Chemstrip® 5 OB, 7

Urine Test Strips For pH, Leukocytes, Nitrite, Protein, Glucose, Ketones, Blood, Hemoglobin

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Chemstrip® 5 OB and Chemstrip® 7 Urine Test Strips are intended for use visually or on the Roche Diagnostics Úrïjas 1100® Urine Analyzer.

Summary:
The Chemstrip Urine Test Strips are multi-parameter test strips, which measure certain constituents in the urine. These measurements are useful in the evaluation of renal, urinary, and metabolic disorders. Chemstrip® 5 OB and Chemstrip® 7 Urine Test Strips are inert plastic strips to which are attached different reagent pads for determining pH, nitrite, leukocytes, protein, glucose, ketones, and blood in the urine. Please refer to the outside box and vial label for the specific parameters of the product you are using. The test pads are uniquely attached to the strip with a nylon mesh which holds the reagent pad in place, protects the pad, and provides for rapid and even wetting of the entire test pad. To prevent urine runover, certain test pads have an inert absorbent paper located between the test pads and the strip.

Chemstrip Urine Test Strips are packaged in a vial with a tightly fitting cap, which contains a drying agent. Each test strip is stable and ready for use when removed from the vial.

Test Principle:
A brief discussion of each test principle follows.

pH: The test pad contains the indicators methyl red and bromothymol blue. These give clearly distinguishable colors over the pH range of 5-9. Colors range from orange through yellow and green to blue.

Leukocytes: Leukocytes in the urine are detected by the action of p-aminobenzaldehyde sulfuric acid to form blue. The indophenol dye formed reacts with a diazotizable dye, such as phthalalizarin, and sodium sulfide to form a diazo dye.

Protein: The detection of protein is based on the so-called "protein error of pH indicators." The indicator used in this test is 3,5,5'-trichloro-1,4-phenylenediamine, which, in a positive reaction, is indicated by a color change from yellow to light green.

Glucose: Glucose detection is based on the enzymatic glucose oxidase/peroxidase (GOD-PDO) method. The reaction utilizes the enzyme glucose oxidase to catalyze the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. In turn, a second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with the chromogen tetrazethiazin to form a green dye complex. A positive reaction is indicated by a color change from yellow to green.

Nitrite: Nitrite in the urine is detected by the method of naphthol AS-D chloroacetate. The reaction involves the formation of a green dye complex, which is indicated by a color change from yellow to green.

Protein: Protein detection is based on the reaction of urine with a diazotizable dye, such as phthalalizarin, and sodium sulfide to form a diazo dye.

Ketones: The ketone test used in this test is based on the reaction of urine with a diazotizable dye, such as phthalalizarin, and sodium sulfide to form a diazo dye. The reaction involves the formation of a green dye complex, which is indicated by a color change from yellow to green.

Blood/Hemoglobin: The chemical detection of blood is based on the presence of the tetrazethiazin to form a green dye complex, which is indicated by a color change from yellow to green.

Ketones: The ketone test used in this test is based on the reaction of urine with a diazotizable dye, such as phthalalizarin, and sodium sulfide to form a diazo dye. The reaction involves the formation of a green dye complex, which is indicated by a color change from yellow to green.

Chemstrip Urine Test Strips are used on any freshly voided urine specimen or on urines collected under special conditions, such as first-morning specimens and post-prandial urines. The urine must be collected in a clean and complete container and should be transferred to the container as soon as possible to prevent loss of content.

Stability: Store test strips at 2°C (36°F) to 30°C (86°F) and do not freeze. Chemstrip urine test strips are stable in the original capped vial until the expiration date. In order to avoid exposure to moisture, the vial must be closed immediately after removal of a strip, using the original stopper, which contains a drying agent.

Procedure:
Materials Provided: 1 vial containing 100 Chemstrip Urine Test Strips.

A visual comparison color scale for reading test results is printed on the vial label.

Material Required, But Not Provided: A timer and a clean specimen collection container.

It is also recommended that commercial control products be used for quality control checks.

Assay:
1. Briefly (no longer than 1 second) dip test strip into urine. Ensure that the chemically impregnated pads on the test strip are thoroughly immersed.
2. Draw the edge of the strip along the rim of the specimen container to remove excess urine.
3. Turn the test strip on its side and press against a piece of absorbent paper to remove any remaining urine.
4. After the appropriate time read the test as follows: Hold strip close to color blocks and match carefully, ensuring that the strip is properly oriented to the color chart on the vial label.

Results:
For the Urisys 1100 Urine Analyzer: Refer to appropriate operator's manual regarding results from the analyzer.

For Visual Use: Results are obtained by direct visual comparison with the color scale printed on the vial label. Always assign the value of the nearest color block.

Quality Control:
Quality control for this procedure consists of following good laboratory techniques and ensuring that reagents have been properly stored and handled according to instructions. The operator should be aware of the sources of error outlined under Limitations. Each laboratory should establish its own quality control protocols.

Commercially prepared control solutions should be used on a regular basis, as established by the institution's quality control protocols. If the expected results are not obtained and the reagent tubes are found to be incorrect, the following steps should be taken:

1. Check the expiration date stamped on the vial label.
2. To verify the Chemstrip 10 MD Urine Test Strip has not been exposed to heat extremes or moisture, open a new vial of test strips and retest.
3. For further information, contact Roche Diagnostics Technical Service Center, 1-800-428-4674, 7 days a week, 24 hours a day, 365 days a year.

