PROCEDURE: MACROSCOPIC URINALYSIS

ISSUE DATE: January 2001
REVISION DATE: February 2011
REVIEWED DATE: March 2017

PRINCIPLE:
A macroscopic urinalysis consists of the examination of the chemical characteristics of urine as well as visual determination of color and clarity to complete the examination process. Siemens Multistix 9 or 10SG reagent strips for urinalysis include test pads for protein, blood, leukocytes, nitrite, glucose, ketone, pH, bilirubin, and urobilinogen. Multistix reagent strips are intended for use to assist diagnosis in kidney function, urinary tract infections, carbohydrate metabolism (e.g. diabetes mellitus), and liver function. The strips also measure physical characteristics, including acid-base balance and urine concentration. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic evaluation is needed. Multistix reagent strips are ready to use upon removal from the bottle and the entire reagent strip is disposable. The reagent strips are for in vitro diagnostic use. They have been determined to be nonhazardous under the guidelines issued by OSHA in 29 CFR 1910.1200(d).

STORAGE:
Store Multistix 10 reagent strips at room temperature (15-30°C) out of direct sunlight. All unused strips must remain in the original bottle. Transferring to any other container may cause reagent strips to deteriorate and become nonreactive. MultiStrips are good until the manufacturer's expiration date on the vial, unless the strips are discolored or exposed to misture. Do not remove the desiccant from the bottle. Protection against exposure to light, heat, and ambient moisture is mandatory to guard against altered reagent activity.

SPECIMEN
10 mL (optimal) freshly voided, well mixed urine. Do Not centrifuge urine. Minimum volume = 1mL. Specimen must be labeled with patient identification. If the urinalysis can not be performed within 30 minutes, the urine should be refrigerated.

UNACCEPTABLE SPECIMENS:
1. Any specimen left at room temperature more than 2 hours.
2. Any refrigerated specimen greater than 8 hours old.
3. Grossly bloody specimens should be sent to the core laboratory for analysis

REAGENTS/MATERIALS
1. Multistix dipsticks
2. Quantimetrix - The Dropper Plus Level 1 and 2.

PROCEDURE - QUALITY CONTROL
1. Remove two dipsticks. Remove cap from Dropper Plus 1 and invert bottle. While holding dipstick, gently squeeze the sides of the dropper bottle and touch the tip of the bottle to the dipstick. Draw across all of the reagent pads, thoroughly saturating each pad. Do not aspirate excess control back into the bottle. Wipe tip with tissue or paper towel. Turn dipstick on its side and drain excess control onto absorbent material. Repeat process for Dropper Plus 2.

2. Read results carefully at the times specified in good light and with the test area held near the appropriate color chart on the bottle label. PROPER READ TIME IS CRITICAL FOR OPTIMAL RESULT.
3. Record the results on the Urine QC Log sheet. Compare the levels to the tolerance values posted on the package insert (make sure that the lot numbers of the control bottles match lot number on the tolerance value sheet). Recap controls. Record results Pos or Neg or as indicated on the vial.

4. If not within limits, repeat testing with another dipstick. If not within limits again, try a new vial of Quantimetrix. If the test fails again, repeat test with a dipstick from a new vial of dipsticks. If difficulties continue, call the Core lab and send the specimen to the laboratory for testing. **DO NOT CONTINUE WITH PATIENT TESTING.**

5. Results must be reported and initialed on the Urine Control Log sheet. QC records will be reviewed by the laboratory Point-of-Care Testing office. Quality Control testing must be performed each day of patient testing. Compliance is 95% or better monthly.

6. Quality control material is stable for 1 month at room temperature. Discard after this time.

7. Additional urine control material is available from the Core Lab at Ext. 44268

**PROCEDURE - PATIENTS**

1. Submerge dipstick in the urine sample. Remove immediately, running the edge of the strip against the rim of the container to remove excess urine. Hold the strip in a horizontal position to prevent possible mixing of chemicals from adjacent areas.

2. Read results carefully at the times specified in good light with the test area color chart on the bottle label.

3. Record result in the appropriate location of the patient chart. A Urine patient log is available to use, or result directly in SLCH patient chart. Record results as Pos or Neg or as designated on the vial of strips.

4. Values not consistent with clinical findings should be confirmed by a clinical laboratory test method.

**LIMITATIONS:**

1. Substances that cause abnormal urine color may affect readability of reagent areas on strip. The color development may be masked or a color produced that could be interpreted as a false positive. Results should include a notation of urine color and a comment about the possible false positive results.

2. Protein: visibly bloody urine may cause falsely elevated results.

3. Blood: Capoten (carperit) may reduce the sensitivity. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction.

4. Leukocytes: Elevated glucose concentrations (> 3 g/dL) may cause decreased test results. The presence of cephalaxin, cephalothin, or high concentrations of oxalic acid may also cause decreased test results. Tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. Positive results may occasionally be due to contamination of the specimen by vaginal discharge.

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5. Nitrites: Pink spots or pink edges should not be interpreted as a positive result. A negative result does not rule out significant bacteriuria. False negative results may occur with shortened bladder incubation of the urine, absence of dietary nitrate, or the presence of nonreductive pathologic microbes.

6. Glucose: Ketone bodies reduce the sensitivity of the test; moderately high ketone levels (40 mg/dL) may cause false negatives for specimens containing small amounts of glucose (75-125 mg/dL), but the combination of such ketone levels and low glucose levels is metabolically improbable in screening.

7. Ketone: False trace results may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Compounds such as mesna (2-mercaptoethane sulfonic acid) that contain sulfhydryl groups may cause false positive results or an atypical color reaction.

8. Bilirubin: Indican (indoxyl sulfate) can produce a yellow-orange to red color response that may interfere with the interpretation of a negative or positive reading. Metabolites of Lodine may cause false positive or atypical results. Atypical colors (colors that are unlike the negative or positive color blocks shown on the color chart) may indicate that bilirubin-derived bile pigments are present in the urine sample and may be masking the bilirubin reaction.

9. Urobilinogen: The test pad may react with interfering substances such as p-aminosalicylic acid and sulfonamides. Atypical color reactions may be obtained if formalin is present. Strip reactivity increases with temperature; the optimum temperature is 22-26°C. The test is not a reliable method for the detection of porphobilinogen.

10. Bilirubin and urobilinogen are very unstable when exposed light.

11. Contamination of the urine specimen with skin cleaners containing chlorhexidine may affect protein, bilirubin and specific gravity test results.

**REFERENCE RANGE:**
Specific gravity values normally range between 1.008 and 1.022 depending on fluid intake

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Normal</th>
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</thead>
<tbody>
<tr>
<td>pH</td>
<td>5 – 8</td>
</tr>
<tr>
<td>Protein</td>
<td>Negative</td>
</tr>
<tr>
<td>Glucose Qual.</td>
<td>Negative</td>
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<tr>
<td>Ketones Qual.</td>
<td>Negative</td>
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<tr>
<td>Bilirubin Qual.</td>
<td>Negative</td>
</tr>
<tr>
<td>Urobilinogen</td>
<td>0.2-1.0 Ehrlich units/dL</td>
</tr>
<tr>
<td>Nitrites</td>
<td>Negative</td>
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<tr>
<td>Leukocyte Esterase</td>
<td>Negative</td>
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REFERENCES:


