocytes: The test records values starting from approx. 10 leukocytes/μL urine. Changes in color that can not be assigned to the negative reference field and faint violet colors after 120 seconds must be evaluated as positive. The color reference fields correspond to the following leukocyte concentrations:

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

A weakened reaction can be expected in the case of proteinuria of over 500 mg/dL and a glucose concentration of over 2 g/dL as well as in the case of patients taking preparations containing cephalixin and gentamycin. Bacteria, trichomonads and erythrocytes do not react with this test. Formaldehyde (as a preservative) can result in a false positive reaction. Boric acid used as preservative decreases the sensitivity of the reaction. Excretion of bilirubin, nitrofruantoin or other strongly-colored compounds may disguise the color of the reaction. Tests with female patients have shown that vaginal discharge can cause a false positive reaction.

Quality Control in professional use

The performance of the test strips should be confirmed by use of positive and negative control solutions. Positive and negative controls should be analyzed once a day, whenever a new bottle of strips is opened, 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.

Reacting substances

(Quantity resp. activity/cm² at time of impregnation)

Blood: tetramethylbenzidine cumene hydroperoxide	31 μg 315 μg	Nitrite: sulfanilic acid quinoline derivative	95 μg 37 μg	pH: methyl red bromothymol blue	3 μg 10 μg
Urobilinogen: diazonium salt	75 μg	Ketones: sodium nitroprusside	180 μg	Density: bromothymol blue copolymer	42 μg 1048 μg
Bilirubin: diazonium salt	29 μg	Glucose: glucose oxidase peroxidase	7 U 1 U	Leukocytes: carboxylic acid ester diazonium salt	16 μg 14 μg
Protein: tetrabromophenol blue	10 μg	tetramethylbenzidine	96 μg		

Directions

In any case, in order to establish a final diagnosis and prescribe an appropriate therapy, the results obtained with test strips should be verified with other medical results.

The effect of medicaments or their metabolic products on the test is not known in all cases. In case of doubt it is recommended not to take the medicaments and then repeat the test.

Only use well washed and clean vessels for urine collection. The presence of usual urine preservatives will not affect the test results.

Remove only as many test strips as are required, and reseal the container immediately after use. Do not touch the test pads. Avoid exposing the strips to sunlight and moisture. Store the container below + 30 °C in a dry place. The test strips are stable, when stored properly up to the date of expiry indicated.


The caps contain a non-poisonous and harmless desiccant. In case this desiccant is swallowed accidentally, then drink plenty of water.

Explanation of symbols can be found in the package insert.


Disposal: Please dispose all used test strips in accordance with your local laws and regulations.

Package units: Tubes of 50 and 100 test strips


Date of change: 06/2014




Verwendbar bis / Use by / Fecha de caducidad / À utiliser avant




Chargencode / Batch identification / Código de lote / Numéro de lot



In-vitro-Diagnostikum / In vitro diagnostics product / Diagnóstico in vitro / Diagnostic in vitro




Diese Teststreifen entsprechen der Richtlinie 98/79/EG vom 27.10.1998 (IVD-Richtlinie) / These test strips conform to the directive 98/79/EG dated 27.10.1998 (IVD-directive) / Las tiras reactivas corresponden a la norma 98/79/EG del 27.10.1998 (IVD-norma) / Les bandelettes correspondent à la directive 98/79/EG du 27.10.1998 (IVD-directive)




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Hersteller / Manufacturer / Fabricante / Fabricant




Artikelnummer / Item number / Referencia / Référence produit




Gebrauchsanweisung beachten / Please read instructions for use! / Observe the instructions de uso. / Respecter les instructions d'utilisation



Temperaturbegrenzung / Permitted storage temperature range / Limites de temperatura / Limites de température



Nicht wiederverwenden / Do not reuse / Producto de un solo uso / Ne pas réutiliser



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