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Urine Test Strips
For In-Vitro Diagnostic Use

Urine Test Strips for the Rapid Determination of Ascorbic Acid, Bilirubin, Blood, Glucose, Ketones, Leucocytes, Nitrite, 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 only well mixed, non-centrifuged urine, which should not be older than 4 hours. First morning urine is recommended. Protect the samples from light.
- If the samples cannot be tested immediately, they should be stored at 2...4°C and brought to room temperature (15...25°C) before testing.
- Collect specimen in clean, well rinsed containers, free of detergents. Do not add any preservatives.
- Do not touch test areas of the reagent strip.
- Immediately after removing the required number of strips, close the container securely using the original cap.
- Immerse the test strip in the urine (approx. 2 sec), so that all reagent areas are covered. Remove excess urine from the strip by wiping the edge of the strip on the urine container or on absorbent paper.
- To prevent interaction from adjacent test areas, hold the strip in a horizontal position during incubation.
- Compare the reagent areas on the strip with the corresponding color chart on the container 60 seconds (60 - 120 seconds for leucocytes) after immersion. Coloration only on the rim of the test pad or after more than 2 minutes after immersion is without meaning and should not be used for interpretation.
- The evaluation should be carried out in diffuse daylight or under a daylight lamp. Light from certain light bulbs can simulate non-specific positive results (protein, leucocytes).

