

**Document Management Number: SOP-0995**

**Document Title: Clinitek Status Urinalysis Procedure**

**Principle:**

The Clinitek Status®+ Urine Chemistry Analyzer is a portable instrument designed to read Siemens Reagent Strips for urinalysis. The instrument is a reflectance spectrophotometer that analyzes the color and intensity of the light reflected from the reagent area and reports the results in clinically meaningful units. Calculations are **NOT** required by the user.

The Clinitek Status®+ is used at the Women's Clinic, the ECU, Urology and the Community Based Outpatient Clinics (CBOC) in Ogden, Orem, Pocatello, West Valley, Roosevelt, and St. George.

**Specimen:**

The specimen of choice is a fresh urine sample, less than 1 hour old. If the urine cannot be tested within 1 hour, refrigerate and test within twenty-four hours. Before testing allow the sample to come to room temperature (20-24°C). If the urine sample has been centrifuged, the specimen must be mixed well before use.

CAP requires that the specimen is labeled with the following information:

1. Full patient name
2. Full patient social security number
3. Date and time of collection

NOTE: Hand hygiene should be observed before and after interacting with each patient. Gloves are to be worn when handling specimens and while completing all testing. Gloves should be changed between patients.

**Materials:**

1. Clinitek Status®+ analyzer
2. Siemens Multistix 10 SG dipsticks stored in the tightly closed container at room temperature (20-24°C). Label container with open date.
  - a. Once removed from the container, if the strip is not used immediately, discard and use another.
3. MAS Urinalysis Liquid Assay Urinalysis Controls Levels 1 and 2.
4. Paper towels
5. Alcohol wipes
6. Disinfectant wipes
7. Cotton tip swabs
8. Distilled water

**Maintenance:**

*Daily:*

1. Inspect outside of analyzer for contamination and clean with disinfectant wipe if needed.
2. Remove strip tray and wipe with a damp cloth and then dry with a clean lint free cloth.

*Weekly:*

1. Remove test table slowly and strip tray.
2. Rinse test table, **EXCEPT THE CALIBRATION BAR**, with water and clean with cotton tipped swab.
3. Rinse the strip tray with water and clean with cotton tipped swab.
4. Check the calibration bar for smudges or scratches and clean with distilled water and lint free clothes. See user manual page 112 for complete instructions.

*Monthly:*

1. Disinfect strip tray and test table, **EXCEPT THE CALIBRATION BAR**.
  - a. Wipe down surfaces, **EXCEPT THE CALIBRATION BAR**, with alcohol wipes.
  - b. Rinse all disinfected surfaces with water and dry with a clean cloth.

*As Needed:*

1. If excess urine remains in the strip tray after testing, wipe the tray with a paper towel before testing the next patient sample.
2. If a urine sample is extremely abnormal (turbid, red, orange, etc) clean the strip tray with an alcohol pad before testing the next patient sample.
3. Clean calibration bar. See user manual page 112 for complete instructions.

**Quality Control:**

Two levels of MAS Quality Control will be run daily. The instrument will not allow patient testing until both levels have passed. The quality control ranges are programmed into the analyzer, by the Ancillary Testing Coordinator, and will notify the user when controls pass. Once opened, the controls are stable for 6 weeks at room temperature (20-24°C) or 3 months refrigerated (2-8°C). If controls are refrigerated, allow control solutions to warm to room temperature before testing.

1. Using the Touch screen hit, “QC Test”
2. Hit “QC Strip”
3. Scan operator ID with the barcode scanner. (The Operator ID is the barcode on the back of your access badge).
4. Hit “Enter”
5. Enter Lot Number using the alpha numeric keypad
6. Enter the expiration date with the up/down arrows.
7. Hit “Enter new lot and expiration date”
8. Scan Strip Lot
9. Hit “Enter”
10. Enter in the expiration date with the up/down arrows.
11. Mix the control solution and place a drop on all the pads of the urine strip.
12. Rim and blot the strip on a clean paper towel.
13. Hit “Start”
14. Place the strip in the strip tray.
15. Wipe tray with paper towel.
16. Once the test is completed the instrument will say Pass or Fail.
17. If instrument is not connected to LIS, record if QC Pass or Fails on the Clinitek®+ Status Maintenance Log and all pertaining lot numbers/expiration dates.
18. If the level fails see the next section for Troubleshooting tips.
19. Repeat steps 11-16 to complete level 2.

If any of the control values fail, patient testing will be locked out by the analyzer and **Troubleshooting** steps need to be performed. Troubleshooting steps are listed below:

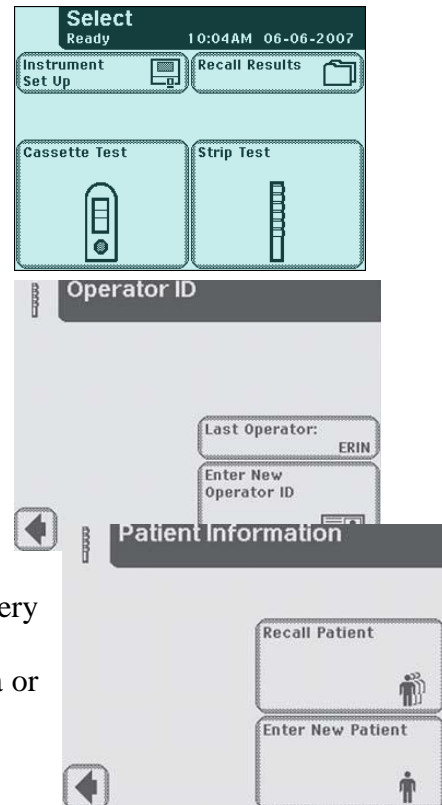
1. Rerun the appropriate unacceptable control level, making sure that the reagent pads of the dipstick are completely covered by the control solution. If control is still unacceptable then perform the following steps:
  - a. Rerun the control with a new bottle of quality control material, if the results are still unacceptable, **DO NOT** report patient results from the Clinitek analyzer and call the Ancillary Testing Coordinator.
  - b. If controls do not pass on the analyzer, pour off all urine samples and send to the main laboratory for analysis.
2. Log all troubleshooting and corrective action taken on the Clinitek Status<sup>®</sup>+ Maintenance log.

