Keywords: clinitek, dipstick, status, urinalysis, urine

I. PURPOSE
This procedure provides instructions for performing urine dipstick testing using Multistix 10SG reagent test strips, utilizing the Clinitek Status+ Connect System. Multistix 10SG reagent test strips for urinalysis include test pads for protein, blood, leukocytes, nitrite, glucose, ketone, pH, specific gravity, bilirubin, and urobilinogen. Multistix 10SG reagent test strips are intended for use in at-risk patient groups.
The reagent test strips also measure physical characteristics, including acid-base balance and urine concentration. Test results may be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.

II. ORDER
A physician's order, standard protocol, or order by another health professional authorized to request laboratory testing is required for point-of-care urine dipstick testing.

III. MATERIALS

<table>
<thead>
<tr>
<th>Reagents/Controls</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Siemens Multistix 10 SG Reagent Strips</td>
<td>SAP Item #107644</td>
</tr>
<tr>
<td>Quantimetrix Dropper Plus Urine Controls (Levels 1 &amp; 2)</td>
<td>SAP# 32234</td>
</tr>
</tbody>
</table>

**Additional Supplies**

<table>
<thead>
<tr>
<th>Additional Supplies</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinitek Printer Paper</td>
<td>SAP Item #105125</td>
</tr>
<tr>
<td>Disposable Gloves</td>
<td></td>
</tr>
<tr>
<td>Alcohol Wipes</td>
<td></td>
</tr>
<tr>
<td>Gauze</td>
<td></td>
</tr>
<tr>
<td>Urine Collection Containers</td>
<td></td>
</tr>
<tr>
<td>Open Dating Labels</td>
<td>Standard Register #11833</td>
</tr>
<tr>
<td>Hospital Approved Disinfectant Wipes</td>
<td></td>
</tr>
</tbody>
</table>

**Equipment**

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinitek Status+ Analyzer</td>
<td>POCT Office</td>
</tr>
<tr>
<td>Clinitek Status Connect Base</td>
<td>POCT Office</td>
</tr>
<tr>
<td>Handheld Barcode Reader</td>
<td>POCT Office</td>
</tr>
<tr>
<td>AC Power Cord and Interface Cables</td>
<td>POCT Office</td>
</tr>
<tr>
<td>Test Table and Test Table Insert</td>
<td>POCT Office</td>
</tr>
</tbody>
</table>
IV. STORAGE AND HANDLING REQUIREMENTS

<table>
<thead>
<tr>
<th>Product</th>
<th>Temperature</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Siemens Multistix 10SG Reagent Test Strips</td>
<td>Room Temperature (15-30°C)</td>
<td>Manufacturer's expiration date.</td>
</tr>
<tr>
<td>Quantimetrix Dropper Plus Urine Controls</td>
<td>Refrigerated (2-8°C)</td>
<td>Manufacturer's expiration date.</td>
</tr>
<tr>
<td>(Levels 1 &amp; 2)</td>
<td>Room Temperature (18-30°C)</td>
<td>One month or manufacturer's expiration date, whichever comes first.</td>
</tr>
<tr>
<td>Clinitek Status+ Connect System</td>
<td>Room Temperature (18-30°C)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

A. Once a bottle of Multistix 10 SG reagent test strips is open, it is required that the bottle is labeled with the open date.
   1. NOTE: Protection against exposure to light, heat, and ambient moisture is mandatory to guard against altered reagent reactivity. All unused strips must remain in the original bottle with the dessicant pack.

B. When refrigerated, bring controls to room temperature (10-15 minutes) prior to use.

C. Once controls are brought to room temperature, it is required that they are labeled with the open date and new expiration date.

D. Never use reagent test strips or controls past their expiration date.

V. SPECIMEN TYPE

A. A freshly voided urine sample may be collected at any time of day in a clean, dry container. Clean catch samples are recommended.

B. The container should allow for complete dipping of all reagent test strip pads.

VI. SPECIMEN COLLECTION AND HANDLING

A. The urine collection container must be labeled with two unique patient identifiers in the presence of the patient (e.g. Name, DOB, MRN, CSN).

B. All labeling must be done on the cup instead of the lid, which may become separated from the specimen.

C. Test the urine within two hours of voiding - sooner if testing for bilirubin or urobilinogen. If unable to test within the recommended time, send the specimen to the core laboratory for testing.

