Memorial Surgery Center at Ridgeview Document

ROCHE CHEMSTRIP 9 URINALYSIS

PURPOSE:

Chemstrip urine testing system is a multi-parameter strip to measure certain constituents in the urine. These measurements are useful in the evaluation of renal, urinary and metabolic disorders. Chemstrip urine tests are inert plastic strips to which are attached different reagent pads for determining pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, blood and hemoglobin in urine. 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 pad.

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. No additional instrumentation is required.

Test Principle: *Brief description 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 5-9. Colors range from orange through yellow and green to blue.

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

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

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

Glucose: Glucose detection is based on the enzymatic glucose oxidase/peroxidase 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 chromagen tetramethylbenzidine to form a green dye complex. A positive reaction is indicatedby a color change from yellow to green.

Ketones: Based on the principle of Legal’s test, sodium nitroprusside and glycine react with acetoacetate and acetone in an alkaline medium to form a violet dye complex. A positive result is indicated by a color change from beige to violet.

Urobilinogen: Urobilinogen is coupled with 4-methoxylbenzene-diazonium-tetraflouroborate in an acid medium to form a red azo dye.

Bilirubin: The detection of bilirubin is based on the coupling reaction of a diazonium salt with bilirubin in an acid medium. The application of 2,6-dichlorobenzene-diazonium-tetrafluoroborate, however which is

used in the test strip is unique. This yields a pink to red-violet color proportional to the total bilirubin concentration.

Blood/Hemoglobin: The chemical detection of blood is based on the strong pseudoperoxidase action of erythrocytes and hemoglobin. Hemoglobin and myglobin, if present, catalyze the oxidation of the indicator by 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 µL of urine, more erythrocytes become visible than would correspond to 1 µL. Separate sets of interpretation color blocks are given for erythrocytes and hemoglobin. Scattered or compact green dots on the yellow test pads are indicative of intact erythrocytes. A uniform green coloration of the test is indicative of free hemoglobin, myglobin, or hemolyzed erythrocytes in the urine.

SPECIMEN:

A random urine specimen. Use universal precautions whenever handling blood or body fluids. Including gloves.

Optimum: A first morning urine specimen that is collected midstream and has a volume of 10 ml. The specimen should be tested as soon as possible. Do not centrifuge or use preservatives. If not processing testing within 2 hours, immediately refrigerate. Protect specimen from direct light and refrigerate no longer than 8 hours. Bring back to room temperature prior to testing. Mix all samples well prior to testing.

Minimum: 2 ml of urine, exceptions being: pediatric samples and cath samples.

Unacceptable specimen: A specimen more than 2 hours old and unrefrigerated. Any urine specimen unlabeled or in an uncapped container or a specimen in a nonsterile container. An unacceptable specimen must be documented in the patient report.

Note: A urine more than 2 hour old unrefrigerated is unacceptable for analysis. Telephone patient and request a new specimen if that is possible. If they cannot recollect, the requesting provider must be called to explain the situation. Explain the unsuitability of such a specimen (the possible loss of any RBC casts, and other formed elements, the increase in protein and bacteria, the decrease of glucose, ketones, bilirubin and urobilinogen). If the provider insists on a urinalysis under those conditions, perform the urinalysis, but add the message:

"Results may be erroneous due to delayed transport of specimen"

MATERIALS:

- Urine Reagent Cobas Chemstrip 9 11895427
- Quality Control Material: MAS level 1 and MAS level 2 urine control.
- Timer
- Clean urine container

QUALITY CONTROL:

Two levels of control 1 and 2 (negative and positive) are performed every morning of use. Results are recorded on the Quality Control log.

Test known positive and negative controls are also performed if one of the below applies:

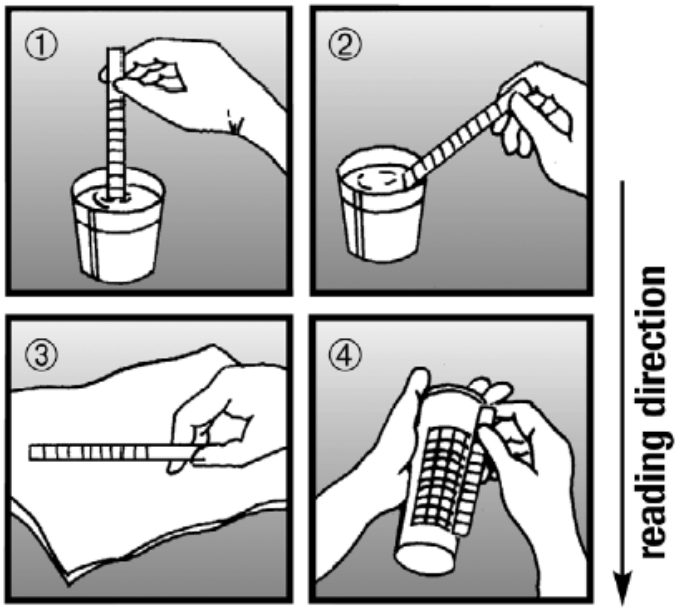
• A new canister of strips is opened
• A new operator uses the strips during training
• Test results seem inaccurate
• After performing maintenance or service on the analyzer

If the QC tests do not provide expected results, perform the following checks:
• Ensure the strips used are not past their expiration date.
• Ensure strips are fresh from a new canister.
• Ensure the controls are not past their expiration date.
• Repeat the test to ensure no errors were made during the test.
Call 1-800-428-4674 for technical assistance.

QUALITY ASSURANCE:
Quality Control logs will be reviewed monthly.
User Competency will be assessed annually.
Test result audits will be performed when clinic rounding takes place.

