Clinical Laboratory Department POLICY AND PROCEDURE

POLICY NUMBER: 925
VERSION: 4

SUBJECT: Urinalysis: Use of Clinitek Status Plus Urine Chemistry Analyzer

PURPOSE:

To provide guidelines for the safe and accurate use of the Clinitek Status Urine Chemistry Analyzer with Bayer Multistix 10 SG Reagent Strips for Urinalysis. This test can be used as definitive or for screening purposes.

POLICY:

Urinalysis with the Clinitek Status Urine Chemistry Analyzer and Bayer Multistix 10 SG Reagent Strips will be used for general screening and/or treatment in assessing a patient's health, per provider's order.

Only designated authorized personnel will perform urinalysis testing with the Clinitek Status Urine Analyzer and must demonstrate competency annually. Competency must be demonstrated to and deemed satisfactory by the Clinical Instructor or designee.

SPECIMEN:

Urine is to be collected in a disposable, clean, plastic dry container. Any random specimen is acceptable, however the first voided morning specimen is recommended. It is also preferred, but not mandatory, that the specimen be collected by a clean catch midstream procedure.

If possible, urine samples should be analyzed within one hour after voiding.

EQUIPMENT, MATERIALS AND STORAGE REQUIREMENTS:

Equipment/Materials:

- Clinitek Status Plus Urine Chemistry Analyzer
- Bayer Multistix 10 SG Reagent Strips
- Clean, dry container for urine specimen
- Gloves
- Urine Control Level 1 (negative) and Urine Control Level 2 (positive).
- Reagent Storage Requirements:

1. The Bayer Multistix 10 SG strips are to be stored at room temperature (18-25° C or 64-77° F)
2. Do not store the Multistix bottle in direct sunlight.
3. The Bayer Multistix 10 SG strips are stable until the recommended manufacturer expiration date printed on the bottle.
4. Upon opening of a new bottle of test strips, the open date and initials of the person opening the bottle must be documented on the bottle.
5. The Urine Control solutions (1 & 2), are ready to use.
6. Open urine control solutions are kept at room temperature (18-25° C or 64-77° F) for 6 weeks.
7. Unopened control solutions are stored at 2-8° C (or 35-46° F) and are stable until the expiration date on the label.
8. The open date and date of expiration are to be recorded on the bottles of control solution, along with the initials of the person opening the bottles.
9. The operating temperature for the Clinitek Status machine is 18-30° C (64-86° F). The ambient operating humidity range for the analyzer is 18-80% relative humidity (non-condensing).

INSTRUMENT SET UP/CALIBRATION:

1. If the Clinitek Status Plus Urine Chemistry Analyzer is off, turn it on by pressing the on/off button located on the front of the instrument. The analyzer will run an automatic system diagnostic test each time it is turned on. The touch screen will guide you through the operation of the analyzer. The first main screen is the "Select" screen. It displays the time and date, and indicates the instrument is ready.
2. A small icon of the instrument without an "X" through it must be in the upper left corner of the screen. This indicates that the Plus base unit is operational and communicating.
3. To insert the test strip table into the instrument, hold it by the end opposite the white bar and with the white bar facing up. Do not touch the white bar. Push the table in about halfway, turn the instrument off, then on again. Do not push the test table fully into the analyzer as the test table may become jammed and prevent the use of the analyzer.
4. If the table is already in the analyzer, by simply turning it on, the table will automatically be kicked out to the correct position.
5. In order to look up a patient's results, return to the main Select screen and touch Recall Results button. Choose Patient and QC Results. Then choose All Results. The results will be in chronological order with the most recent test result at the top of the screen. To view details, touch the Select button.
6. To power down, press the on/off button until you hear a beep. The test table will retract into the analyzer. If there is no strip on the test table, the door will close and the analyzer will switch off. Before turning the analyzer off, always ensure that there is no strip on the test table and that the table is clean. If a strip is still on the test table, the table will be pushed out, where it will remain, and the analyzer will turn off. In order to retract the table, turn the analyzer on, and then off again without a strip on the test table.