VII. INTERFERING SUBSTANCES

Substances that cause abnormal urine color may affect the readability of test pads on urinalysis reagent strips. These substances include visible levels of blood or bilirubin and drugs containing dyes (i.e. Pyridium, Azo Gantrisin, Azo Gantanol), nitrofurantoin (Macrodantin, Furadantin), or riboflavin.

Levels of ascorbic acid normally found in urine do not interfere with these tests.

Refer to the Siemens Multistix® 10SG Package Insert (Appendix A) for additional information.
VIII. SAFETY PRECAUTIONS
   A. Follow ICPM IFC023 Infection Control and Prevention: Standard and Transmission-based Isolation Precautions.
   B. All patient specimens, QC materials, and used Multistix 10SG reagent test strips must be considered potentially infectious, handled with care, and disposed of in a JHMI-approved receptacle.
   C. As applicable, refrigeration used for QC materials is to be used only as designated.
      1. Refrigerator temperatures are to be monitored, and documentation of that monitoring must be kept readily available for review.

IX. PERFORMING QUALITY CONTROL (QC) TESTS
   A. Two levels of Quality Control, normal and abnormal, must be performed with all results within acceptable limits:
      1. At least once a week on each instrument in use.
      2. When opening a new lot and/or shipment of reagent strips.
      3. When opening a new bottle of reagent strips.
      4. When patient results are questionable.
      5. At least once a year by each operator to maintain competency.
   B. Procedure:
      1. Prepare QC and reagent strips:
         a. Verify that controls and reagent strips are dated and within both the manufacturer's expiration date and the open vial expiration date, as applicable.
         b. If QC solutions have been stored refrigerated, allow them to come to room temperature for at least 15 minutes.
      2. Prepare the analyzer:
         a. If the Clinitek Status+ Connect System is turned off, press and hold the button until the analyzer powers on.
         b. The test table will emerge and the system will complete a self-test.
         c. Observe the computer icon at the top left of the display screen. If an "X" appears across the computer icon, wait for the "X" to disappear (this may take a minute or two).
         d. Every seven (7) days, the Clinitek Status+ Connect System executes QC lockout.
            i. If QC is due (system locked), the strip test icon will appear as a small rectangle at the lower right edge of the screen. Both levels of QC must be successfully completed prior to the analyzer allowing patient testing.
      3. Enter QC and strip information into the analyzer:
         a. Touch "QC Test Due" on the display.
         b. Select "QC Strip Test".
         c. Scan JHED ID barcode at the prompt for "Operator ID", then select Enter. Alternately, you can manually enter your JHED ID.
         d. Select "Enter lot and expiration date". Refer to the information on the left-hand side of the screen to direct which level of control must be tested.
         e. Scan the lot number from the control bottle, then select Enter.
f. Enter the room temperature expiration date, or manufacturer's expiration date if stored refrigerated, for the control (Year, Month, Day) using the up and down arrows, then select Enter.

g. Select "Enter new lot and expiration date" for the strip.
h. Scan the barcode on the reagent strip bottle to pull in both.

4. Perform the test:
   a. Ensure the test table insert is positioned for the reagent strip (see Figure 1).
   b. Gently mix the control solution by inverting several times.
   c. Remove one reagent strip from the bottle and place it on a clean, absorbent material. Tightly recap the bottle.
   d. Remove the lid from the QC bottle.
   e. Touch the "START" icon on the analyzer to start the 8 second timer, during which the following steps must be completed:
      i. Holding the reagent strip at a downward angle in one hand, invert the control bottle with the other hand and apply 3-4 drops of control solution to the first pad closest to the "Siemens" end of the strip. 
         NOTE: Do not touch the tip of the control bottle to the reagent strip.
      ii. Allow the control solution to run down the reagent strip and dampen each test pad.
      iii. Remove excess control solution by gently blotting the edge of the reagent strip on the absorbent material (see Figure 2).
      iv. Place the reagent strip in the test table channel with the test pads facing up.
      v. Gently slide or push the reagent strip to the end of the channel without touching the pads on the strip.
   f. The test table will retract following the 8 second countdown.
      NOTE: If the reagent test strip is not in place when the test table retracts, do not try to apply it while the table is retracting. Wait until an error message displays on the screen, then repeat testing using a new reagent test strip.
   g. After placing the reagent test strip in the test table insert channel, recap the QC bottle and set aside.
   h. After the timed testing process, the table will emerge and the results will display on the screen as "PASS" or "FAIL".
      i. Remove and discard the reagent strip in the proper waste container.
      j. Clean the test table insert with a soft, absorbent material, like gauze or a Kimwipe.
      k. Select "Done".
      l. Repeat steps 3d through 4k for the second level of control, as indicated by the instrument.
      m. Both levels of QC must pass before patient testing can be performed.

