

Test strips for rapid determination of blood, protein, ascorbic acid, glucose and pH-value in urine

Use

Screening test for early detection and supervision of diabetes and for detecting diseases of the kidneys and urinary tract.
Only for use by authorized persons.

Instructions for use

Dip the reagent 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 compare the test strip with the colour scale. Colour changes that take place after more than 2 minutes are of no significance. The urine should not be more than 2 hours old when tested.

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.

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.

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 to green to turquoise).

Evaluation – Sources of Error

Blood: The minimum sensitivity of the test strip is 5 to 10 erythrocytes/ μ L 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/ μ L resp.
 hemoglobin concentration out of ca. 10, ca. 50, ca. 250 Ery/ μ L

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.

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.

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

0 (negative), 10(+) and 20(++) mg/dL 0 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 \geq 1000 mg/dL or

neg. (yellow), neg. or normal (greenish), 2.8, 8.3, 27.8 and \geq 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.

Reactive ingredients

(minimum quantity resp. activity/cm² at time of expiry)

Blood:		Glucose:	
tetramethylbenzidine	59 μ g	glucose oxidase	3.2 U
cumene hydroperoxide	253 μ g	peroxidase	0.2 U
Protein:		o-tolidine	65 μ g
tetrabromophenol blue	7.5 μ g	pH:	
Ascorbinsäure:		methyl red	2.8 μ g
2,6-dichlorophenolindophenol	7.5 μ g	bromothymol blue	10 μ g

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 paper. 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. Should this desiccant be swallowed, 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

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