

URINALYSIS TEST INSTRUCTIONS

URINALYSIS TEST DESCRIPTION

Urine 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:

Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes

Test results are intended to provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and bacteriuria. Urine Reagent Strips are packaged along with a drying agent in a plastic bottle. Certain configurations of strips may also be read instrumentally, using the appropriate Urine Chemistry Analyzers.

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. Allow refrigerated specimen to return to room temperature before testing.

URINALYSIS PROCEDURE

1. Use fresh urine specimen that is less than 4 hours old into a clean, dry container.
2. Remove one strip from the bottle and replace the cap. Briefly (no longer than one second) immerse all reagent areas into specimen. Wipe off excess urine on the rim of the container.
3. Hold strip in horizontal position. Refer to the bottle label for specific reagent areas on the product. Compare the test areas with the color scale on the label. Proper reading times are critical for optimal results. See each reagent time as indicated. Coloration

Read Time: 60 seconds

Sensitivity: 60-620 $\mu\text{g/L}$ (hemoglobin)

Hemoglobin and myoglobin catalyze the oxidation of the indicator by an organic hydroperoxide. Hemoglobin, hemolyzed erythrocytes, and myoglobin are indicated by a uniform green coloration of the test patch. Ascorbic acid does not interfere with the test.

pH

Read Time: 60 seconds

Sensitivity: pH5 to pH8.5

The test strip contains the indicators methyl red and bromothymol blue.

Protein

Read Time: 60 seconds

Sensitivity: 0.15-0.3g/L (albumin)

The test is based on the principle of the protein error of pH indicators. The reaction is extremely sensitive toward albumin (practical sensitivity limit 6mg albumin/dL). Quinine, quinidine, chloroquine, and tolbutamide do not affect the test, nor does a high pH (up to pH9). False positive results may be obtained with highly buffered or alkaline urine. False positives may also be obtained by contamination with quaternary ammonium compounds, or chlorhexidine based disinfectants.

appearing only along the edges of the test or developing after more than two minutes has no diagnostic value.

REAGENT INFORMATION

Glucose

Read Time: 30 seconds

Sensitivity: 4-7mmol/L (glucose)

This test is based on the specific glucose-oxidase/peroxidase reaction. 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.

Bilirubin

Read Time: 30 seconds

Sensitivity: 7-14 $\mu\text{mol/L}$ (bilirubin)

The test for bilirubin is based on the coupling of bilirubin with a diazonium salt. 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. False negatives may be produced by metabolites of drugs that give a color at low pH or by ascorbic acid concentrations in excess of 1.4mmol/L. Indoxyl sulfate may also interfere with the interpretation of a negative or positive bilirubin reading.

Urobilinogen

Read Time: 60 seconds

Sensitivity: 3 $\mu\text{mol/L}$ (urobilinogen)

A stable diazonium salt reacts almost immediately with urobilinogen to give a red azo dye. Colors lighter than that shown for 1mg/dL (17 $\mu\text{mol/L}$) constitute a normal finding. Formalin, p-aminobenzoic acid and substances known to interfere with Erlich's reagent, such as p-aminosalicylic acid and sulfonamides, may interfere with the accuracy of test.

Nitrite

Read Time: 60 seconds

Sensitivity: 13-22 $\mu\text{mol/L}$ (nitrite ion)

The test is based on the principle of Griess's test and is specific for nitrite. The reaction re-

Ketone

Read Time: 40 seconds

Sensitivity: 0.5-1.0mmol/L (acetoacetic acid)

Based on the principle of Legal's test, this test reacts with acetoacetic acid in urine. It does not react with acetone or β -hydroxybutyric acid. 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. Captopril, Mesna (sodium 2-mercapto-ethane sulfonate) and other substances containing sulfhydryl groups may produce false-positive results.

Specific Gravity

Read Time: 45 seconds

Sensitivity: SG 1.000 to 1.030

This test reflects the ion concentration of urine and correlates well with the refractometric method. If urine pH \geq 7, then add 0.005 to SG obtained. In presence of protein (100 and 500mg/dL) or ketoacidosis, results tend to be elevated. An increase in SG due to glucose concentrations (>56mmol/L) is not indicated by the test.

Blood

veals 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. Administration of antibiotics or chemical drugs should be discontinued 3 days before the test.

Leukocytes

Read Time: 2 minutes

Sensitivity: 5-15 cells/ μL

Normal urine generally yields negative results. Positive results are clinically significant. The reaction is not affected by bacteria, trichomonads or erythrocytes present in the urine.

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Formaldehyde (stabilizer) may cause false-positive reactions not affected by bacteria, trichomonads or erythrocytes present in the urine. Formaldehyde (stabilizer) may cause false-positive reactions. If the urine specimen has a pronounced intrinsic color (for example due to the presence of bilirubin or nitrofurantoin), the reaction color may be intensified due to an additive effect. Urinary protein excretions >500 mg/dL and urinary glucose excretions >2 g/dL may diminish the intensity of the reaction color, as can cephalixin and gentamicin if administered in high daily doses.

RECOMMENDED HANDLING PROCEDURES

All unused strips must remain in the original bottle. Transfer to another container may cause reagent strips to deteriorate and become nonreactive. Do not remove desiccant from bottle. Do not open container until ready to use. Opened bottles should be used within 3 months after first opening.