5. After selecting "Done" following completion of both controls, a QC Results Summary screen will appear. If both levels of QC have passed, "Done" must be selected a second time.

C. If results fall outside the acceptable range, a "FAIL" message will appear on the QC Results Summary screen and the "Repeat Failed QC Test(s)" button must be selected.
   1. Verify QC and reagent test strips are withing the expiration date and that they have been properly stored.
   2. Ensure proper technique is being used to continue with testing as directed by the analyzer.
      a. If Level 1 QC fails, the Clinitek will automatically advance to Level 2 QC before requiring a repeat of Level 1.
      b. If Level 2 QC fails, the QC Results Summary screen will include an additional button to "Repeat Failed QC Test(s)". Press this to repeat the applicable level(s) of QC.
   3. If the repeat falls within the acceptable ranges and a "PASS" message appears, the QC Summary Screen will summarize this information. Press "Done" to acknowledge successful QC and continue with patient testing.
   4. If the QC fails a second time, open a new bottle(s) of QC. Repeat test.
   5. If the QC fails a third time, open a new bottle of reagent test strips. Repeat test.
6. If the QC fails with the new QC solution(s) and reagent test strips, DO NOT PERFORM ANY PATIENT TESTING.
   a. Contact the POCT office at 410-955-2645 or by emailing POCTGroup@exchange.johnshopkins.edu. If assistance is required outside of business hours, a CORUS message may be sent to "POCT Consult".

Figure 1

Figure 2

X. PATIENT TEST PROCEDURE
When both levels of QC have successfully been completed and patient testing is available, the "Strip Test" icon will appear as a large square on the home screen (see Figure 3).

A. Prepare for the test:
   1. Ensure the specimen is properly labeled as indicated in Section VI. Specimen Collection and Handling.
   2. Ensure the reagent test strips are not expired and have been QC'd, as applicable.

B. Program the patient test on the analyzer:
   1. Select the "Strip Test" icon.
   2. Scan JHED ID barcode at the prompt for "Operator ID", then select Enter. Alternately, you can manually enter your JHED ID.
   3. Select "Enter New Patient".
   4. Scan the barcode on the patient's label to generate the CSN (10-digit number) on the Enter Patient ID screen.
      a. NOTE: If any identifier other than a CSN is used to perform testing, the results will be held as an exception and require intervention to post the results to the patient's chart.
   5. Select "Enter new lot and expiration date" for the strip.
   6. Scan the barcode on the Multistix 10SG bottle to import the strip lot number and expiration date.

C. Perform the test:
   1. Gently mix the patient specimen by swirling several times.
2. Remove a reagent test strip and place it on a clean, absorbent material, then immediately recap the reagent test strip bottle.

3. Remove the specimen container cap.

4. Touch the "START" icon, which will start an 8 second countdown. The following steps must be completed during this countdown:
   a. Holding the reagent strip in one hand, apply the specimen to the strip in one of three ways:
      i. Pour the specimen gently down the strip into an appropriate waste container or sink.
      ii. Use a transfer pipette to draw up specimen and apply several drops to the reagent strip, similar to the way in which QC is applied.
      iii. Carefully dip the entire reagent strip into the specimen container.
         1. NOTE: If you dip a strip or non-sterile pipette into the specimen, it cannot later be sent for a urine culture.
   b. Be sure to dampen each test pad.
   c. Remove excess specimen from the reagent strip by blotting the edge of the strip on the absorbent material.
   d. Place the reagent strip in the test table channel with the test pads facing up.
   e. Gently slide or push the reagent strip to the end of the channel without touching the pads on the strip.

5. The table will retract eight (8) seconds after touching the "START" icon.
   a. NOTE: If for any reason, the reagent test strip is not in place when the test table retracts, do not try to apply it while the table is retracting. Wait until the error message displays on the screen, then repeat testing using a new reagent test strip.

6. During reagent test strip analysis, a "Select Appearance" screen displays. To select the appearance of the urine sample, perform the following steps. Refer to Appendix B for additional information:
   a. Visually observe the urine sample.
   b. If the urine sample is yellow and clear, select "Yellow and Clear".
   c. If the urine sample is not yellow and clear, select "Other" and select a color then select a clarity option and select Next.