### Calibration:

Calibrations are completed automatically by the instrument with each patient sample.

### Procedure:

1. Verify patient name and social security number.
2. Testing is started from the main *Select* screen.
3. Hit “Strip Test”
4. ALWAYS select “Enter new Operator ID”  
This will help ensure that the correct operator is always entered.
5. Scan in your Operator ID with the barcode scanner.
6. Hit “Enter”
7. ALWAYS select “Enter new Patient”  
This will help ensure that the correct patient is chosen every time.
8. Scan in the patient ID using the label printed from Vista or hand type in the Patient ID. (Full SSN)
9. Hit “Enter”
10. The next screen that appears is “Prepare test”



11. Mix urine sample well and dip the dipstick.
12. Rim and blot the dipstick on a clean paper towel.
13. Place stick on the tray, neatly against the edge.
14. "Select Appearance"
15. Select the appropriate option between "Yellow and Clear" and "Other" for more options.

16. Select the appropriate color if you chose "Other" and then hit "Next"

17. Select the appropriate clarity and then hit "Next"

18. The screen will now display either "Analyzing" if the test is not yet complete or "Results" if testing is complete. To see the remainder of the results hit the "More" button.

19. Enter the strip lot and expiration date using the up/down arrows or choosing "Use Last Lot"

20. Discard dipstick and wipe tray with a clean paper towel.

21. Abnormal results will be flagged with an "\*".

**NOTE:** If the following analytes have an "\*" next to the result; the samples needs to be poured off into a preservative tube and sent to the main laboratory at the Salt Lake City Medical Center for a microscopic.

- a. **Leukocyte Esterase**
- b. **Nitrite**
- c. **Blood**
- d. **Protein**

**Note:** Clinics within the hospital (ECU, Women's and Urology) can send the sample in the original container without preservative to the main laboratory for a microscopic urinalysis.

**\*\*Patients receiving prenatal care will only have their urine sent to the laboratory if the physician finds it necessary and a clean catch urine will be collected.**

Refer to the Urine Microscopic Specimen Collection procedure for instructions on preparing the specimen for transport.

**Result Entry:**

The Clinitek Status+ urine analyzer is interfaced with VistA and automatically sends the patient results to VistA.

**Manual Result Entry (Backup):**

If the interface does not work, use the following procedure to manually enter the patient results into CPRS.

- a. Log into CPRS.
- b. Click "NOTES" along bottom tab.
- c. Click "Templates" on left hand side.
- d. Click "Shared Templates".
- e. Click on "Ancillary Testing"
- f. Double click on "Pregnancy Test (Urine hCG)" Reminder Dialog
- g. Select Location, Click "OK".
- h. Select Progress Note Title, Click "OK"
- i. Fill out reminder dialog, see example.
- j. Click "Finish".
- k. Select Primary Provider
- l. Sign Note

### Expected Values:

Normal Urine Reference Ranges	
Analyte	Result
<b>pH</b>	<b>5 – 9</b>
<b>Specific Gravity (SG)</b>	<b>&lt;= 1.005 to &gt;= 1.030</b>
<b>Bilirubin</b>	<b>Negative</b>
<b>Glucose</b>	<b>Negative</b>
<b>Ketones</b>	<b>Negative</b>
<b>Leukocyte Esterase</b>	<b>Negative</b>
<b>Nitrite</b>	<b>Negative</b>
<b>Protein</b>	<b>Negative</b>
<b>Urobilinogen</b>	<b>0.2 – 2.0 EU/dL</b>

### Troubleshooting:

See Clinitek Status<sup>®</sup>+ Urine Chemistry Analyzer User Manual for details starting with page 97.

### Limitations:

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 (e.g., Pyridium, Azo Gantrisin, Azo Gantanol) nitrofurantoin

(Macrochantin, Furadantin), or riboflavin. Levels of ascorbic acid normally found in urine do not interfere with these tests.

For a complete list of all interferences consult the Siemens Multistix ® 10 SG package insert.

**Procedural Notes:**

1. If for any reason the specimen cannot be run the same business day the sample should be poured off into the yellow urine preservative tubes, refrigerated, and sent to the main laboratory at the Salt Lake City, Veterans Affairs Medical Center.
2. To order Siemens Multistix 10 SG dipsticks or MAS Urinalysis Liquid Assay Urinalysis Controls Levels 1 and 2 contact the Ancillary Testing Coordinator at ext. 1595.

**References:**

1. Siemens Multistix ® 10 SG package insert Rev 06/10 USA.
2. Clinitek Status ® + Urine Chemistry Analyzer User Manual 135057 Rev. A, 2009-11 Tarrytown, NY 10591-5097 USA.

**Revision History**

Section	Change	Date	Requester	Approver
Header	Update header	02/02/2017	Hung Ho	E. Hart MD
Font, Size	New Time Roman, 12	02/02/2017	Hung Ho	E. Hart MD