PROCEDURE:

QUALITY CONTROL:

Principles

1. Must be performed each day the clinic is open to patients.
2. Must include both Urine Control solutions, level 1 and 2.
3. QC results must react as expected before patient testing can be performed.
4. Additional QC should be done if a new lot of test strips are opened or if there is any question about instrument performance.

Quality Control Solution Procedure:

1. Check expiration date of solutions. Once opened, they are stable at room temperature (18-25° C or 64-77° F) for 6 weeks or manufacturer's expiration date, whichever comes first.
2. Check expiration date of the Bayer Multistix 10 SG test strips. Shelf life is per manufacturer.
3. If the Clinitek Status Plus Urine Chemistry Analyzer is off, turn it on by pressing the on/off button located on the front of the instrument. Choose "QC Test Due" from the main Select screen. Follow the prompts by entering or scanning "Operator ID" as the operator's employee ID number. Then enter or scan the lot numbers of the controls and strips as prompted.
4. Wash hands and don gloves.
5. Remove one test strip from bottle. Using Urine Control level 1 solution, drop approximately 8-10 drops of the solution into a clean test tube or like container. Wet all the test pads of the strip with the solution. Immediately remove the strip. Drag the edge of the strip against the container rim to remove excess solution.
6. AT THE SAME TIME, touch the START button.
7. Place the Reagent test strip, with the test pads facing up, into the middle trough of the test strip table. Slide the strip along the table until it touches the end of the trough. (You have 8 seconds to dip the test strip, blot the edge of the strip and place it on the test strip table.)
8. If any analyte did not pass, you MUST add a note by pressing the QC Notes button. This is a free text field. Press PRINT. QC results will not automatically print.
9. Remove the Reagent test strip and discard in appropriate waste container.
10. Repeat steps with Urine Control level 2 solution.
11. Remove gloves and wash hands.
12. Any result, which falls outside the expected range, must be considered out-of-control. Corrective action must be taken and documented before testing patient specimens.
13. Both levels of QC must be run within 10 minutes of each other, or it will time out and QC will fail. The first QC will not count even if it passed, and will have to be repeated.

Corrective Action for Quality Control Failure:

1. Confirm that both the test strips and the control solutions have not exceeded the expiration dates.
2. Repeat the procedure with the same control solution(s) and/or container of test strips, using a new test strip each time, a maximum of twice before trying a new action.
3. Repeat with new test strips or control solutions if needed.
4. Record all corrective action and follow-up by entering a QC note in the analyzer.
5. If proper results are still not obtained, consult the POCT Coordinator or laboratory personnel. No patients can be tested until QC is acceptable.

PATIENT TEST:

Patient Test Procedure:

1. Must have a provider's order (either in Cerner or as a written standing order).
2. Turn the analyzer on and ensure that the test strip table is in place.
3. Identify patient with at least 2 acceptable identifiers.
4. Follow infection control guidelines.
5. Explain the procedure to the patient and provide them with the necessary supplies, including a label with their full name and medical record number for the urine container.
6. Wash hands and don gloves.
7. Obtain urine specimen from the patient.
8. If the Clinitek Status Plus Urine Chemistry Analyzer is off, turn it on by pressing the on/off button located on the front of the instrument. Choose "Strip Test" from the main Select screen. Follow the prompts by entering or scanning "New Operator ID" as the operator's employee ID number. Then enter "Patient ID" by scanning the patient's FIN number. Never enter the FIN number manually. The next screen will be "Prepare Test."
9. Dip a Bayer Reagent strip into the urine specimen. Be sure all the pads are wet.
10. Immediately remove the Reagent strip from the urine, dragging the edge of the strip along the edge of the container as you remove. Blot by touching the edge of the strip to a paper towel to remove excess urine. AT THE SAME TIME, touch the Start button.
11. Place the Reagent test strip, with the test pads facing up, into the middle trough of the test strip table. Slide the strip along the table until it touches the end of the trough. (You have 8 seconds to dip the test strip, blot the edge of the strip and place it on the test strip table.) The table is automatically pulled into the instrument for reading. DO NOT TOUCH THE TEST TABLE.
12. While the strip is being analyzed, you will be asked to record the color and clarity of the specimen.
13. After the test is complete, make sure to press DONE. If this is not done, it will not chart.
14. Results will chart automatically. NEVER enter the UA results manually into Cerner. If this is done, TWO results will post to Cerner
15. Remove gloves and wash hands.

