Title: Urine Dipstick Visual Procedure
Cross References: Urine Dipstick Visual Training and Competency Record
Urine Dipstick Visual Quality Control Log Outpatient sites
Urine Dipstick Visual Quality Control Log PCS
MGH POCT QC Storage Ordering and Documentation Guide

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This document outlines policies and procedures that deal with the test being described. In an effort to be concise some information may be excluded from the manufacturer’s recommended procedure. It is recommended that operators familiarize themselves with the manufacturer’s product information that accompanies each package.

**Level of Personnel:** All RNs, NPs, PCAs, MAs, who have successfully completed initial training and maintained annual competency.

**Testing Site:** All sites approved and on file with the Pathology Service’s POCT Division

### Scope

Urine test strips are used for screening: Glucose, Ketone, Specific Gravity, Blood, pH, Protein, Nitrite*, and Leukocytes. (*The Department of Patient Care Services does not utilize nitrite.)

Urine test strips may also be used as a definitive test in managing selected drug therapies. Refer to attending physician for positive results.

Additional information can be found in the manufacturer’s insert provided with each container and in the reference section of this procedure.

### Regulatory Requirements

1. Each testing site must have a documented quality control program, which is developed in collaboration with or has been approved by the MGH Pathology Service.

2. All test results must be maintained in patient records with all required information for four years

   Required information:

   1. Patient’s name
   2. Medical Record Number
   3. Patient’s gender
   4. Patient’s age or date of birth
   5. Date & time test collected, performed and reported
   6. Ordering Physician
   7. Responsible physician (if not 6)
   8. Reference or Target Range
   9. Test Performed
   10. Test units
   11. Lab name

3. Additional information that must be retained for four years:

   1. Testing personnel records
   2. Quality control results
   3. Product information (i.e. serial number, lot numbers, expiration dates, etc.), information on quality control and any remedial action
   4. QC charts, maintenance sheets, reference and critical ranges

4. Other

   1. Universal precautions must be observed when handling any patient specimen.
   2. A physician’s order or standing order is required prior to performing test.
   3. The Hospital Hand Hygiene policy must be adhered to at all times.

### Critical Elements

1. Test strips are stored at room temperature.

2. The test strip container must be labeled with date QC’d and initialed.
3. Opened containers must be closed immediately after removal of strip, using the original lid, in order to avoid exposure to moisture.

4. Quality Control must be performed whenever a new container of strips is opened, every 30 days, and whenever a container is found open (see QC procedure).

5. Test pads MUST be read within specific time intervals. Leukocytes must always be read last at the 2 minute mark.

### Test Kits/Supplies/Equipment

<table>
<thead>
<tr>
<th>Product</th>
<th>Vendor</th>
<th>Manufacturer #</th>
<th>Peoplesoft #</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traceable Instant-Recall Memory Timer</td>
<td>Fisher Scientific</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Strips Bayer</td>
<td>Owens and Minor</td>
<td>03372164PHC</td>
<td>PS#28143</td>
<td></td>
</tr>
<tr>
<td>Multistix 8 SG</td>
<td>Siemens</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermo Fisher Sentry Urine Dipstick Controls</td>
<td>Fisher Scientific</td>
<td>URN5005</td>
<td>Thermo Scientific #23-029-375</td>
<td>Note: On Campus Patient Care Service sites should e-mail MGH POCT Coordinator or page 35058 for Controls. All Other Sites must purchase product from outside vendor. Request “longest outdating possible.”</td>
</tr>
</tbody>
</table>

### Specimen Collection
Collect FRESH urine specimen in a clean, dry container. Mix well before testing.

Use PACE labels if available. Place the label on the bottle and NOT on the cover. All labeling must have two patient identifiers per hospital policy.

### Visual Test Procedure

<table>
<thead>
<tr>
<th>Action</th>
<th>Consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Mix urine well prior to testing.</td>
<td>Samples not well mixed may give inaccurate results.</td>
</tr>
<tr>
<td>2. Remove one strip from container and REPLACE CAP.</td>
<td>Replace cap immediately to avoid exposure to moisture to remaining strips.</td>
</tr>
<tr>
<td>3. QUICKLY IMMERSE reagent area of the strip COMPLETELY in fresh urine.</td>
<td>Dip and remove immediately to avoid dissolving the reagent.</td>
</tr>
<tr>
<td>4. Remove excess urine by drawing edge of strip along the specimen container rim then blot edge of strip on a paper towel.</td>
<td>Do not to touch pads on the paper towel.</td>
</tr>
<tr>
<td>4. Hold strip in a flat, horizontal position.</td>
<td>This avoids possible mixing of dyes and chemicals from adjacent pads.</td>
</tr>
</tbody>
</table>
5. Compare reagent pads to corresponding Color Chart on the bottle label. Hold the strip close to the color blocks and match carefully and reading pads from bottom (glucose) to top (Leukocytes).