7. After the timed testing process, the table will emerge and results will display on the screen.
   a. If utilizing wired connectivity, the results will post automatically to the patient's chart.
   b. Abnormal results are marked with a "*" and will be flagged in Epic.
   c. If a printed copy of the result is desired, press the printer icon.

8. Remove and discard the reagent test strip in the proper waste container.

9. Clean the test table insert with a soft, absorbent material, such as gauze or a Kimwipe.

10. Select "Done".
XI. REFERENCE RANGES

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Expected Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>Negative</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>Negative</td>
</tr>
<tr>
<td>Ketone</td>
<td>Negative</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>1.001 - 1.035</td>
</tr>
<tr>
<td>Blood</td>
<td>Negative</td>
</tr>
<tr>
<td>pH</td>
<td>4.6 - 8.0</td>
</tr>
<tr>
<td>Protein</td>
<td>Negative</td>
</tr>
<tr>
<td>Urobilinogen</td>
<td>Negative - 1.0 mg/dL</td>
</tr>
<tr>
<td>Nitrite</td>
<td>Negative</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>Negative</td>
</tr>
</tbody>
</table>

XII. REPORTABLE RANGE

Results are translated into the Reportable Ranges seen in Epic when performing interfaced testing.

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Reportable Range (Clinitek)</th>
<th>Reportable Range (Epic)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>Negative, Trace, 1+, 2+, 3+</td>
<td>Negative, 100 mg/dL, 250 mg/dL, 500 mg/dL, 1000 mg/dL</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>Negative, 1+, 2+, 3+</td>
<td>Negative, Small, Moderate, Large</td>
</tr>
<tr>
<td>Ketone</td>
<td>Negative, Trace, 1+, 2+, 3+, 4+</td>
<td>Negative, Trace, Small, Moderate, Large, Large</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>≤1.005, 1.010, 1.015, 1.020, 1.025, ≥1.030</td>
<td>No Difference</td>
</tr>
<tr>
<td>Blood</td>
<td>Negative, Trace-lysed, Trace-intact, 1+, 2+, 3+</td>
<td>Negative, Trace-hemolyzed, Trace-intact, Small, Moderate, Large</td>
</tr>
<tr>
<td>pH</td>
<td>5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5</td>
<td>No Difference</td>
</tr>
<tr>
<td>Protein</td>
<td>Negative, Trace, 1+, 2+, 3+</td>
<td>No Difference</td>
</tr>
<tr>
<td>Urobilinogen</td>
<td>0.2 mg/dL, 1.0 mg/dL, 2.0 mg/dL, 4.0 mg/dL, ≥8.0 mg/dL</td>
<td>Negative, Negative, 2.0 mg/dL, 4.0 mg/dL, ≥8.0 mg/dL</td>
</tr>
<tr>
<td>Nitrite</td>
<td>Negative, Positive</td>
<td>No Difference</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>Negative, Trace, 1+, 2+, 3+</td>
<td>Negative, Trace, Small, Moderate, Large</td>
</tr>
<tr>
<td>Color</td>
<td>Yellow, Light yellow, Dark yellow, Amber, Brown, Red, Orange, Green, Pink, Blue, Other</td>
<td>No Difference</td>
</tr>
<tr>
<td>Clarity</td>
<td>Clear, Cloudy, Slightly Cloudy, Turbid, Other</td>
<td>No Difference</td>
</tr>
</tbody>
</table>
XIII. RESULTS INTERPRETATION

Refer to REAGENT PERFORMANCE section in the SIEMENS Multistix® 10SG Package Insert (Appendix A) for additional information regarding expected values, sensitivity, and performance characteristics of each of the analytes.

A. Glucose:
   1. Small amounts (<30 mg/dL) of glucose are normally excreted by the kidney, which are usually below the test sensitivity level.
   2. Results between Negative and 100 mg/dL may be significantly abnormal if found consistently.

B. Bilirubin:
   1. Normal adult urine contains approximately 0.02 mg/dL of bilirubin, not detectable by even the most sensitive methods.
   2. Trace amounts of bilirubin are sufficiently abnormal to warrant further investigation.

C. Ketone:
   1. Normally, no ketones are detectable in urine.
   2. Trace results may occur during physiological stress conditions, such as fasting, pregnancy, and frequent strenuous exercise.

