In-vitro-Diagnostikum

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Medi-Test Combi 10®L

Test strips for rapid determination of blood, urobilinogen, bilirubin, protein, nitrite, ketones, ascorbic acid, glucose, pH-value 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 colour scale. The best time for comparison is after 30 seconds. Colour 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 colour.

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 colour 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 coloured 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 coloured complex.

Ascorbic acid: The detection is based on the decolouration of Tillmans reagent. In the presence of ascorbic acid a colour change takes place from blue to red.

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 colour between pH 5 and pH 9 (from orange togreen to turquoise).

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 colour.

Evaluation – Sources of Error

Blood: The minimum sensitivity of the test strip is 5 to 10 erythrocytes/µL urine corresponding to approx. 0.015 mg hemoglobin/dL urine. Intact erythrocytes are indicated by flecky discolourations of the test field. The colour 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 colour 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 colour 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 colouration.

Bilirubin: The minimum sensitivity of the test strip is 0.5 to 1 mg bilirubin/dL urine. The colour 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 colouration 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 colour 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 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 colouration may be masked by the presence of medical dyes (e.g. methylene blue) or beetroot pigments.

Nitrite: The test detects concentrations from 0.05 to 0.1 mg nitrite/dL urine. Every pink colour indicates a bacterial infection of the urinary tract. The colour 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 urin 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 10 mg/dL acetoacetic acid or 50 mg/dL acetone are indicated. The colour 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 variable colours.
β-Hydroxybutyric acid is not detected. Phthalein compounds interfere by producing a red colouration.

Ascorbic acid: The colour fields correspond to the following values:

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

Only for information!

Glucose: Pathological glucose concentrations are indicated by a colour change from green to bluish green. Yellow or greenish test fields should be considered negative or normal. The colour fields correspond to the following ranges of glucose concentrations:

neg. (yellow), neg. or normal (greenish), 50, 150, 500 and ≥ 1000 mg/dL or
neg. (yellow), neg. or normal (greenish), 2.8, 8.3, 27.8 and ≥ 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 colour scale gives a clear distinction of pH value between pH 5 and pH 9.

Leukocytes: The test records values starting from approx. 10-25 leukocytes/µL urine. Changes in colour that can not be assigned to the negative reference field and faint violet colours after 120 seconds must be evaluated as positive. The colour 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 cephalexin and gentamycin. Bacteria, trichomonads and erythrocytes do not react with this test. Formaldehyde (as a preservative) can result in a false positive reaction. Excretion of bilirubin, nitrofruantoin or other strongly-coloured compounds may disguise the colour of the reaction. Tests with female patients have shown that vaginal discharge can cause a false positive reaction.

Reactive ingredients

(minimum quantity resp. activity/cm^2 at time of expiry)

Blood:		**Nitrite:**		**Glucose:**	
tetramethylbenzidine	59 µg	sulfanilic acid	80 µg	glucose oxidase	3.2 U
cumene hydroperoxide	253 µg	quinoline derivative	25 µg	peroxidase	0.2 U
				tetramethylbenzidine	70 µg
Urobilinogen:					
diazonium salt	28 µg	**Ketones:**		**pH:**	
		sodium nitroprusside	116 µg	methyl red	2.8 µg
Bilirubin:				bromothymol blue	10 µg
diazonium salt	26 µg				
Protein:		**Ascorbic acid:**		**Leukocytes:**	
tetrabromophenol blue	7.5 µg	2,6-dichlorophenolindophenol	7.5 µg	carboxylic acid ester	10.6 µg
				diazonium salt	4.4 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 accidently, then drink plenty of water.
Explanation of symbols can be found in the package insert.
Disposal: Please dispose all used dipsticks in accordance with your local laws and regulations.
Package units: Tubes of 50 and 100 dipsticks
Date of change: 12/2010

A029689 / P 120/5

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