Documentation:

1. Patient results are automatically printed on the tape from the instrument.
2. At the end of each day (or month if the clinic volume is low) remove the tape from the instrument and store the tape away from the sunlight or direct lighting.

Reference Range:

Color and appearance	Yellow and clear.
pH	5.0 – 7.5.
Specific gravity	1.001 – 1.030.
Protein	Negative.
Glucose	Negative.
Ketone	Negative.
Bilirubin	Negative.
Blood	Negative.
Nitrate	Negative.
Leukocyte esterase	Negative.
Urobilinogen	<0.2 EU/dL.

Abnormal Results

1. All results which fall outside of the normal reference ranges indicated above should be verified by sending the specimen for urinalysis to the laboratory, if clinically indicated. This is up to the discretion of the provider.
2. All specimens that need further testing in the laboratory must be refrigerated until sent.

MAINTENANCE:

Cleaning the Test Strip and Test Strip Insert:

1. The test strip insert must be cleaned each day of use.
2. Remove the insert. Rinse both sides of the insert under running water. Dry and replace the insert.
3. The Test Table must be cleaned weekly. Fill a tall, narrow container (e.g. Empty Multistix bottle) to a depth of about 4 inches with Isopropyl Alcohol. Make sure that the solution does not come in contact with the white calibration bar. Place the insert and/or test table into the solution for 2-10 minutes. Rinse the alcohol off of both sides of the table with running water. Check the white calibration bar for dirt or discoloration. If it is dirty or discolored, gently wipe and clean it with a new cotton-tipped stick or lint-free cloth wetted with water. Solvents of any kind must never be used. TAKE CARE NOT TO SCRATCH OR DISCOLOR THE WHITE CALIBRATION BAR. Dry the test table thoroughly with a soft cloth or lint-free tissue.
4. The outside of the analyzer shall be cleaned with facility approved disinfectant after each day of use. Do not use any type of solvent, oil, grease, silicone spray,

or lubrication on the analyzer. Take care to avoid liquid from entering the printer compartment or pooling on the screen.
5. The counter top at the workstation where the analyzer is used shall be cleaned after each day of use with facility approved disinfectant.

Loading the Paper Roll:

1. Open the printer cover by pulling up on the tab.
2. Open the paper roll compartment cover by pressing down on its tab and pulling out.
3. Lift the paper holding arm into the open, upright position.
4. Place the new paper roll into the printer paper compartment with the paper unrolling from underneath and toward the compartment wall.
5. Feed the paper up along wall and through the printer. Once you have approximately 4 inches of paper through the printer then feed the edge of the paper through the printer cover.
6. Push the paper holding arm down into the closed position.
7. Close the printer and paper roll covers by clicking them into position.

D. PROCEDURE NOTES:

1. Dip test areas in the urine completely, but briefly, to avoid dissolving the reagents.
2. Protection of the test strips against ambient moisture, light and heat is essential to guard against altered reagent reactivity. Keep the cap on the bottle.
3. Discoloration or darkening of reagent areas may indicate deterioration; strips must not be used for testing - discard.
4. Using a first morning specimen or one that has incubated in the bladder for four hours or more optimizes nitrite test results.
5. It is especially important to use fresh urine to obtain optimal results with bilirubin and urobilinogen tests. These compounds are very unstable when exposed to room temperature and light.
6. Prolonged exposure of urine to room temperature may result in microbial proliferation with resultant changes in pH. A shift to alkaline pH may cause false positive protein results. Urine containing glucose may decrease in pH as organisms metabolize the glucose. Bacterial growth from contaminating organisms may cause false positive blood reactions from the peroxidases produced. In random urine specimens from females, a positive result for leukocytes may be due to a source external to the urinary tract.
7. Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein (and to a lesser extent, specific gravity and bilirubin) test results.
8. Substances that cause abnormal urine color, such as drugs containing azo dyes, may affect the readability of the reagent areas on the urinalysis reagent strips. The color development on the reagent pad may be masked, or a color reaction may be produced on the pad that will be interpreted as a false positive. Such specimens should not be run on this analyzer.