Limitations:
Test results through including interfering substances for each reagent are shown below.

pH Test: No known interferences when handled according to instructions.

Leukocyte Test: This test is not affected by leukocytes in concentrations up to 10,000/mL or by bacterial contamination in urine. Specimens should not be collected in containers that have been cleaned with strong oxidizing agents. Do not use preservatives.

Nitrates: Nitrates in the urine and this effect interferes with visual interpretation of the test strip. High levels of azo compounds (azo dyes) in the urine and urinary glucose may interfere with the visual test strip. A visual test strip may interfere with the test results. Studies show that formaldehyde and nitrous oxide may cause false-positive reactions.

Nitrite Test: Large amounts of ascorbic acid (see under glucose) decrease the sensitivity of the test. False-positive readings may be produced by medication that color urine red or which turns red in an acid medium (e.g., phenolphthalein).

Protein Test: False-negative results may be found in strongly basic urine (pH > 8) or during therapy with phenolphthalein, when the presence of protein is not detected by the color reaction.

Glucose Test: The effect of acetic acid (acetic acid) in the urine due to ingestion of vitamin tablets, antibiotics or fruit juices has been eliminated at glucose concentrations of 100 mg/dL and above so that false-negative readings may only rarely occur even at high concentration of acetic acid.

False-positive readings may be produced by strong oxidizing agents in the urine container.

Ketone Test: Phenyketones or other ketones in the urine container may be administered for liver and kidney function tests. False-positive reactions may result.

2-Mercaptoethanol sulfonate sodium (MESNA) or other sulfhydryl-containing compounds may cause false-positive results.
Blood/Hemoglobin Test: False negative results are obtained when formalin is used to preserve the urine. Nitrite in excess of 10 mg/dL in the urine (which is rare in urinary tract infections) delays the reaction. False-negative results can be produced by residues of strongly oxidizing cleaning agents in the urine container. Urine from menstruating females will occasionally yield a positive result. This test has not been found to be affected by the ingestion of reasonable quantities of ascorbic acid.

**Expected Values:**
- pH: Urine pH values generally range from 5 to 6 units. The most frequent pH values for the first morning specimens in healthy subjects are between 5 and 6.

**Leukocytes:** Normal urine should produce no color reaction. A "trace" finding indicates a possible borderline situation, and it is recommended that the test be repeated on a fresh urine sample from the same patient. Positive and repeated trace findings indicate the need for further testing of the patient and/or urine sample in accordance with the medically accepted procedures for pyuria.

**Nitrates:** A concentration as low as 0.05 mg/dL of nitrate will produce a slightly pink coloration of the test pad. This indicates a positive result.

**Proteins:** A color change from yellow to light green/green will occur if protein is present in urine. The concentrations given on the vial label correspond with the albumin concentration in urine. Pathological proteinuria will usually produce persistent values above 30 mg/dL. Clinical significance of the trace result should be determined by additional testing.

**Glucose:** Due to the test's sensitivity, glucose should not be detectable in normal urine. Therefore, any positive reaction should be followed by further diagnostic evaluation of the patient, such as a quantitative blood glucose or a glucose tolerance test.

**Ketones:** Ketone bodies should not be detected in normal urine with this test. Fasting or starvation diets may cause positive indications. In known pathological conditions such as diabetes, the presence of ketones may be useful as an index of metabolic status.

**Blood/Hemoglobin:** A trace result is equivalent to 5–10 Ery/A. Erythrocyte excretion up to 5 Ery/L may be expected in normal urine.** Levels above these certainly warrant further diagnostic evaluation of the patient.

**Performance Characteristics:**

The performance characteristics have been determined both in the laboratory and in clinical tests. For visually read strips, accuracy is a function of the manner in which the color blocks on the vial label are determined and the discrimination of the human eye in the tests. Precision is difficult to assess in a test of this type because of the variability of the human eye. It is for this reason that each user is encouraged to develop his own standards for performance.

**pH Values:** pH values from pH 5 to pH 9 may be red to within 1 unit.

**Leukocytes:** Studies were conducted to compare test pad color development from urines with values obtained by the microscopic method. Clinical testing yielded the following sensitivity and specificity data:

- n = 203
- Sensitivity = 97.2%
- Specificity = 95.7%

**Nitrite:** Up to 50% of all patients with urinary tract infections can be detected by analysis of the first-morning urine specimen.** A positive result will be detected in 50 to 70% of patients with urinary tract infections by use of a random urine specimen. This is dependent on the number of bacteria, nitrite content, and retention time of the urine in the bladder. Prolonged urinary retention in the bladder (4–6 hours) may be necessary to obtain an accurate result. The frequency of false-positive results in normal patients is negligible (less than 1%).

**Proteins:** In 90% of urines tested, albumin concentrations of 6 mg/dL or greater produced a color change. The test pad is more sensitive to albumin than globulin. Bence-Jones proteins and mucoproteins.

**Glucose:** In 90% of urines tested, glucose concentrations of 40 mg/dL or greater produced a positive result. Sugars other than glucose that may be found in urine were tested and found not to react with the reagent. Reducing substances will not give positive results.

**Ketones:** In 90% of urines tested, acetone at 8 mg/dL, or acetone at 70 mg/dL, will produce a positive reaction. Beta-hydroxybutyric acid does not contribute to the color development.