CALIBRATION:
N/A

PROCEDURE:
1. Take a test strip out of the container. Close the container again with the original desiccant stopper immediately after removal of the strip. This is important as otherwise some test areas may become discolored due to moisture and incorrect results may be obtained. Do not use discolored strips. In case of doubt perform a quality control test.
2. Mix the urine sample well.
3. Briefly, no longer than 1 second, dip test strip into the urine. Ensure all the pads are totally immersed. (Figure 1)



4. Draw the edge of the strip along the rim of the specimen container to remove excess urine. (Figure 2)

5. Turn the test strip on its side and press against a piece of absorbent paper to remove any remaining urine. (Figure 3)
6. After the appropriate time read the test (Figure 4): 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.
7. Color change after 3 minutes from immersion are not of clinical value. Color changes that occur only along the edge of the test pad should be ignored. Careful removal of excess urine (Figures 2 and 3) should eliminate this effect.
8. Record results on log sheet and in patient record.

RESULT REPORTING:

- **Color:** Report as colorless, straw, yellow, amber, or whatever color you see.
- **Appearance**: Report as clear, hazy, cloudy or turbid.
- **pH**: Report as whole from 5.0 to 9.0.
- **Protein**: Report as negative, trace, 30 (1+), 100 (2+), or 500 (3+).
- **Glucose**: Report as normal, 50 mg/dL, 100 mg/dL, 250 mg/dL, 500 mg/dL or 1000 mg/dL.
- **Nitrite**: Positive, or Negative
- **Ketones**: Report as negative, small (1+), mod (2+), or large (3 +).
- **Bilirubin**: Report as negative, 1+, 2+, or 3+.
- **Blood/Hemoglobin:** Report as negative, trace, 50, or 250.
- **Urobilinogen**: Report as normal, 1, 4, 8 or 12.

REFERENCE RANGES:

- **Color**: colorless, straw, yellow
- **Clarity**: *Male*: clear ; *Female*: clear, hazy
- **pH:** 5.0 - 8.0
- **Protein:** negative
- **Glucose:** negative
- **Ketones:** negative or 1+ when fasting
- **Bilirubin**: negative
- **Blood/Hemoglobin:** negative on *males* and *non-menstruating females*
- **Urobilinogen**: normal to 1.0
- **Leucocyte Esterase**: *Male*: negative ; *Female*: negative

LIMITATIONS OF PROCEDURE:

pH: No known interferences when handled according to instructions.

Leukocytes: This test is not affected by erythrocytes in concentrations up to 10,000/µL or by bacteria common in urine. Specimens should not be collected in containers that have been cleaned with strong oxidizing agents. Do not use preservatives. The drugs cephalexin and gentamicin have been found to interfere with this test. In addition nitrofurantoin colors the urine (dark yellow or brown) and this effect interferes with visual interpretation of the test strip. High levels of albumin (≥500 mg/dL) in the urine and urinary glucose excretions in excess of 1 g/dL may interfere with test results. Studies show that formaldehyde and medication with imipenem, meropenem and clavulanic acid may cause false positives.

Nitrites: Large amounts of ascorbic acid decrease the sensitivity of the test. False-positive readings may be produced by medication that colors the urine red in acid medium (phenazopyridine).

Protein: False-positive results may be found in strongly basic urine (ph 9 or higher), during therapy with pheazopyridine, when infusions of polyvinylpyrrolidone (blood substitutes) are administered, and when residues of disinfectants containing quaternary ammonium groups or chlorohexidine are present in the urine container.

Glucose: The effect of ascorbic acid (Vitamin D) retained 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 sot that false-negative readings may only rarely occur, even at high concentrations of ascorbic acid. False-positive readings may be produced by strong oxidizing cleaning agents in the urine container.

Ketones: Phenylketone or phthalein compounds that may be administered for liver and kidney function tests can produce red-orange to red color shades which, are however, readily distinguishable from the colors obtained with ketone bodies. 2-Mercaptoethane sulfonate sodium (MESNA) or other sulfhydryl-containing compounds may cause false-positive results.

Urobilinogen: The total absence of urobilinogen cannot be detected. Most normal urines give a slight pink reaction. The test gives the color reaction with urobilinogen as with stercobilinogen; however, the differentiation is not of diagnostic importance. Urine from patients who are being treated with phenylazopyridine may show a false-positive reaction. Nitrite concentrations above 5 mg/dL or formaldehyde concentraions above 200 mg/dL (as a preservative) may cause a decrease in the color reaction.

Bilirubin: Large amounts of ascorbic acid present in urine following the ingestion of medication containing vitamin C or fruit juices lower the sensitivity of the test. In case of doubt, the test should be repeated on urine voided at least 10 hours after the last administration of vitamin C. Elevated concentrations of nitrite, as in urinary tract infections, may result in lower bilirubin values. Large amounts of urobilinogen in the urine affect the color change of the bilirubin test, but not enough to get a positive test. False-positive readings may be produced by medication that colors the urine res, or which turns red in an acid medium (phenazopyridine).

Blood/Hemoglobin: False negative readings are obtained when formalin is used to preserve the urine. Nitrite in excess of 10 mg/dL in the urine (which is rare in UTIs) delays the reaction. False-positive 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.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

RELATED DOCUMENTS:

UA QC Log

REFERENCES:

Cobas Chemstrip 2 GP, 2 LN, 9, 10 with SG Package insert

DOCUMENT REVIEW:

Authored/ Revised By: Emily Gaulke, MLS (ASCP)[CM]
Laboratory Director: Dennis Gaskill, MD 11/25/2021
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