ERROR MESSAGES AND CORRECTIVE ACTION:

Error messages will be displayed when the analyzer detects something that needs attention. Some errors disable the instrument completely and some only warn of a problem. All errors must be taken care of before the error message will be removed.

- A Paper Roll Icon displays on the Print Help button on the Select Ready screen. It indicates that the printer is out of paper. Replace the paper.
- A profile picture of the unit with an X through it appears when the analyzer is not connected to the base. Check and tighten the cables on the analyzer. Call the lab if this cannot be corrected.
- Two computers with an X through them indicate a remote connection could not be established. Turn the unit off, then on again. If this does not correct, call the lab.
- If the test table movement is irregular or slow, it indicates a heavy buildup of dried urine on the test table. Clean the test table.
- If an error message appears, review the error messages listed below.

Error Message	**Corrective Action**
E01	Low battery power. Replace the batteries.
E02	Failure of calibration data. Contact Lab.
E03-E08, E21, E22, E90-E93	Failure of computer software. Contact Lab.
E10 or E48	Loss of test results. Power off, then on after 2 seconds. Repeat the test.
E11	Failure of test table. It is positioned improperly. Make sure it is in place. Move it in or out of the analyzer slightly to reposition the test table. If the error remains, with the analyzer powered on, disconnect the power cord from the back of the unit and connect it back in. Press the on/off button to power it back up. If the error remains, contact the lab.
E12	Failure of LED. An LED light source failed. Contact the lab.
E20	Failure of clock. Contact the lab.
E23	Low battery power. Contact the lab.
E24	No printer paper. Replace the paper.
E25, E64, E65	Failure of automatic calibration. Clean the calibration bar. If the error remains after cleaning, contact the lab.
E27	Setup failure. Power off the analyzer for 2 seconds. Then power it back up.
E28	Printer error. Lift the printer cover. Push the paper holding arm back into position.
E50	Incorrect strip type or tilted strip. Verify that you correctly placed the strip on the test table insert. If error remains, contact the lab.
E52	Invalid barcode. Repeat the test using the correct barcode.
E53	Strip Test selected but cassette detected. Repeat the test using the Cassette Test.

E54	Cassette Test selected but strip detected. Repeat the test using the Strip test.
E56	Incorrect size test table. Repeat the test with the correct test table.
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. Repeat the test ensuring that you correctly position the strip on the test table. If the error remains, examine the test table insert to ensure that the small, white line located near the tip of the strip is present and not damaged. If the line is damaged, contact the lab.
E59	Inverted strip positioned on the test table. Repeat the test with a fresh strip and ensure that it is correctly positioned on the test table.
E60	Tilted strip. Repeat the test with a fresh strip and ensure that the strip is correctly positioned on the test table.
E61	Dry strip. Repeat the test with a fresh strip and ensure that it has been in contact with the sample.
E62	Light Ingress. Too much light is reflecting on the analyzer. Move the unit to a location with lower lighting.
E63	Failure to find end of strip. Repeat the test with a fresh strip and ensure that it is correctly positioned on the test table.
E67 or E68	Sampling error. A sample flow issue with the cassette test might have been detected.
E69	Strip quality problem. When the analyzer performed a QC check, the strip quality failed. This detects whether the strip was compromised due to humidity exposure. Also, some patient samples that are highly pigmented or have very high leukocyte levels might falsely cause this error. Remove the strip and discard. Repeat with a fresh strip that meets the quality requirements.

REFERENCES:

Clinitek Status Plus Analyzer Operator's Guide, Siemens Medical Solutions Diagnostics, Tarrytown, NY, Rev. C, 2011-12.
Clinitek Status Connect System Operator's Guide, Siemens Medical Solutions Diagnostics, Tarrytown, NY Rev B, 2011-06.
Bayer Multistix 10 SG package insert.

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