CHEMSTRIP 10 WITH SPECIFIC GRAVITY (SG) - URINE TEST STRIP

PURPOSE

Rapid, semi-quantitative measurement of multiple urine chemistry parameters at the point of care. The test is useful in the initial evaluation and monitoring of renal, urinary, and metabolic disorders.

PRINCIPLE

The CHEMSTRIP urine test system (Roche Corporation) is a multi-parameter test strip that simultaneously measures specific gravity, pH, nitrite, protein, glucose, ketones, leukocytes, and blood in urine. Different reagent pads attached to inert plastic strips change color as they react with the various constituents to be measured. The color change provides semiquantitative measurements which are read visually against a standard color chart on the test strip container.
See the package insert for individual principles and composition of reagent pads.

**TESTING PERSONNEL**

- Qualified Licensed Registered Nurses (RNs) and approved Health Care Providers

**SPECIMEN**

- Freshly voided urine collected in a clean container deep enough to allow complete immersion of the reagent pads on the test strip. Do not use preservatives.

- Stability: Perform testing within one hour of collection.

- Specimen labeling is not required when testing is performed in the presence of the patient and only the sample from one patient is tested at a time. If the potential for specimen mix-up exits, the specimen container must be labeled with patient’s full name and medical record number.

**REAGENTS AND SUPPLIES**

1. Chemstrip 10 with SG, Roche Corporation. Available through Materials Management. Date container and record the lot number when the container is opened.

2. Absorbent paper or gauze.

3. KOVA Liqua-Trol normal and abnormal controls. Controls are stored in the Clinical Laboratory, and may be obtained from the POCT Service. Ranges for new lot(s) of controls are verified by the Hematology Division prior to expiration date of the old lot(s).

   Store controls at 2 - 8° C until the expiration date located on the label(s). Do not freeze.

4. Timer.

**QUALITY CONTROL:**

1. Abnormal and normal controls are run daily by qualified ward/clinic personnel.
2. Remove the controls from the refrigerator and warm for 15 minutes to room temperature (18 - 30º C).

3. The lot number on the bottle of KOVA Liqua-Trol should be the same as the lot number on the record form. Check the expiration date. Control bottle should have date opened on it. This date should also be on the record form.

4. Gently swirl the control to assure good mixing, open the vial cap and apply KOVA Liqua-Trol directly onto the reagent strips with a spraying technique. Hold the reagent strip horizontally, ensure good pad saturation and remove excess control by tilting the reagent strip on its edge on a paper towel. Each pad should be thoroughly moistened.

5. Read the urine dipsticks following the same procedure as patient specimen.

6. Promptly recap the bottle and return the controls to refrigerated storage.

PROCEDURE:

A. Using two patient identifiers, verify patient’s identity, and explain procedure to patient and/or family.

B. Observe universal precautions; wear gloves and other personal protective equipment as appropriate.

C. Urine should be in a container that permits complete immersion of the test strip reagent area. Mix the urine thoroughly before testing.

D. Remove a strip from the container. Close the container immediately. Prolonged exposure of strip to air can cause false positive results. Check strip against color blocks on Chem 10 container to ensure no pad has been prematurely activated.

E. Briefly (no longer than 1 second) dip the test strip into the urine. The entire test strip reagent area must be totally immersed.

F. Draw the edge of the strip along the rim of the specimen container to remove excess urine.

G. On a piece of absorbent paper or gauze, turn the strip on its side and tap once to remove excess urine and to prevent possible mixing of chemicals.

H. Holding the strip close to the color blocks on the Chemstrip 10 container and orienting the strip to the color chart on the container, match the color of each pad to a corresponding color on the container.
All values may be read between:

- specific gravity: 60 seconds
- pH: 60 seconds
- leukocyte esterase: 60-120 seconds
- nitrite: 60 seconds
- protein: 60 seconds
- glucose: 60 seconds
- ketones: 60 seconds
- blood: 60 seconds

**Caution:**

- False positive protein result may be obtained if the urine pH is >9
- Reagent pad colors are stable up to 120 seconds after immersion. Color changes that occur after 2 minutes from immersion are irrelevant and should be ignored. Color changes that occur only along the edge of the test pads should be ignored as well (careful removal of excess urine should eliminate this effect).

**REPORTING RESULTS**

Report the results in the medical record as read off the standardized color chart:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Normal Result</th>
<th>Abnormal Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific Gravity</td>
<td>1.000 – 1.030</td>
<td>&lt; 1.000 or &gt;1.030</td>
</tr>
<tr>
<td>Leukocyte Esterase</td>
<td>Negative (“neg”)</td>
<td>1-3+</td>
</tr>
<tr>
<td>pH</td>
<td>5.0 - 9.0</td>
<td>&lt; 5.0 and &gt; 9.0</td>
</tr>
<tr>
<td>Nitrite</td>
<td>Negative (“neg”)</td>
<td>1-3+</td>
</tr>
<tr>
<td>Protein:</td>
<td>Negative (“neg”)</td>
<td>1-3+</td>
</tr>
<tr>
<td>Glucose:</td>
<td>Normal (“neg”)</td>
<td>1-4+</td>
</tr>
<tr>
<td>Ketones:</td>
<td>Negative (“neg”)</td>
<td>1-3+</td>
</tr>
<tr>
<td>Blood</td>
<td>Negative (“neg”)</td>
<td>1-3+</td>
</tr>
</tbody>
</table>

- Reporting can be in a designated place on the physical examination record or as part of the progress note.
PROCEDURE NOTES:

A. Bilirubin and urobinogen are not reported.

B. Staff approved to perform this Point of Care Test must first pass Color Discrimination Testing provided by Occupational Health or the Clinical Laboratory.

LIMITATIONS

A. Glucose Test

False positive results may be produced by strong oxidizing cleaning agent residues in the urine container. False negative results may occur due to high concentrations of ascorbic acid from ingestion of vitamins, antibiotics or fruit juices. At glucose concentrations of 100 mg/dL and above, this effect has been eliminated, so that false negative readings should be rare, even at high concentrations of ascorbic acid.

B. Protein Test

The following may cause false positive readings:

1. strongly basic urine (pH 9 or higher);
2. therapy with phenazopyridine;
3. with infusion of polyvinylpyrrolidone (found in blood substitutes);
4. residues of disinfectants containing quaternary ammonium groups or cholorhexidine in the urine container.

REFERENCES:

1. Package Insert provided by Roche Corporation for Chemstrip 10 with SG, 2007-01.

2. Package Insert provided by HYCOR Biomedical, Inc., KOVA Liqua-Trol. 10/06.


DISTRIBUTION:

A. POCT Master Procedure Binder (2M 14)

C. Approved Point of Care Testing locations.
SIGNED: Zane Amenhotep, MD, Division Chief Hematology; Eberhard Fiebig, MD, Director