URINALYSIS 10 PARAMETER TEST STRIPS

INSTRUCTIONS FOR USE

Intended Use
Urinary Reagent Strips (URS) are used for quick and simultaneous semi-quantitative and qualitative screening of multiple urine parameters in one easy testing format. The testing range can be any combination of the following parameters:

- Ascorbic Acid
- Bilirubin
- Blood
- Glucose
- Ketones
- Leucocytes
- Nitrite
- Specific Gravity
- pH
- Protein
- Creatinine
- Urobilinogen

For use as a preliminary screening test for diabetes, liver disease, haemolytic diseases, urogenital and kidney disorders and metabolic abnormalities during routine examinations. General preventative medicine.

Procedure

SPECIMEN COLLECTION
Collect urine in a clean container and test as soon as possible. Do not centrifuge. The use of urine preservatives is not recommended. If testing cannot be performed within one hour after voiding, refrigerate the specimen immediately at 2 – 4°C. Allow refrigerated urine specimen to return to room temperature (15 – 25°C) before testing.

URINALYSIS PROCEDURE
1. Use fresh urine specimen that is less than 4 hours old. Collect urine into a clean, dry container, free of detergents.
2. Remove one strip from the container taking care not to touch the reagent areas. Immediately replace the cap.
3. Briefly (no longer than one second) immerse all reagent areas into the urine sample. Wipe off excess urine by wiping the edge of the strip on the urine container or on absorbent paper.
4. Hold strip in a horizontal position to prevent interaction from adjacent areas.
5. Refer to the label on the container for specific reagent areas on the strip. Compare the test areas with the colour scale on the label 60 seconds after immersion (60 – 120 seconds for leucocytes).

Proper reading times are critical for optimal results. Coloration appearing only along the edges of the test pads or developing after more than two minutes after immersion has no diagnostic value.

Clinical Use, test Principles, Expected Values, Limitations

Bilirubin: Intended to measure the levels of bilirubin conjugates in urine. Measurement of bilirubin and its conjugates are used in the diagnosis and treatment of certain liver and bile diseases. The test for bilirubin is based on the coupling of bilirubin with a diazonium salt under acidic conditions. Normally no bilirubin is detected in the urine even by the most sensitive methods. The slightest discoloration of the reagent area constitutes a positive (i.e. pathologic) result. Concentrations of 0.5 mg/dl and more lead to a colour of red-orange peach and indicate the early stage of a liver disease. The pH of the urine does not affect the test reaction. False negatives may be produced by metabolites of drugs that give a colour at low pH, by the presence of nitrates and/or ascorbic acid concentrations in excess of 1.4 mmol/l. Indoxyl sulphate may also interfere with the interpretation of a negative or positive bilirubin reading. The presence of urobilinogen can enhance the sensitivity of the test field whilst urine indicine may cause atypical colouration.

Detection range: 1 – 4 mg/dl or 17 – 70 µmol/l.

Blood: Intended to detect occult blood in urine. Occult blood indicates urological or kidney diseases. Microhaematuria does not affect the colour of urine and is only detectable microscopically or by chemical detection methods. The detection of blood is based on the pseudoperoxidative activity of haemoglobin and myoglobin, which catalyze the oxidation of an indicator by an organic hydroperoxide and a chromogen to produce a green colour. Intact erythrocytes are indicated by punctual colourations (spots) on the test pad, and haemoglobin and myoglobin by a uniform green colouration. Large concentrations of ascorbic acid may cause lower readings in urine containing occult blood. False positive results are usually caused by residues of peroxide (from cleansing agents), formaline or by the activities of microbial oxidase from urogenital tract infections. The significance of a positive result varies from patient to patient and should be evaluated in the overall clinical assessment of the patient.

Detection range: 5 – 300 Ery/ml.

