Keywords: refractometer, SG, urine specific gravity

Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. PURPOSE</td>
<td>1</td>
</tr>
<tr>
<td>II. ORDER</td>
<td>1</td>
</tr>
<tr>
<td>III. MATERIALS</td>
<td>2</td>
</tr>
<tr>
<td>IV. REAGENTS AND STORAGE</td>
<td>2</td>
</tr>
<tr>
<td>V. SAFETY PRECAUTION</td>
<td>2</td>
</tr>
<tr>
<td>VI. SAMPLE COLLECTION AND LABELING</td>
<td>2</td>
</tr>
<tr>
<td>VII. CLEANING</td>
<td>2</td>
</tr>
<tr>
<td>VIII. QUALITY CONTROL AND CALIBRATION</td>
<td>3</td>
</tr>
<tr>
<td>IX. PATIENT TESTING</td>
<td>4</td>
</tr>
<tr>
<td>X. RESULTS REPORTING</td>
<td>4</td>
</tr>
<tr>
<td>XI. REFERENCE RANGE</td>
<td>5</td>
</tr>
<tr>
<td>XII. LIMITATIONS</td>
<td>5</td>
</tr>
<tr>
<td>XIII. TRAINING</td>
<td>5</td>
</tr>
<tr>
<td>XIV. COMPETENCY</td>
<td>5</td>
</tr>
<tr>
<td>XV. PROFICIENCY TESTING</td>
<td>5</td>
</tr>
<tr>
<td>XVI. CORRELATION SAMPLES</td>
<td>5</td>
</tr>
<tr>
<td>XVII. RELATED DOCUMENTS</td>
<td>6</td>
</tr>
<tr>
<td>XVIII. APPENDICES</td>
<td>6</td>
</tr>
<tr>
<td>XIX. REFERENCES</td>
<td>6</td>
</tr>
<tr>
<td>XX. SPONSOR AND DEVELOPER</td>
<td>6</td>
</tr>
<tr>
<td>XXI. SIGNATURE</td>
<td>6</td>
</tr>
<tr>
<td>Appendix A: Blank QC Logsheet</td>
<td>Click Here</td>
</tr>
<tr>
<td>Appendix B: Blank Logsheet</td>
<td>Click Here</td>
</tr>
<tr>
<td>Appendix C: Refractometer User's Guide</td>
<td>Click Here</td>
</tr>
<tr>
<td>Appendix D: Specific Gravity Competency Assessment Checklist</td>
<td>Click Here</td>
</tr>
</tbody>
</table>

I. PURPOSE

This procedure provides instructions for performing urine specific gravity testing on Urine samples.

II. ORDER

A physician’s order, standard protocol or order by other healthcare professional authorized to request laboratory tests is required for urine specific gravity testing.
III. MATERIALS
The following materials are needed to perform this procedure.

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Supplies</th>
<th>Reagents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refractometer</td>
<td>• Deionized water (room temperature)</td>
<td>• Quantimetrix Urine Control Set</td>
</tr>
<tr>
<td></td>
<td>• Gauze pads</td>
<td>• Central Stores Item #32234</td>
</tr>
<tr>
<td></td>
<td>• Plastic transfer pipettes</td>
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IV. REAGENTS AND STORAGE
Urine controls are stable one month at Room Temperature (18 – 25 °C), (64 – 77 °F) or until manufacturer’s expiration date when stored refrigerated (2 – 8 °C), (35 – 46 °F).

Control vials should be dated by the user when opened depending on the storage temperature.

Deionized water can be aliquotted to a clean container and labeled as such with a one-week expiry.

Do not use controls or aliquotted water past their expiration dates.

V. SAFETY PRECAUTION
Adhere to all Standard Precautions and CDC handwashing guidelines when performing this procedure.

VI. SAMPLE COLLECTION AND LABELING
A. No special patient preparation is required.
B. Label the container in the presence of the patient using two patient identifiers to verify patient’s identity. The label should be placed on the container, not on the lid.
C. Provide the patient with a clean, pre-labeled urine container. The label should include the patient’s name, history number, date and time of collection.
D. If a transfer pipette is used, the label must be on the pipette.
E. ALL samples leaving the patient’s bedside must be labeled.
F. Do Not Centrifuge, use urine preservatives or refrigerate the sample before testing.
G. Test the urine as soon as possible after collection.

VII. CLEANING
Frequency: After each patient or QC sample.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
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<tbody>
<tr>
<td>1</td>
<td>Apply deionized water with a transfer pipette to the surface of the prism so it is covered.</td>
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</tbody>
</table>
Gently dry the prism surface and the plastic surface cover with a gauze pad. DO NOT USE BLEACH to clean the Refractometer.

VIII. QUALITY CONTROL AND CALIBRATION

Two levels of Quality Control are tested each day of use. Patient testing cannot be performed until the control levels have been run and are within the established ranges. A deionized water blank is also performed daily to check the calibration of the Refractometer.