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 and blood test. The detection is based on the decoloration of Tillmans reagent. In the presence of ascorbic acid a color change takes place from grey blue to orange. As ascorbic acid already in low concentrations can disturb various test fields, especially the glucose and blood assay in low concentrations, the test must be repeated if the ascorbic acid reaction is positive, however, at the earliest 10 hours after the last vitamin C intake (medication, fruit, vegetables). Values of 5 – 10 mg/dl or 0,6 – 1,1 mmol/l 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 acid by coupling of bilirubin with a diazonium salt. Normally, no bilirubin is detectable in urine. Concentrations of 0,5 mg/dl and more lead to a color of red-orange peach and indicate the early stage of a liver disease. The reaction is unaffected by pH of urine. False low or negative results may be simulated by large amounts of vitamin C or Nitrite or by longer exposure of the sample to direct light. Increased concentrations of urobilinogen can reinforce the sensitivity of the test field. Different urine contents (e.g. urine indicane) can lead to atypical coloration. For metabolites of drugs see urobilinogen. The color fields correspond to the following values: 0 (negative), 1(+), 2(++), 4(+++) mg/dl or 0 (negative), 17(+), 35(++), 70(+++) µmol/l. Values of 0,5 – 1 mg/dl Bilirubin are indicated.
Blood: - Intended to detect occult blood in urine. Occult blood indicates serious urological or kidney diseases. Microhaematuria does not affect the colour of urine and is only detectable by microscopic or chemical tests. The detection is based on the pseudoperoxidative activity of hemoglobin and myoglobin, which catalyze the oxidation of an indicator by an organic hydroperoxide and a chromogene producing a green color. Larger amounts of ascorbic acid which may be present in urine after a high intake of vitamin C (e.g. vitamin tablets, antibiotics or fruit juices) can lead to lower or falsely negative results. Control ascorbic acid test pad! In addition an inhibitory effect is produced by gentisic acid, uric acid, glutathione. Falsely positive reactions can also be produced by a residue of peroxide containing cleansing agents, activities of microbial oxidase due to infections of the urogenital tract or by formaline. The significance of a positive result varies from patient to patient. For establishing an individual diagnosis, it is therefore indispensable to take into consideration also the clinical manifestations. The color fields correspond to the following values: 0 (negative), approx. 5-10, approx. 50, approx. 300 Ery/µl. Values of approx. 5 Erythrocytes/µl are indicated.
Glucose: - Intended to measure glucosuria (glucose in urine). Urinary glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, and hyperglycemia. 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. Normally, glucose cannot be detected in the urine although small amounts are secreted also by the healthy kidney. Changes in the coloration less than 50 mg/dl (2.8 mmol/l) are to be considered normal. High concentrations of ascorbic acid in urines with a low glucose concentration (up to 250 mg/dl) may inhibit the reaction and lead to lower or false negative results. Repeat the test one day after stopping the intake of vitamin C. Pay attention to the ascorbic acid field. In addition an inhibitory effect is produced by gentisic acid, a pH value of <5 and high specific gravity. False positive reactions can also be produced by a residue of peroxide containing cleansing agents or others. The color fields correspond to the following ranges of glucose concentrations:normal,50,100,250,500 and 1000 mg/dl or normal,2,8,5,6,14,28 and 56 mmol/l.Values of 40 mg/dl glucose are indicated.
Ketones: - Intended to detect ketones in urine. Identification of ketones is used in the diagnosis and treatment of acidosis (a condition characterized by abnormally high acidity of body fluids) or ketosis (a condition characterized by increased production of ketone bodies) and for monitoring patients with diabetes. Acetone and acetoacetic acid react with sodium nitroprusside in alkaline solution to give a violet colored complex (Legal's test). Normally the urine is free of ketones. Detectable concentrations of ketones can originate from physiological stress (fasting, pregnancy, excessive sport). Phenylketones in higher concentrations will produce variable colors. ß-Hydroxybutyric acid is not detected. Phthalein compounds and derivatives of anthrachinone interfere by producing a red coloration in the alkaline range which may mask the coloration of ketones. The color 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. Values of 5 mg/dl acetoacetic acid or 50 mg/dl acetone are indicated.
Leucocytes: - Intended to detect leucocytes in urine. Leucocytes indicate inflammatory diseases of the kidneys and the urinary tract, and suggests need for further investigation. The test is based on the esterase activity of granulocytes. This enzyme splits heterocyclic carboxylates. The component released reacts with a diazonium salt producing a violet color. Urines of healthy subjects do not contain any leucocytes. Positive results, even when constantly varying from "negative" to "25", are to be considered as clinically relevant. Strongly colored compounds (e.g. nitrofurantoin) may disturb the color of the reaction. Glucose or oxalic acid in high concentrations, drugs containing cephalexine, cephalothine or tetracycline can lead to weakened reactions. Falsely positive results may be caused by contamination with vaginal secretion. The color fields correspond to the following values: 0 (negative), approx. 25, approx. 75, approx. 500 Leuko/µl. Values of 10-20 leucocytes/µl are indicated.
Nitrite: - Intended to identify nitrite in urine. Nitrite identification is used in the diagnosis and treatment of urinary tract infections of bacterial origin. The color test is based on the principle of the Griess reaction. Any degree of pinkorange coloration should be interpreted as a positive nitrite test suggestive of =105 organisms/ml urine. Negative results do not exclude significant bacteriuria (insufficient incubation, urinary tract infections due to bacteria not containing nitrate reductase). Before testing the patient should ingest vegetable-rich meals, reduce fluid intake and discontinue antibiotic and vitamin C therapy 3 days prior to the test. False positive results may occur in stale urines, in which nitrite has been formed by contamination of the specimen and in urines containing dyes (derivatives of pyridinium, beetroot). A negative result even in the presence of bacteriuria can have the following reasons: bacteria not containing nitrate reductase, diet with low nitrate content, high diuresis, high content of ascorbic acid or insufficient incubation of the urine in the bladder. Red or blue borders or edges which may be present must not be interpreted as a positive result. Values of 0,05-0,1 mg/dl Nitrite are indicated.
pH: - Intended to estimate the pH of urine. Estimations of pH are used to evaluate the acidity or alkalinity of urine as it relates to numerous renal and metabolic disorders and in the monitoring of patients with certain diets. Persisting high pH-values indicate urinary tract infections. The test paper contains indicators which clearly change color between pH 5 and pH 9 (from orange to green to turquoise).The pH value of fresh urine of healthy people varies between pH 5 and pH 6. Bacterial contamination may lead to false results. Red borders which may be present in neighbourhood to the nitrite field must not be taken into consideration The color fields correspond to the following pH values: 5, 6, 7, 8, 9.
Protein: - Intended to identify proteins in urine. Identification of urinary protein is used in the diagnosis and treatment of renal diseases. The test is based on the „protein error" principle of the indicator. The test is especially sensitive in the presence of albumin. Other proteins are indicated with less sensitivity. Normally, no protein is detectable in the urine of healthy subjects. Pathological proteinuria normally start with >30 mg/dl. Falsely positive results are possible in highly alkaline urine samples (pH > 9) and in the presence of high specific gravity, after infusions with polyvinylpyrrolidone (blood substitute), after intake of medicaments containing quinine and also by disinfectant residues containing quaternary ammonium groups in the urine sampling vessel. The color 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.Values of approx. 15 mg/dl Albumine are indicated.
Specific Gravity / Density: - Intended to provide an estimation of renal ability of urine concentration or urine dilution. The specific gravity of urine varies in accordance with the drinking quantity as well as different disorders. A highly diluted urine e.g., a SG of approx.1.000 can indicate a failure of the renal concentration ability. In addition, the determination of specific gravity is also important indicator for a manipulation (e.g., urine dilution of sample) at the screening for drug abuse. The test is based on a color change of the reagent from blue green to greenish yellow depending on the concentration of ions in the urine. The test permits the determination of urine density between 1.000 and 1.030. The normal value varies between 1.015-1.025. The color scale has been optimized at a pH of the urine of 6. Highly alkaline (pH>8) urines lead to slightly low results, highly acid (pH<6) urines may cause slightly higher results. Glucose and urea do not interfere. The color fields correspond to the values of 1,000; 1,005; 1,010; 1,015; 1,020; 1,025; 1,030. **Urobilinogen:** - Intended to detect and estimate urobilinogen (a bile pigment degradation product of red cell hemoglobin) in urine. Estimations obtained by this device are used in the diagnosis and treatment of liver diseases and hemolytic (red cells) disorders.The test is based on the coupling of urobilinogen with a stabilised diazonium salt to a red azo compound. The normal concentration of urobilinogen in urine goes from 0.1 – 1.8 mg/dl (1.7 – 30 µmol/l). Concentrations of > 2.0 mg/dl (35 µmol/l) are considered to be pathological. The reaction is unaffected by pH of urine. Higher concentrations of formaldehyde or exposure of the urine to light for a longer period of time may lead to lowered or falsely negative results. Beetroot or metabolites of drugs which give a color at low pH (phenazopyridine, azo dyes, p-aminobenzoic acid) may cause false positive results. 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.

