For In-Vitro Diagnostic Use

Urine test strip for the qualitative and quantitative determination of ascorbic acid, bilirubin, blood, glucose, ketones, leukocytosis, nitrile, pH-value, protein, specific gravity and urobilinogen. Refer to the carton and label for specific parameter combination on the product you are using.

Intended Use

For use as a preliminary screening test for diabetes, liver diseases, haemolytic diseases, urogenital and kidney disorders and metabolic abnormalities.

Procedure and Notes

• Use mixed, well-rinsed, non-centrifuged urine without preservatives.
• Ensure that urine is free of ketones. Detectable concentrations of ketones can originate from physiological stress (fasting, strenuous exercise, diabetes mellitus) or pathophysiologically (e.g. cancer, sepsis, alcoholism).
• The detection is based on the color reaction (acetone) and does not provide information on the origin of ketones.
• Immediately after removing the required number of strips, close the container securely using the original cap.
• Store diagnostic test strips protected from direct sunlight and humidity. Store the tubes in a cool and dry place.
• Do not use discolored urine test strips.
• Do not reuse.
• Do not test too thick urine samples.
• Do not touch test areas of the reagent strip.
• Do not use discolored urine test strips.
• Do not interpret results in urine samples containing formaldehyde. The presence of formaldehyde may lead to lower negative results. Repeat the test one day after the last vitamin C intake.

Clinical Utility, Test Principles, Expected Values, Limitations

Ascorbic Acid: - Intended to measure the level of ascorbic acid (vitamin C) in urine. Ascorbic acid in higher quantities may cause interferences especially with the glucose test.
• Use only well mixed, non-centrifuged urine, which should not be stored for more than 4 hours. First morning urine is recommended.
• Values of at least 5 – 10 mg/dl (0.6 – 1.1 mmol/l) acetone are indicated.

Bilirubin: - Intended to measure the levels of bilirubin conjugates in urine. Measurements of urinary bilirubin and its conjugates are used in the diagnosis and treatment of certain liver and bile diseases. A red azo compound is obtained in the presence of acetic acid by coupling of bilirubin with a diazotized salt. Normally, no bilirubin is detectable in urine. Conditions such as bile leak, intravascular hemolysis, cirrhosis or liver disease may increase bilirubin concentrations in the urine.
• Values of at least 0.05 – 0.1 mg/dl (6.5 – 13 µmol/l) bilirubin are indicated.

Glucose: - Intended to identify proteins in urine. Identification of urinary protein is used in the diagnosis and treatment of kidney diseases. The test is based on the "protein error" principle of the indicator. The test is especially sensitive in the first 30 minutes after voiding the sample. Other proteins may be also detected in the urine of healthy subjects. Falsely positive results are possible in highly alkaline urine samples (pH > 7.0) and in the presence of high specific gravity, after infusions with polyvinylpyrrolidone (blood substitute), after intake of medications containing quinine and also by digestant residues containing quaternary ammonium groups in the urine sampling vessel. The color fields correspond to the following ranges of albumin concentrations:
• Negative, 15 (trace), 30, 100 and 500 mg/dl or negative, 0.15 (trace), 0.3, 1.0 and 5.0 mg/l. Values of approx. 15 mg/l Albumin are indicated.

Reagent Composition in the Tests

Ascorbic acid: 2.6-dichlorophenolindophenol 0.7% Bilirubin: diazotum sodium salt 3.1% Tetraphenylboron-2-methoxy-4-hydroxy 2.0%; isopropylbenzeno-hydroperoxide 21.0% Glucose: glucose oxidase 2.1%; peroxidase 0.9%; o-tolidine-hydrochloride 5.0% Ketones: sodium nitroprusside 2.0% Leucocytes: carboxylic acid ester 0.4%; diazotum sodium salt 0.2% Nitrite: tetrahydrodiazotium-3-(5-chloro-1-phenylazo)-6-sulfonic acid 1.9% pH: methyl red 2.0%; bromthymol blue 10.0% Protein: tetrabromophenol blue 2.0% Specific Gravity: bromphenol blue 2.8% Urobilinogen: diazotum sodium salt 3.8%

Storage and Stability

Keep diagnostic test strips protected from direct sunlight and humidity. Store the tubes in a cool and dry place (storage temperature 2..30°C). Under proper conditions test strips are stable until the stated expiry date.

Notes

• 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 medications or their metabolic products on the test is not known in all cases. In case of doubt it is recommended to perform the test in duplicate and repeat the test. However, stopping taking the drugs may not only be done after respective instruction of the doctor.
• Due to the fact that the content of the urine is not constant (e.g. content of activators or inhibitors which may vary from sample to sample, changing ion concentration), the conditions of the reaction are not always the same and the results are not always comparable. For this reason the normal values are only a rough indication.
• For retroreflectometric reading, please read carefully the detailed instructions for use of the instruments. As a result of the differing spectral sensitivities of the human eye and the optical system of the instruments, it is always possible to obtain precise agreement between the values obtained by visual reading and those obtained in the instrument.
• Do not use discolored urine test strips.
• The material safety data sheet contains further safety-related information. It is available for download from our website (http://www.analyticon-diagnostics.com).

References

• For handling of the test strips, please observe the general working instructions for laboratories.
• For in vitro diagnostic use only. For professional use only – not for self-testing.
• Avoid swallowing and contact with eyes and mucous membranes. Keep away from children.
• For in vitro diagnostic use only. Contact is only allowed in laboratories.
• Literature: Thomas L.: Clinical Laboratory Diagnosis, TH-Books, Frankfurt/Main 1998

Symbols

= Read package insert; = Expired; = Store at; = Do not reuse;
= The product complies with European legislation; = In vitro Diagnostikon. 
= LOT Number; = Catalogue Number

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