D. Specific Gravity:
   1. If the specific gravity of a random urine is 1.023 or greater, the concentrating ability of the kidneys can be considered normal.

E. Blood:
   1. Normally, no hemoglobin is detectable in urine. Occult blood occurs in urine as intact RBCs and hemoglobin, which can occur during urological, nephrological, and bleeding disorders.
   2. The significance of Trace results may vary among patients, and clinical judgement is required for assessment on a case-by-case basis.

F. pH:
   1. Certain dietary conditions can produce acid or alkaline urine, which can be useful in the treatment of some calculi.

G. Protein:
   1. Protein present in urine may be the result of urological and nephrological disorders.
   2. Clinical proteinuria is indicated with a strip result at or above 30 mg/dL.
   3. Urinary protein excretions may be temporarily elevated in the absence of renal abnormality due to strenuous exercise, orthostatic proteinuria, dehydration, UTIs, and acute illness with fever.

H. Urobilinogen:
   1. Normally present in urine at concentrations up to 1.0 mg/dL.
   2. A result of 2.0 mg/dL represents an abnormal result, and the patient should be evaluated further for hemolytic and hepatic disease.
   3. Evaluation of both bilirubin and urobilinogen help in differential diagnosis of jaundice, as well as other liver and biliary disorders.

I. Nitrite:
   1. Normally, no nitrite is detectable in urine.
   2. Many enteric gram-negative organisms produce positive results when their number is greater than 105/mL.
J. Leukocytes:
   1. Normally, no leukocytes are detectable in urine.
   2. An increase is an indication of pyuria and is found in nearly all diseases of the kidney and urinary tract; however, pyuria may often be present in non-infective conditions.
   3. Trace results may be of questionable clinical significance, unless observed repeatedly.

XIV. DOCUMENTATION

Patient results will automatically transmit to the electronic medical record, provided no error in entry of the current patient CSN has been made, and the computer icon in the top left corner of the screen does not have an "X" over it. If there is an "X" on the computer icon, follow the steps in Procedural Notes and/or Maintenance to troubleshoot and resend results.

The result will display under the "Labs" tab in Epic as "Urine Dipstick, Automated, Point of Care".

XV. LIMITATIONS

A. As is true with any diagnostic test, clinical diagnosis should not be based solely on a single test result. Clinical diagnosis should incorporate all available clinical and laboratory data.

B. Refer to REAGENT PERFORMANCE section in the SIEMENS Multistix® 10SG Package Insert (Appendix A) for additional information regarding limitations of each of the analytes.
   1. Glucose:
      a. Moderately high ketone levels (40 mg/dL) may cause false negatives in specimens containing small amounts of glucose (75-125 mg/dL).
   2. Bilirubin:
      a. Indican (indoxyl sulfate) and metabolites of Lodine (etodolac) may interfere with result interpretation.
   3. Ketone:
      a. False Trace results are possible in highly pigmented urine specimens.
   4. Specific Gravity:
      a. On Siemens reagent dipsticks, specific gravity is dependent upon ions in urine. Results may differ from those obtained via other methods.
   5. Blood:
      a. Microbial peroxidase associated with UTIs may cause a false positive reaction.
   6. pH:
      a. Bacterial growth by certain organisms may cause a marked alkaline shift (>8.0), due to urea conversion to ammonia.
   7. Protein:
      a. Visibly blood urine may cause falsely elevated results.
   8. Urobilinogen:
      a. Strip reactivity increases with temperature; the optimum temperature is 22-26°C (72-79°F).
      b. This test is not a reliable method for detection of porphobilinogen.
9. Nitrite:
   a. Pink spots or pink edges should not be interpreted as a positive result.
   b. False negative results may occur with shortened bladder urinary incubation, absence of dietary nitrate, or the presence of non-reductive pathological microbes.

10. Leukocytes
   1. Glucose results at or above 3 g/dL may falsely decrease leukocyte results.
   2. Positive results are possible due to contamination of the specimen with vaginal discharge.

XVI. PROCEDURAL NOTES

A. Do not remove the strip from the bottle until right before it is to be used for testing.
   1. After removing the reagent strip, recap the bottle immediately.
   2. If the dessicant packet has been removed from the Multistix 10SG bottle, discard the bottle and use a fresh bottle.
      a. NOTE: Both levels of QC must be performed successfully before performing patient testing with strips from a new bottle.