Reagent Composition in the Tests
Ascorbic acid: 2,6-dichlorophenolindophenol 0,7%
Bilirubin: diazonium salt 3,1%
Blood: tetramethylbenzidine-dihydrochloride 2,0%, isopropylbenzol-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%; diazonium salt 0,2%
Nitrite: tetrahydrobenzo[h]quinolin-3-ol 1,5%; sulfanilic acid 1,9%
pH: methyl red 2,0%; bromothymol blue 10,0%
Protein: tetrabromophenol blue 0,2%
Specific Gravity: bromothymol blue 2,8%
Urobilinogen: diazonium salt 3,6%

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 up to 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 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. However, stopping taking the drugs should 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 which may lead to variations of the intensity and the color in rare cases.
- For reflectometric 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 not always possible to obtain precise agreement between the values obtained by visual reading and those obtained in the instrument.
- For handling of the test strips, please observe the general working instructions for laboratories.
- For in vitro diagnostic use only. For trained staff only – not for self testing.
- Avoid swallowing and contact with eyes and mucous membranes. Keep away from children.
- Each laboratory should evaluate it's own standards for quality control.
- Literature: Thomas L.; Clinical Laboratory Diagnosis, TH-Books, Frankfurt/ Main 1998

Symbols

= read package insert
= Expiry
= Store at
= this product is conform to the directive 98/79EG dated 27.10.1998
= In vitro Diagnosticum
= LOT Number
= catalogue number

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