Glucose: Intended to measure glucose (glucosuria) in urine. Glucose measurement is used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and hyperglycaemia. This test is based on the specific glucose oxidase (GOD) – peroxidase (POD) reaction with a chromogen. It is independent of pH and not affected by presence of ketone bodies. Test reactivity, however, decreases as the SG of the urine increases. Reactivity may also vary with temperature. Small amounts of glucose are filtered by healthy kidneys, therefore changes in the colouration of less than 50 mg/dl (2.8 mmol/l) are considered normal. Ascorbic acid in urines with low glucose concentrations (up to 250 mg/dl) may inhibit the colour reaction and lead to lower or false negative results. If the urine contains ascorbic acid, the test should be repeated one day after vitamin C intake has been stopped. Other inhibitory substances include high specific gravity, gentisic acid and pH values higher than 5.

Detection range: 50 – 1,000 mg/dl (2.8 – 56 mmol/l).

Ketones: Intended to detect ketones in urine. Identification of ketones is used in the diagnosis and treatment of acidosis of ketosis and for monitoring patients with diabetes. Based on the principle of Légal’s test, this test reacts with acetoacetic acid and acetone in alkaline solution to form a violet coloured complex. Normal urine specimens usually yield negative results, however, detectable levels may be observed during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. It does not react with 8-Hydroxybutyric acid, Captopril, Mesna (sodium 2-mercaptopo-ethane sulfonate) and other substances containing sulphhydrol groups may produce false-positive results. Phenylketones in high concentrations will cause variable colours. Phthalein compounds and anthracidine derivatives interfere with the test by producing a red colouration which may mask the reaction of ketones.

Detection range: 25 – 300 mg/dl (2.5 – 30 µmol/l).

Leucocytes: Intended to detect leucocytes in urine. A positive leucocyte results indicates an inflammatory disease of the kidneys and the urinary tract and suggests the need for further investigation. The reaction is based on the release of leucocyte esterase from lysed neutrophils, which react with an ester, producing a pyrrole compound. The pyrrole reacts with a diazo salt yielding a violet colour. Urine from healthy subjects do not contain any leucocytes. Any positive result is to be considered as clinically relevant. The reaction is not affected by bacteria, trichomons or erythrocytes present in the urine. Formaldehyde (stabilizer) may cause false-positive reactions. If the urine specimen has a pronounced intrinsic colour (for example due to the presence of bilirubin or nitrofurantoin), the reaction colour may be intensified due to an additive effect. False positive results may be caused by contamination with vaginal secretion. Urinary protein excretions >500 mg/dl and urinary glucose excretions >2 g/dl may diminish the intensity of the reaction colour, as can cephalaxine, cephalothine, tetracycline and gentamicin if administered in high daily doses.

Detection range: 25 – 500 Leuko/µl.
Nitrite: Intended to detect the presence of nitrite in urine. Detection of nitrite in the urine aids in the treatment of urinary tract infections of bacterial origin. The test is based on the principle of Griess’s test and is specific for nitrite. The reaction reveals the presence of nitrite and hence indirectly of nitrite-forming (Gram Negative) bacteria in the urine by a pink discoloration of the test patch. Even a slight pink coloration is indicative of significant bacteriuria. Prolonged urinary retention in the bladder (4-8hours) is essential in order to obtain an accurate result. A negative result does not preclude a bacterial infection (insufficient incubation, urinary tract infection due to bacteria not containing nitrite reductase). Administration of antibiotics or chemical drugs including vitamin C should be discontinued 3 days before the test. False positive results usually occur with stale urines in which nitrite has been formed by contamination of the urine specimen and in urines containing dyes (beetroot, pyridinium derivatives). False negative results can be caused by various factors including vitamin C, low nitrate content diet, bacteria not containing nitrate reductase, high diuresis, and insufficient incubation time in the bladder. A reaction pad showing red or blue borders should not be interpreted as a positive result.

Detection range: ≥ 0.05 mg/dl.

pH: Intended to estimate the pH of urine. Estimation of urinary pH is used to determine the alkalinity or acidity of urine and aids in the monitoring of patients on specific diets. Abnormal urinary pH values relate to many renal and metabolic disorders. Persistently high pH values may be indicative of urinary tract infections. The pH reaction is based on an indicator that changes colour from 5 to 9. The pH of healthy individuals varies between pH 5 and pH 6. Bacterial contamination may lead to false results.