**READ TIMES ARE CRITICAL.** Some colors continue to intensify for a short time and then fade.

<table>
<thead>
<tr>
<th>ANALYTE</th>
<th>READ TIME after DIP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>30 seconds</td>
</tr>
<tr>
<td>Ketone</td>
<td>40 seconds</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>45 seconds</td>
</tr>
<tr>
<td>Blood</td>
<td>60 seconds</td>
</tr>
<tr>
<td>pH</td>
<td>60 seconds</td>
</tr>
<tr>
<td>Protein</td>
<td>60 seconds</td>
</tr>
<tr>
<td>Nitrite</td>
<td>60 seconds - not approved for P.C.S. staff</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>120 seconds</td>
</tr>
</tbody>
</table>

**COLOR CHANGES THAT OCCUR 2 MINUTES AFTER DIPPING HAVE NO DIAGNOSTIC VALUE.**

**Documentation**

Results must be recorded in one of the following manners:

1. in the patient’s record, or
2. on a patient log or
3. on another approved permanent record.

**Note:** All records must be retained and retrievable for 4 years.

**Quality Control (QC)**

**Critical Elements:**

1. The Sentry Urine Dipstick control solutions must be dated and initialed when opened.
2. Sentry controls should be refrigerated when not in use, but are stable for 6 months when stored at room temperature.
3. The QC test results and remedial action (if any) must be documented on the QC log.
4. Label the test strip container with the date the QC was performed and your initials. (This should be the same date as when the container was initially opened).

**Q.C. Procedure:**

<table>
<thead>
<tr>
<th>Actions</th>
<th>Consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Remove the controls from the refrigerator and allow to reach room temperature prior to testing.</td>
<td>Controls should be returned to the refrigerator immediately after use, but are stable for 6 months at room temperature</td>
</tr>
<tr>
<td>2. Take the normal Sentry QC bottle and compare the lot number on the QC log with the number of the bottle; they should match.</td>
<td>A new QC log must be used when a new QC lot is used.</td>
</tr>
</tbody>
</table>
3. Gently swirl solution, flip open the dropper tip cap, invert and apply Sentry urine control directly onto the reagent strips by gently squeezing the bottle. The reagent strip should be held horizontally, ensure good pad saturation and remove excess control by tilting dipstick on its edge and blot on a paper towel. Recap control vial.

Test pads should not touch paper towel. Test pads must be thoroughly soaked to ensure uniformity during readings.

4. Read the urine dipsticks pads within recommended time intervals.

Reading pads within specified time intervals is essential. Not doing so may give erroneous results.

5. Document results on log for each pad.

6. Compare with expected ranges.

Manufacturer ranges must be confirmed when new lot of QC is received. See QC reference range section below.

7. If outside expected ranges, reapply to pad that failed.

8. If still outside of range, see troubleshooting section or contact POCT Coordinators.

9. If acceptable, repeat 2-7a using abnormal level

10. Recap both controls and return to refrigerator

QC Acceptable Range Validation:
The quality control manufacturer provides target ranges on the package inserts that accompany the control material. However, these reference ranges may vary with strip and quality control lots. Whenever a new strip or quality control lot is used, the expected reference range must be verified.

Manufacturer’s ranges are validated for use by the test sites (see Range verification). Due to the size and scope of Patient Care Services, a single lot of quality control material is centrally stored and ranges validated by the POCT program. A single lot of test strips are sequestered at Owens and Minor to reduce the variability of lots. Log sheets with the pre-printed lot numbers and ranges are posted on the POCT website. Test sites may utilize the same ranges if they obtain the same lot numbers.

Once the range is validated, it is to be used to determine acceptable performance of the urine dipsticks. Should the results obtained fall outside the expected reference range, the quality control must be repeated. If the repeat fails again, refer to the troubleshooting section or contact the POCT Coordinators. Document remedial action taken using CA codes under the troubleshooting section. Patient samples should not be tested until the problem has been corrected.

Manufacturer’s QC Range Verification (Sites not reporting to Patient Care Services & Sites Off-Campus)

1. Analysis of QC:
   A. Dip and read the normal urine control solution, adhering to the proper read times shown on the Reagent Strip Vial (Multistix 8SG). Record the result on the QC log.
   B. Compare the results obtained with the ranges printed on the Quality Control package insert. (IMPORTANT: Q.C. lot numbers on QC product and package insert must match.)
   C. If values are within the reference ranges provided by the QC manufacturer, record the manufacturer’s ranges on a new urine dipstick control log. This will be your new QC range. Repeat steps A and B with abnormal urine control solution.
   D. If values obtained are outside the reference range provided by the QC manufacturer, notify the MGH POCT Coordinators at x61462 or 3-5392 and document corrective action taken (use codes found in troubleshooting section).

2. Keep the package insert with the QC logs and retain them for 4 years.

3. A new QC log should be used whenever a new QC lot or strip lot is used.
Documentation:
All quality control results and other required information must be recorded on the QC log (Appendix C for Patient Care Services and Appendix D for non-Patient Care Services).

