Chemstrip 5 OB, 7

Intended use
Urine test strips for pH, leukocytes, nitrite, protein, glucose, ketones, blood, and hemoglobin. Chemstrip 5 OB and Chemstrip 7 urine test strips are intended for use visually or on the Roche Diagnostics Urisyrs 1100 Urine Analyzer.

Summary
Chemstrip urine test strips are a multi-parameter test strips that 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, indication of leukocytes, nitrite, protein, glucose, ketones, and blood and hemoglobin in urine. 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, that 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 bromthymol blue. These give clearly distinguishable colors over the pH range of 5-8. Colors range from orange through yellow and green to blue.1,2

Leukocytes: Leukocytes in urine are detected by the action of esterase, present in granulocytic leukocytes, which catalyzes the hydrolysis of an indoxylcarbontic acid ester to indoxyl. The indoxyl formed reacts with a diazoniun salt to produce a purple color.

Nitrite: Nitrite, if present, reacts with an aromatic amine to give a diazoniun salt, which couples with sulfanilamide to yield a red-violet azo dye.3,4,5

Protein: The detection of protein is based on the so-called "protein error of pH indicators." The indicator used in this test is 3,3',5,5'-tetrachlorophenol-3,4,5,6-tetramethylbenzidine. A positive reaction is indicated by a color change from yellow to light green/brown.6

Glucose: Glucose detection is based on the enzymatic glucose oxidase/peroxidase (GOD/POD) 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 tetrathymolbenzidine to form a green dye complex. A positive reaction is indicated by a color change from yellow to green.6,7

Ketones: The ketone test used in this test pad is based on the reaction of sodium nitroprusside and glycine with acetoacetate and acetoacetic anhydride in an alkaline medium to form a violet dye complex. A positive result is indicated by a color change from beige to violet.8,9,10

Blood/Hemoglobin: The chemical detection of blood is based on the strong pseudoperoxidase action of erythrocytes and hemoglobin. Hemoglobin and myoglobin, if present, catalyze the oxidation of the indicator by the organic peroxide contained in the test pad. Intact erythrocytes hemolyze on the test pad, and the liberated hemoglobin produces a green dot. Since the test pad absorbs several uL of urine, more erythrocytes become visible than would correspond to 1 uL.9,10,11,12,13,14,15

Separate sets of color blocks are given for erythrocytes and hemoglobin. Scattered or compacted green dots on the yellow test pad are indicative of intact erythrocytes. A uniform green coloration of the test is indicative of free hemoglobin, myoglobin, or hemolyzed erythrocytes in the urine.

Reagent composition
See the outside of the test strip box for reagent composition.

Precautions and warnings
For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents. Disposal of all waste material should be in accordance with local guidelines.

Warning
Avoid contact with skin and mucous membranes; flush affected areas with copious amounts of water. Get immediate medical attention for eyes or if ingested.

Gloves: The "universal precautions" recommended by the Centers for Disease Control and Prevention should be followed whenever blood or body fluids are handled. These precautions include wearing gloves.

Storage and stability
Store test strips at 2-30 °C (36-86 °F). Do not freeze.

Chemstrip urine test strips are stable in the original capped vial until the listed 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.

Specimen collection and preparation
Chemstrip urine test strips may be 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 container and should be tested as soon as possible after collection. Do not centrifuge or use preservatives. If testing cannot be performed within two hours after collection, the specimen should be immediately refrigerated at 2-8 °C and returned to room temperature before testing. Mix urine thoroughly before testing. Urine should be collected in a container which allows complete immersion of the reagent pads on the test strip. If a clearly voided urine is not collected, a positive test result for leukocytes or blood may be due to a source of leukocytes or blood external to the renal-urinary system.

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.

Materials 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 the urine. Ensure that the chemically impregnated pads on the test strip are totally 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.

All test pads should be read at 1 minute. If the Leukocytes pad indicates a trace result, it should be read again at 2 minutes.

Any color changes appearing only along the edges of the test areas, or developing after more than 2 minutes, do not have any diagnostic significance. Careful removal of excess urine (steps 2 and 3) should eliminate this effect.

Calibration
Calibration of Chemstrip 5 OB and Chemstrip 7 urine test strips by the user is not required.

Quality control
Quality control for this procedure consists of following good laboratory techniques and ensuring that reagents have been properly stored and specimens handled according to instructions. The operator should be aware of the sources of error outlined in Limitations. Each laboratory should establish its own goals for adequate standards of performance.

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 repetition of the assay excludes errors in technique, the following steps should be taken:

1. Check the expiration date stamped on the vial label.
2. To verify that the Chemstrip 5 OB, 7 urine test strips have not been exposed to heat extremes or moisture, open a new vial of test strips and retest.
Blood/Hemoglobin: A trace result is equivalent to 5-10 Ery/L. Erythrocyte excretion up to 5 Ery/L may be expected in normal urine. Levels above this certainly warrant further diagnostic evaluation of the patient. Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

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 reading 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 from pH 5 to pH 9 may be read 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:

\[ n = 200 \]
Sensitivity = 97.2 %
Specificity = 90.1 %

Nitrates: Up to 90 % 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, nitrile content and retention time of the urine in the bladder. Prolonged urinary retention in the bladder (4-8 hours) may be necessary to obtain an accurate result. The frequency of false-positive results in normal patients is negligible (less than 1 %).

Protein: 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, acetoacetate at 9 mg/dL or acetone at 70 mg/dL will produce a positive reaction. Beta-hydroxybutyric acid does not contribute to the color development.

Blood/Hemoglobin: Differentiation of hemoglobin from erythrocytes can be determined by the color comparison chart on the vial label. In 90 % of urines tested, concentrations of 5 Ery/L and hemoglobin content corresponding to 10 Ery/L produced a positive result. A field study of 637 freshly voided urine specimens in routine diagnosis produced no false-negative results and in only a small percentage of cases, recorded a higher erythrocyte concentration than the ten-field sediment method.

Sensitivity Summary: The following table summarizes the sensitivity data obtained with the Urises 1100 Urine Analyzer. This table lists the level of analyte that is generally detectable as positive when tested with a centrifuged urine pool. Because of inherent variability in clinical urines, lower levels may be detected under certain conditions.

<table>
<thead>
<tr>
<th>Reagent Pad</th>
<th>Urises 1100 Analyzer</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood</td>
<td>5 - 20</td>
<td>Ery/L</td>
</tr>
<tr>
<td>Glucose</td>
<td>30 - 40</td>
<td>mg/dL</td>
</tr>
<tr>
<td>Ketone (acetacetic acid)</td>
<td>5 - 15</td>
<td>mg/dL</td>
</tr>
<tr>
<td>Leucocytes</td>
<td>30 - 35</td>
<td>Leu/L</td>
</tr>
<tr>
<td>Nitrite</td>
<td>0.06 - 0.10</td>
<td>mg/dL</td>
</tr>
<tr>
<td>Ketones</td>
<td>25 - 32</td>
<td>mg/dL</td>
</tr>
</tbody>
</table>

Items available from Roche Diagnostics:

- Chemstrip 10 MD urine test strips, 100 tests
- Chemstrip 10 with 5G urine test strips, 100 tests
- Chemstrip 9 urine test strips, 100 tests
- Chemstrip 7 urine test strips, 100 tests
- Chemstrip 5 OB urine test strips, 100 tests
- Chemstrip 2 GP urine test strips, 100 tests
- Chemstrip 2 LN urine test strips, 100 tests

References
8. Keeton A. Abstracts of papers presented at the 129th meeting of the American Chemical Society, p. 31c. Dallas, April, 1956.

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