Protein: Intended to detect the presence of protein in the 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 to albumin and less sensitive to other proteins. Normally, no protein is detectable in the urine of healthy individuals. False positive results are obtained with urine of high alkalinity, urine with high specific gravity, and urine containing quinine, polyvinylpyrrolidone (PVP) or quaternary ammonium compounds (disinfectant residue).

Detection range: 30 – 500 mg/dl or 0.3 – 5 g/l.

Specific Gravity: Intended to provide an estimation of renal ability (urine concentration or dilution). The specific gravity of urine varies with fluid intake and can be an indicator of certain disorders. Highly diluted urine (SG 1.000) can indicate a failure of the renal concentration ability. Specific gravity can also serve as an indicator of urine tampering when screening for drug abuse. The test reaction is based on a change of density correlating with the concentration of ions present in the urine. This allows for urine density to be estimated between 1.000 and 1.030. The normal value varies between 1.015 and 1.025. Since pH has an influence on the test, the reaction has been optimised for urine with a pH of 6. Highly alkaline urine (pH >8) will yield slightly lower results, while highly acidic urine will yield slightly higher results. The test is not affected by glucose or urea.

Detection range: 1.000 – 1.030.

Urobilinogen: Intended to detect and estimate Urobilinogen in urine. Urobilinogen (a bile pigment degradation product of red cell haemoglobin) is used in the diagnosis and treatment of liver diseases and haemolytic disorders. The test principle is based on the coupling of a stabilised diazonium salt with urobilinogen to form a red azo compound. The normal urobilinogen concentration in urine ranges from 0.1 – 1.8 mg/dl (1.7 – 30 µmol/l). Any value higher than 2 mg/dl (35 µmol/l) is considered pathological. The urinary pH does not affect the test. Traces of formaldehyde in the urine and exposure of urine to light may cause lowered or falsely negative results. Beetroot and drug metabolites which give a colour at a low pH (azo dyes, p-amino benzoeic acid, phenazopyridine) may cause false positive results.

Detection range: 2 – 12 mg/dl or 35 – 200 µmol.

Reagent Composition:
- Bilirubin: diazonium salt 3.1%
- Blood: TMB 2.5%; cumene hydroperoxide 18.0%
- Glucose: GOD 2.1%; POD 1.0%
- Ketones: 3.1%
- Leucocytes: pyrrole ester 0.5%; diazonium salt 0.2%
- Nitrite: tetrahydrobenzo[h]quinolin-3-ol 1.6%; sulfanilic acid 1.9%
- pH: methyl red 2.1%; BTB 10.9%
- Protein: tetrabromothymol blue 0.21%
- Specific Gravity: BTB 2.9%
- Urobilinogen: diazonium salt 3.7%

Storage and Stability
Urine reagent strips are packaged along with a drying agent contained in the cap of the plastic container. Containers should be kept tightly closed at all times. Keep product away from sunlight and humidity at all times. Store the containers in a cool dry place. Under proper conditions test strips are stable up to the expiry date printed on the packaging.

Notes
- All results should be considered in conjunction with a proper clinical assessment. Positive results should preferably be confirmed by other laboratory methods. In the case of monitoring, results should always be discussed with a clinician before any action is taken.
- Do not interpret results after 60 seconds (120 seconds for leucocytes) as this may lead to false results.
- For single use only. Do not use more than once.
- The product is intended for professional use only, not for self testing. Do not use for analysing any fluids other than urine. Avoid contact with mucous membranes. Do not swallow. Please observe standard laboratory practice when handling urine reagent strips and urine.
- Certain configurations of strips may also be used with an instrument reader. For instrument use, refer to the instrument instructions. Differences may occur when visual results are compared to results obtained with an instrument reader.
- Keep out of reach of children.
- Discard used strips in a medically and environmentally responsible manner.

Disclaimer: The manufacturer, importer, distributor, pharmacy and medical professional does not accept any liability whatsoever for any consequent actions resulting from interpretations of the test result.