Troubleshooting and Corrective Action

<table>
<thead>
<tr>
<th>Possible Causes</th>
<th>Reason</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tests are not read within designated read time intervals</td>
<td>Each test pad must be read within specific time windows for accurate results.</td>
<td>Repeat the test, reading the color change within the time designated on the color chart.</td>
</tr>
<tr>
<td>The cover on the strips is not tightly sealed.</td>
<td>Moisture can be absorbed by the pads, affecting the quality of the test.</td>
<td>If improperly stored, obtain fresh strips and retest.</td>
</tr>
<tr>
<td>QC material is not stored in the sealed refrigerator.</td>
<td>The QC product can deteriorate at room temperature or if the refrigerator door was not properly sealed.</td>
<td>If you suspect the product was not properly stored, retest using fresh control material.</td>
</tr>
<tr>
<td>Expiration dates were exceeded on strips and QC.</td>
<td>Products perform best when they are used before the expiration dates.</td>
<td>If expired, retest with fresh product(s).</td>
</tr>
<tr>
<td>Color is not uniform.</td>
<td>Incomplete or non-uniform wetting of pads will give non-uniform color reactions.</td>
<td>Repeat the test, properly soaking the pads.</td>
</tr>
<tr>
<td>Color is not uniform.</td>
<td>Excess material should be blotted and strips should be kept flat to avoid mixing of dyes from adjacent pads.</td>
<td>Soak pad(s), and then blot the end of the strip on a paper towel, using caution not to touch pads to the towel.</td>
</tr>
<tr>
<td>The reference range is not appropriate for strip or QC lots.</td>
<td>Specific strip lots are matched with specific QC lots.</td>
<td></td>
</tr>
<tr>
<td>The individual reading the pads may be color blind.</td>
<td>Individuals who are color blind may not be able to perform this test properly.</td>
<td>Ask someone else to perform this test for you.</td>
</tr>
</tbody>
</table>

CA Codes:  
- R = Retested within range  
- O = Retest still outside  
- S = New test strips or lot  
- C = New controls  
- T = Adjusted technique to reflect procedure  
- M = QC/strip lot not matched  
- E = Expiration dates exceeded  
- P = Contacted POCT Coordinator

Competency Assessment

A. Initial Orientation and Training
The competency assessment checklists are utilized to document operator training and competency. All operators must read the procedure manual and complete the “Training and competency assessment record” (Appendix A) after in-service training.

The training and competency assessment record (Appendix A) provides documentation for training and competency using the following methods:

1. Successfully Complete Learning Assessment Quiz
2. Direct observation performing two levels of quality control

B. Annual Competency (Appendix A), choose any two of the following:
   1. Successfully Complete Learning Assessment Quiz
   2. Successfully performing quality control
   3. Successful split sample comparisons

C. Expired Operators:
   Operators that fail to meet competency requirements within 365 days will be considered non-compliant and are not allowed to perform patient testing. The following requirements must be met to recertify:
   1. The operator will be required to undergo retraining
   2. The operator will be required to complete the “Learning Assessment Quiz” and one of the above-mentioned methods of competency.

References

Table 1: Laboratory Correlations of Urine Dipstick Results with Clinical Conditions

<table>
<thead>
<tr>
<th>Test</th>
<th>Clinical Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>Respiratory or Metabolic Acidosis&lt;br&gt;Respiratory or Metabolic Alkalosis&lt;br&gt;Defects in renal tubular secretion and re-absorption</td>
</tr>
<tr>
<td>Protein</td>
<td>Glomerular membrane damage&lt;br&gt;Impaired tubular re-absorption&lt;br&gt;Multiple myeloma&lt;br&gt;Preeclampsia&lt;br&gt;Orthostatic or postural proteinuria&lt;br&gt;Diabetic nephropathy</td>
</tr>
<tr>
<td>Glucose</td>
<td>Diabetes mellitus&lt;br&gt;Impaired tubular re-absorption&lt;br&gt;Pregnancy with possible latent diabetes mellitus.</td>
</tr>
<tr>
<td>Ketone</td>
<td>Diabetes ketoacidosis&lt;br&gt;Starvation</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>Hepatitis&lt;br&gt;Cirrhosis&lt;br&gt;Biliary obstruction</td>
</tr>
<tr>
<td>Nitrite</td>
<td>Cystitis&lt;br&gt;Pyelonephritis&lt;br&gt;Monitoring of patients at high risk for urinary tract infection&lt;br&gt;Screening of urine culture specimens</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Patient hydration and dehydration&lt;br&gt;Loss of renal tubular concentrating ability&lt;br&gt;Diabetes insipidus&lt;br&gt;Identification of unsatisfactory specimens due to low specific gravity</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>Urinary tract infection&lt;br&gt;Screening of urine culture specimens</td>
</tr>
</tbody>
</table>