B. Discoloration or darkening of the test pads may indicate deterioration. If this is evident, or if test results are questionable or inconsistent with expected findings, the following steps are recommended:
   1. Confirm that the product is within the expiration date printed on the label.
   2. Check strip performance by running quality control.
   3. Retest with fresh reagent strips. If proper results are not obtained, contact the POCT office at 410-955-2645 or by sending an email to POCTGroup@exchange.johnshopkins.edu.

C. Contamination of a urine specimen with certain skin cleansers may affect test results for protein, and to a lesser extent specific gravity and bilirubin.

D. It is especially important to use fresh urine to obtain optimal results with the tests for bilirubin and urobilinogen, as these compounds are very unstable when exposed to room temperature and light.

E. Do not push the test table fully into the analyzer, as this may prevent use of the analyzer.

F. Do not use anything hard or pointed on the touch screen.

G. Do not move or bump the test table while the analyzer calibrates, as this may cause the calibration to fail.

H. Keep the white calibration bar on the test table clean and do not touch unless performing as needed maintenance. Damage to the calibration bar could affect test results and analyzer functionality. See Section XVIII. Maintenance.

I. Patient test results can be searched by Patient ID (CSN) or by date, or all results can be viewed. See Appendix C for procedural steps.

XVII. MAINTENANCE

Daily: Clean the analyzer exterior and screen.

A. Always keep the outside of the Clinitek Status+ analyzer and screen clean and free of dust:
   1. Put on gloves.
   2. Power off the analyzer by pressing the on/off button for 3 seconds.
   3. Wipe the outside and screen with a damp (not wet) hospital-approved disinfectant wipe.
   4. Wipe the display with a clean cloth dampened with water to remove any residue.
   5. Dry the display with a clean, dry cloth, such as a Kimwipe. Alternately, let air dry before powering the analyzer back on.
Weekly: Clean the test table and test table insert.

A. At least weekly and more frequently, as needed:
   1. Put on gloves.
   2. Remove the test table insert (see Figure 4).
   3. Remove the test table by pulling it fully out of the analyzer.
   4. Drain the drip tray, if necessary.
   5. Wet a cotton-tipped stick with warm water and thoroughly scrub the test table and table insert, except for the white calibration bar (see Figure 5).
      a. If disinfection is necessary, use a hospital approved disinfectant wipe on the test table and table insert without touching the solution onto the white calibration bar.
   6. Rinse both sides of the table insert and test table under running water.
   7. Dry the test table thoroughly (except for the white calibration bar) with a soft cloth or lint-free tissue.
      a. NOTE: If time allows, air drying is the recommended method.
   8. Examine the white calibration bar on the test table for dirt or discoloration.
      a. If the white calibration bar appears clean and unmarked, insert the test table into the analyzer by pushing it in just over halfway. Insert the table insert.
         i. NOTE: Take care, as pushing the test table more than halfway into the analyzer may cause a jam.
      b. If the bar appears dirty or discolored, clean the calibration bar as described below.

As Needed: Clean the white calibration bar.

A. Check the calibration bar for cleanliness weekly and clean only if needed.
   1. Put on gloves.
   2. Remove the insert from the test table (see Figure 4).
   3. Remove the test table by pulling it fully out of the analyzer.
   4. Drain the drip tray, if necessary.
   5. Examine the white calibration bar on the test table for dirt or discoloration under good lighting (see Figure 5).
      a. NOTE: Take care to not touch the calibration bar. Fingerprints or lint on the bar could cause unreliable test results.
   6. If the white calibration bar appears clean and unmarked, perform the following steps:
      a. Hold the test table at the end opposite the white calibration bar, with the white calibration bar facing upward.
      b. Push the test table firmly but slowly just over halfway into the analyzer.
         i. NOTE: Do not push the test table fully into the analyzer, or a jam may occur.
      c. Re-seat the test table insert.
   7. If the white calibration bar is dirty or discolored:
      a. Wet a cotton-tipped stick or lint-free cloth with distilled water and gently wipe and clean the calibration bar.
         i. NOTE: Do not scratch the white calibration bar. Marks and stains could cause inaccurate test results, especially for hCG tests.
         ii. NOTE: Do not use solvents of any kind to clean the bar, as this could destroy the bar.
      b. Allow the test table to air dry.
      c. Inspect the surface for dust, foreign material, scratches, or scuffs.
d. If you cannot completely clean the calibration bar or if the bar still has marks, contact the POCT office at 410-955-2645 or by emailing POCTGroup@exchange.johnshopkins.edu.

e. If the calibration bar is free from scratches and foreign materials, place the test table into the analyzer as described in step 6.