LIMITATIONS OF PROCEDURE

Comparison to the color chart is dependent on the interpretation of the color chart. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single test result or method.

Glucose: Moderate amounts of ketone bodies (40mg/dL or greater) may decrease color development in urine containing small amounts of glucose (75-125 mg/dl). However, such concentration of ketone simultaneously with such glucose concentration is metabolically improbable in screening. The reactivity of the glucose test decreases as the SG of the urine increases. Reactivity may also vary with temperature.

Bilirubin: Reactions may occur with urine containing large doses of chlorpromazine or rafampen that might be mistaken for positive bilirubin. Indican (indoxyl sulfate) and metabolites of Lodineã may cause false "positive" test results.

gentamicin have been found to interfere with this test. High urinary protein of 500mg/dL or above diminish the intensity of the reaction color. Elevated glucose concentration or high specific gravity may caused decreased test results.

EXPECTED VALUES

Glucose: Small amounts of glucose are normally excreted by the kidney. Concentrations as little as 0.1 g/dl glucose, read either at 10 or 30 seconds, may be significantly abnormal if found consistently. At 10 seconds, results should be interpreted qualitatively; for semi-quantitative results, read at 30 seconds only.

Bilirubin: Normally, no bilirubin is detectable in urine by even the most sensitive method. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. Atypical colors (colors produced which are different than the negative or positive color blocks shown on the Color Chart) may indicate that bilirubin derived bile pigments are present in the urine sample and are possibly masking the bilirubin reaction.

Ketone: Normally, no ketones are present in urine. Detect-

Ketone: Color reaction that could be interpreted as "positive" may be obtained with urine specimens containing MESNA or large amounts of phenylketones or L-dopa metabolites.

Specific Gravity: The chemical nature of the specific gravity test may cause slightly different results from those obtained with the specific gravity methods when elevated amounts of certain urine constituents are present. Highly buffered alkaline urine may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities (100-750 mg/dl) of protein.

Blood: The sensitivity of the blood test is reduced in urine with high specific gravity and/or high ascorbic acid content. Microbial peroxidase, associated with urinary tract infection may cause false positive reactions.

pH: If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as "running over" may occur, in which the acid buffer from the protein reagent area run onto the pH area, causing a false lowering in the pH

able levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy, and frequent strenuous exercise. In starvation diets, or in other abnormal carbohydrate metabolism situation, ketones appear in the urine in excessively large amounts before serum ketones are elevated.

Specific Gravity: Random urine may vary in specific gravity from 1.003-1.040+. Twenty-four hour urine from normal adults with normal diets and normal fluid intake will have a specific gravity of 0.016-1.022 . In severe renal damage the specific gravity is fixed at 1.010, the value of the glomerular filtrate.

result.

Protein: False positive results may be obtained with highly alkaline urine. Contamination of the urine specimen with quarterary ammonium compounds may also produce false positive results.

Urobilinogen: The test area will react with interfering substances known to react with Ehrlich's reagent, such as porphobilinogen and p-aminosalicylic acid. This test is not a reliable method for the detection of porphobilinogen. Drugs containing azo-dyes (e.g. Azo Gantrisin) may give a masking golden color. The absence of urobilinogen cannot be determined with this test.

Nitrite: The pink color is not quantitative in relation to the number of bacteria present. Any degree of pink coloration should be interpreted as a positive nitrite test suggestive of 10 or more organisms/ml. There are occasional urinary tract infections from organisms, which do not contain reductase to convert nitrate to nitrite.

Leukocytes: Highly colored urine and the presence of the drugs cephalixin (Keflex®) and

Blood: Any green spots or green color developing on the reagent area within 40 seconds is significant and the urine should be examined further. Blood is frequently, but not invariably, found in the urine of menstruating females.

pH: newborn: 5-7 thereafter: 4.5-8 average: 6.

Protein: In 24-hour urine, 1-14 mg/dl of protein may be excreted by the normal kidney. A color matching any color block greater than trace indicates significant proteinuria. For urine with high specific gravity, the test area may most closely match the trace color block even though only normal concentrations of protein are present. Clinical judgement is

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needed to evaluate the significance of trace results.

Urobilinogen: In a healthy population, the normal urine urobilinogen range obtained with this test is 0.2-1.0 Ehrlich Unit/dl. A result of 2.0 EU/dl may be of clinical significance and the same patient sample should be evaluated further.

Nitrite: Normally no detectable amount of nitrite is present in urine. The nitrite area will be positive in a proportion of cases of significant infection, depending on how long the urine specimens were retained in the bladder prior to collection. Retrieval of positive cases with the nitrite test range from as low as 40%, in instances where little bladder incubation occurred, to as high as 80% in instances where a minimum of 4 hours incubation occurred.

Leukocytes: Normal urine specimens generally yield negative results with this test. A trace result may be of questionable clinical significance and it is recommended that the test be repeated using a fresh sample from the same patient. Repeated trace and positive results are of clinical significance.

STORAGE AND STABILITY

Store at room temperature between 15°-30°C (59°-86°F) and out of direct sunlight.

WARNINGS AND PRECAUTIONS

Urine Reagent Strips are for in vitro diagnostic use. Do not touch test areas of Urine Reagent Strips.

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