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48667.268 CHEMSTRIP 10 WITH SPECIFIC GRAVITY (SG) - URINE TEST STRIP

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Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Periodic review	Designated Reviewer	4/23/2020	1.0	Caroline Tolman-Salinas Caroline Tolman-Salinas	
Approval	Lab Director	5/29/2018	1.0	Barbara Haller, MD, PhD Barbara Haller	
Approval	Laboratory Manager	5/29/2018	1.0	Mary Eugenia-Allen Mary Allen	
Approval	POCT Senior Supervisor	5/22/2018	1.0	DEBORAH NEGRI	

Signatures from prior revisions are not listed.

Prior History

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.0	Approved and Current	Initial version	5/15/2018	5/29/2018	Indefinite

Author: Original: Margaret Fong, Carol Hogan; Revising: Caroline Tolman-Salinas
Approved by Barbara Haller on 5/29/2018.
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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 semi-quantitative 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. Store test trips at 2-30ºC. 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. 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 - 8º 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:

Parameter	Normal Result	Abnormal Result
Specific Gravity	1.000 – 1.030	< 1.000 or >1.030
Leukocyte Esterase	Negative (“neg”)	1-3+
pH	5.0 - 9.0	< 5.0 and > 9.0
Nitrite	Negative (“neg”)	1-3+
Protein:	Negative (“neg”)	1-3+
Glucose:	Normal (“neg”)	1-4+
Ketones:	Negative (“neg”)	1-3+
Blood	Negative (“neg”)	1-3+

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

PROCEDURE NOTES:

A. Bilirubin and urobilinogen are not reported.

B. 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 chlorohexidine 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.

3. McPherson RA and Pincus MR (eds.). Henry's Clinical Diagnosis and Management by Laboratory Methods. 21st ed., pp. 397-407; 2007.

DISTRIBUTION:

A. POCT Master Procedure Binder (2M 14)

C. Approved Point of Care Testing locations.