VIII. TROUBLESHOOTING

A. In the event of an error, testing will be stopped immediately, and an Error Code will appear on the analyzer screen. The table below describes the Error Messages, and Action(s) to take when troubleshooting.

B. When recommended Corrective Actions include "Contact the POCT Office":" 
1. During business hours (Monday-Friday 7:30-15:00), call 410-955-2645 or email POCTGroup@exchange.johnshopkins.edu.
2. During off hours, POCT Consult on CORUS may be contacted in the event of a critical issue that cannot wait until the next business day.
   a. NOTE: The JHH Core Lab is the backup for all POCT Urine Dipstick testing.

<table>
<thead>
<tr>
<th>Error Code</th>
<th>Error Message</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>E02</td>
<td>Failure of calibration data</td>
<td>Contact the POCT Office.</td>
</tr>
<tr>
<td>E03, E04, E05, E06, E07, E08, E21, E22, E90, E91, E92 or E93</td>
<td>Failure of computer software</td>
<td>Contact the POCT Office.</td>
</tr>
</tbody>
</table>
| E10 or E48 | Loss of test results                 | 1. Press the on/off button for 2 seconds to power down; leave off for at least 30 seconds.
                                           2. Press the on/off button to restart the analyzer.
                                           3. Repeat the test.          |
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Resolution</th>
</tr>
</thead>
</table>
| E11  | Failure of test table due to improper positioning.| 1. Move the test table in or out of the analyzer slightly to reposition, but no more than halfway in.  
|      |                                                  | 2. If the error remains, with the analyzer powered on, pull the power cord from the back of the analyzer, and leave the analyzer powered off for at least 30 seconds.  
|      |                                                  | 3. Plug the cord back in, then press the on/off button to restart the analyzer.  
|      |                                                  | 4. If the error remains with the test table in place, contact the POCT Office. |
| E12  | Failure of LED                                   | Contact the POCT Office.                                                 |
| E20  | Failure of clock                                 | Contact the POCT Office.                                                 |
| E24  | No printer paper                                 | Replace the printer paper by selecting Error Report to view the instructions or by opening the printer paper compartment cover to view the instructions inside. |
| E25  | Failure of automatic calibration                 | Clean the calibration bar. If the error remains after cleaning, contact the POCT Office. |
| E25, E64 or E65 | Failure of automatic calibration | Clean the calibration bar. If the error remains after cleaning, contact the POCT Office. |
| E28  | Printer error                                    | 1. Lift the printer paper compartment cover.  
|      |                                                  | 2. Push the gray paper holding arm back down into position. |
| E50  | Incorrect strip type or tilted strip              | Verify correct placement of the strip on the test table insert.  
|      |                                                  | Analyzer operation may be checked by running a yellow and clear patient sample, as needed. |
| E53  | Strip Test selected but cassette detected         | Repeat the test using the Cassette Test function.                        |
| E54  | Cassette Test selected but strip detected         | Repeat the test using the Strip Test function.                           |
| E57  | Missing strip or cassette                         | Repeat the test and ensure that you correctly position the strip or cassette on the test table. |
| E58  | Misplaced strip                                  | 1. Repeat the test, ensuring correct positioning of the strip on the test table.  
|      |                                                  | 2. If the error remains, examine the test table insert to ensure that the small, grayish/white line located near the tip of the strip (on the strip side of the insert) is present and not damaged.  
<p>|      |                                                  | 3. If this line is damaged, contact the POCT Office.                     |
| E59  | Inverted strip positioned on the test table      | Repeat the test with a fresh strip, ensuring the strip is correctly positioned on the test table. |
| E60  | Tilted strip                                     | Repeat the test with a fresh strip, ensuring the strip is correctly positioned on the test table. |</p>
<table>
<thead>
<tr>
<th>Error Code</th>
<th>Description</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>E61</td>
<td>Dry strip</td>
<td>Repeat the test with a fresh strip, ensuring all reagent pads are introduced to sample.</td>
</tr>
<tr>
<td>E62</td>
<td>Light Ingress</td>
<td>Too much light is reflecting on the analyzer. Move the analyzer to a location with lower lighting.</td>
</tr>
<tr>
<td>E63</td>
<td>Failure to find end of strip</td>
<td>Repeat the test with a fresh strip, ensuring correct positioning on the test table.</td>
</tr>
</tbody>
</table>
| E69        | Strip quality problem        | When the analyzer performed a quality check, the strip quality failed. The quality check detects whether the strip was compromised due to humidity exposure. Highly pigmented specimens or those with very high leukocyte levels may erroneously cause this error.  
1. Remove the defective strip and discard.  
2. Repeat the test with a fresh strip that meets the quality requirements. |
C. Troubleshooting the Analyzer Operation given symbols present on the Select Ready screen:

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Symbol" /></td>
<td>No Printer Paper</td>
<td>Displays on the Print Help button on the Select Ready screen, indicating that the printer is out of paper. An advisory message also displays. Replace the empty paper with a new one, following the instructions under the printer paper compartment cover.</td>
</tr>
</tbody>
</table>
| ![Symbol](image2.png) | No Connector             | Indicates that the analyzer is not connected to the connector.  
1. Disconnect the double-sided black connector, then blow into it to remove any dust accumulated. Invert the positioning of the connector when reconnecting.  
2. If the issue persists more than 2 minutes after completing step 1, contact the POCT Office. |
| ![Symbol](image3.png) | No Remote Connection     | Indicates the wired connection between the analyzer and the server does not exist.  
1. Press and hold the on/off button to power down the analyzer.  
2. Unplug the power cord from the analyzer for 30 seconds.  
3. Plug the power cord back into the analyzer, then power on the analyzer.  
4. If the issue persists more than 2 minutes after completing steps 1-3, contact the POCT Office. |
XIX. DOWNTIME

Instrument Downtime:

A. When the Clinitek Status+ Connect system cannot be used for patient testing due to QC, calibration, or instrument failure and all troubleshooting steps have been performed, contact the POCT office at 410-955-2645 or by emailing POCTGroup@exchange.johnshopkins.edu during business hours (Monday-Friday, 7:30-15:00).
   1. During off-hours, contact the POCT Office for all urgent issues that cannot wait until the next business day by sending a CORUS message to “POCT Consult”.
   2. In the absence of a back-up analyzer, send patient specimens to the Core Laboratory.

Epic and/or Telcor Downtime:

A. The Clinitek Status+ Connect System may still be used for QC and patient testing, but will results will not automatically cross.
   1. NOTE: Do not manually document results on patient charts unless directed to do so by the POCT Office.

B. Once connectivity is re-established and the computer icon at the top left of the display screen shows a connection, results will begin posting to patient charts automatically. If results are missing, contact the POCT Office for additional guidance and refer to Appendix B for steps to Resend Results as needed.

XX. OPERATOR TRAINING

A. Testing may be performed only by testing personnel who have been trained by a Point-of-Care Coordinator, Nurse Educator, or designated unit trainer. Training records must be kept in the employee's personnel file and a copy sent to the Point-of-Care Testing office.

B. Initial Training must include the following:
   1. Review and acknowledge the SOP.
   2. Successful performance of both levels of liquid quality control associated with the testing personnel's JHED ID.
   3. Completion of the initial competency assessment checklist (see Appendix D), to be kept in the employee's personnel file and a copy sent to the POCT Office.
   4. Passing score on the quiz following the MyLearning module.

C. All Initial Training and Competency requirements must be completed prior to performing any patient testing.

XXI. OPERATOR COMPETENCY

In order to maintain ongoing competency and not lose access to the analyzer, all testing personnel must successfully complete both levels of controls and the MyLearning module at least once a year.

The POCT Office competency cycle follows the fiscal year. Testing personnel who do not complete requirements during a given competency cycle will require re-completion of Initial Training and Competency prior to being regranted access to the analyzer.

XXII. REFERENCES


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XXIII. SIGNATURES

<table>
<thead>
<tr>
<th>Electronic Signature(s)</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>William Clarke</td>
<td>03/14/2023</td>
</tr>
<tr>
<td>Medical Director of Point of Care Testing</td>
<td></td>
</tr>
<tr>
<td>Andrew Satin</td>
<td>03/14/2023</td>
</tr>
<tr>
<td>CLIA Laboratory Director</td>
<td></td>
</tr>
<tr>
<td>Brian Matlaga</td>
<td>03/15/2023</td>
</tr>
<tr>
<td>CLIA Laboratory Director</td>
<td></td>
</tr>
<tr>
<td>Scott Newsome</td>
<td>03/21/2023</td>
</tr>
<tr>
<td>CLIA Laboratory Director</td>
<td></td>
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</tbody>
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