1. Bring Quality Control specimens to room temperature.
2. Check expiration date of QC specimens.
3. Record the date, time, lot numbers and expiration dates of control vials on the Specific Gravity QC log sheet.
4. Close the surface cover plate on the Refractometer so its lays flat on the prism surface.
5. Holding the Refractometer horizontally, apply a drop of deionized water with a plastic transfer pipette to the notched bottom of the surface cover plate. The liquid will be drawn into the space between the surface cover plate and the prism surface by capillary action. Take care to avoid lifting the surface cover plate before the reading is made.
6. Point the Refractometer toward a light source at an angle that gives optimal contrast.
7. Rotate the eyepiece until the specific gravity scale is in focus.
8. Read the value on the scale where the sharp boundary line between the light and dark fields crosses the scale.
9. Deionized water should read 1.000 +/- 0.0005. If the reading is not 1.000 +/- 0.0005, reclean the Refractometer and repeat the test with water. If the reading is still not 1.000, STOP TESTING and contact the POCT office. Record all results on the QC log. Clean prism surface and surface cover plate with a gauze pad moistened with sterile water. Dry with a clean gauze pad.
10. Apply 1 drop of well-mixed Level 1 Normal Control to the notched bottom of the surface cover plate as described above. Continue as with Steps 6 through 8. Record the result on the QC log.
11. Use gauze moistened with sterile water to wipe the surface cover plate and prism surface. If surface cover plate is not well cleaned before the next sample is loaded, an erroneous or fuzzy reading may result.
12. Repeat steps 10 and 11 using the Level 2 Abnormal Control. Record the results on the QC log.
13. Compare the results to the acceptable ranges of the controls. If the control results are not within the acceptable range consult the corrective action flow chart on the next page.
IX. PATIENT TESTING
Patient specimens will only be analyzed after the operator has confirmed that acceptable QC has been performed and documented each day of use.

1. Obtain a properly labeled sample and ensure that it is well-mixed.
2. Close the surface cover of the Refractometer so that it lays flat on the prism surface.
3. Use a gauze pad moistened with water to wipe the surface cover plate and prism surface. Dry both areas with a gauze pad. If the prism surface cover plate is not cleaned well before the sample is loaded, an erroneous or fuzzy reading may occur.
4. Apply 1 drop of sample with plastic transfer pipette to the notched bottom of the surface cover plate. The liquid will be drawn into the space between the surface cover plate and the prism surface by capillary action.
5. Point the refractometer toward a light source at an angle that gives optimal contrast.
6. Rotate the eyepiece until the specific gravity scale is in focus.
7. Read the value on the scale where the sharp boundary line between the light and dark fields crosses the scale.
8. Clean the prism surface and surface cover plate with a gauze pad moistened with deionized water. Dry with a clean gauze pad.

X. RESULTS REPORTING
A. Record test results in the patient’s medical record with the collection date, time, Refractometer ID number and operator’s initials.
B. Patient specific gravity results will be noted in the patient’s chart in a manner that will distinguish POCT results from Core Lab results.
C. Results greater than 1.035 are reported as “>1.035.”
D. Unexpected results should be repeated on the same device or in the Core Laboratory.
XI. REFERENCE RANGE
Correlation with the Core Laboratory has been established, and the reference ranges adopted.

1.003 – 1.030

XII. LIMITATIONS
Limitations of refractometry include:

1. For in vitro use only
2. For use in temperatures between 16 °C (60 °F) and 38 °C (100 °F) for accurate results.
3. Instrument can be damaged by temperatures greater than 66 °C (150 °F)
4. Instrument eyepiece and focusing ring can be damaged by immersion into water.

XIII. TRAINING
Initial training includes:

1. Educator or unit-based training
2. My Learning Course and post-test
3. QC performed and observed by educator or unit-based trainer
4. Documentation on Operator Competency checklist

XIV. COMPETENCY
Ongoing competency will include:

A. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing
B. Monitoring the recording and reporting of test results
C. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
D. Direct observation of performance of instrument maintenance and function checks
E. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples
F. Evaluation of problem-solving skills

Competency will be evaluated 6 months after initial training and annually thereafter.

XV. PROFICIENCY TESTING
The Point-of-Care Testing Office provides the unit with proficiency test samples three times a year. These samples are tested by a staff member in the same fashion that a patient sample is tested. The testing of proficiency samples should be rotated among trained operators.

XVI. CORRELATION SAMPLES
The Point-of-Care Testing Office provides the unit with correlation samples twice a year. These samples are tested by a staff member in the same fashion that a patient sample is tested and should be rotated among trained operators. The results are compared to other results for specific gravity within the hospital that are tested using a Refractometer, urine dipstick or automation.
XVII. RELATED DOCUMENTS
1. Specific Gravity by Refractometer Correlations — HPO SG001
2. Proficiency Testing Handling, Performance and Documentation — HPO GEN001

XVIII. APPENDICES
1. Urine Specific Gravity Blank QC Logsheet
2. Urine Specific Gravity Blank Logsheet
4. Specific Gravity Competency Assessment Checklist

XIX. REFERENCES
4. Quantimetrix QC Dropper Plus Point-of-Care Urinalysis Dipstick Control Level 1&2 Package insert, Redondo Beach, CA 90278-1205 USA, M044741B-03/23

XX. SPONSOR AND DEVELOPER
Sponsor:
Pathology Performance Improvement
Developer:
Point of Care Testing Office
Review Cycle: Two (2) years

XXI. SIGNATURE

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<thead>
<tr>
<th>Electronic Signature(s)</th>
<th>Date</th>
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<tbody>
<tr>
<td>William Clarke Medical Director of Point of Care Testing</td>
<td>10/26/2023</td>
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<tr>
<td>Aaron Tobian CLIA Laboratory Director, Johns Hopkins Hospital</td>
<td>10/26/2023</td>
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