FHN

Procedure Title:	Clinitek Status/Status + With Connect Base Macroscopic Urinalysis

Date Revised/Reviewed	By (signature)	Summary of Revisions	Reviewed by Laboratory Director	Date Approved
1/19/21	C. Engbert	Updated QC frequency and references		
12/15/21	C. Engbert	Update references		
5/2/22	C. Engbert	Added Uristix 4		
10/26/22	C. Engbert	Update to patient ID requirement		
1/26/23	C. Engbert	No updates		

CLINITEK STATUS/STATUS+ WITH CONNECT BASE
Macroscopic Urinalysis

PRINCIPLE:

The CLINITEK Status+ Urine Chemistry Analyzer is a portable, easy to use analyzer. It is designed to read only Siemens Healthcare Diagnostics Reagent Strips for Urinalysis.

This analyzer is intended for the measurement of the following in urine: Albumin, Bilirubin, Blood (Occult), Creatinine, Glucose, Ketone, Leukocytes, Nitrite, pH, Protein, Protein-to-Creatinine Ratio, Albumin-to-Creatinine Ratio, Specific Gravity, and Urobilinogen.

These measurements are used to assist diagnosis in the following areas:

- Kidney function
- Urinary tract infections
- Metabolic disorders (such as diabetes mellitus)
- Liver function

Tests performed using the CLINITEK Status+ analyzer are intended for in vitro diagnostic use only.

The CLINITEK Status+ analyzer is intended for near patient (point-of care)facilities and centralized laboratory locations.

SPECIMEN REQUIREMENTS:

Patient Preparation:

- Random urine - None

Specimen Type and Collection Method:

- A fresh urine specimen (<2 hours at room temperature) collected in a clean, dry, covered container. If testing is delayed (>2 hours after collection), the specimen should be refrigerated for preservation. Allow the urine specimen to return to room temperature prior to testing.

Special Handling or Storage Conditions:

- Follow good laboratory practices when handling urine specimens. Always observe universal precautions when handling patient specimens and any contaminated materials. Dispose of all contaminated materials in an approved biohazard container.

Criteria for Specimen Rejection:

- **DO NOT ACCEPT THE FOLLOWING:**
    - specimens that have remained at room temperature for longer than 2 hours
    - specimens with urine preservatives
    - specimens that arrive in homemade containers (glass jars, pill bottles, etc.)
    - leaking specimen containers

EQUIPMENT, REAGENTS, AND SUPPLIES:

Equipment or Instrumentation:

- CLINITEK® Status/Status+ Analyzer with Connect base

Reagents & Materials:

- Positive and Negative Quantimetrix control solutions
- MULTISTIX® 10 SG Reagent Strips
- Uristix 4 Reagent Strips

Reagent Performance Parameters:

- Refer to the package insert of the Reagent Strips for specific performance characteristics. Refer to Table 1 in this document under "Limitations of the Procedure" for possible interfering substances.

Storage Requirements:

- *CLINTEK® Status/Status+ Analyzer*
    - Ambient Operating Temperature Range 18° to 30°C (64° to 86°F)
    - Optimum Operating Temperature Range 22° to 26°C (72° to 79°F)
    - Ambient Operating Humidity Range 20% to 85% Relative Humidity
- *MULTISTIX® 10 SG & Uristix 4*
    - Initial and date the reagent bottle when first opening. Make sure the desiccant remains in the Reagent Strips bottle**. Remove a strip from the bottle immediately before testing. Replace the bottle cap immediately and tightly after removing the reagent strip.** Avoid touching the test areas (pads) of the reagent strip.
    - Store the reagent strips at room temperature between 15°-30°C (59°-86°F). Do not use reagent strips after the expiration date. Avoid storing reagent strip bottle in direct sunlight.
    - Discoloration or darkening of the reagent areas may indicate deterioration. If this is evident, confirm the expiration date and/or check performance with a known positive control. If unacceptable results are obtained, discard the deteriorated strips and retest using a new, unopened bottle of reagent strips.
- *CONTROL SOLUTIONS*
    - Initial and date the reagent bottle when first opening.
    - Store at 2-8°C.
    - Follow the manufacturer's expiration dates.
    - Once the bottle is opened it is stable until the expiration date on the bottle.
    - Do not use the control solution after the expiration date.

CALIBRATION:

- The CLINITEK® Status/Status+ Analyzer performs a "self-test" each time it is turned on. Each time a test is run, the instrument performs additional checks and calibrates itself using the white plastic bar located on the end of the test strip table. Take care not to scratch the white bar while cleaning the table and **DO NOT** use solvents of any kind to clean the bar.

INSTRUMENT MAINTENANCE:

Clean the test table and test table insert on a daily basis or more frequently if necessary, to ensure test result accuracy and prevent contamination and bacterial growth.

Daily Cleaning:

- To clean the test table and test table insert, perform the following steps:
  - Remove the test table by pulling it slowly out of the analyzer.
  - Lift the table insert to remove it from the test table.
  - Drain the drip tray, if necessary.
  - Wet a cotton-tipped stick with water and thoroughly scrub the test table and table insert, except for the white calibration bar.
  - Rinse both sides of the table insert and test table under running water.
  - Dry the test table thoroughly (except for the white calibration bar) with a soft cloth or lint-free tissue.
    - Examine the white calibration bar on the test table for dirt or discoloration.
    - If the white calibration bar appears clean and unmarked, go to next step.
    - If the bar appears dirty or discolored, clean the calibration bar, as described in *Cleaning the White Calibration Bar*.
  - Insert the test table, pushing it in more than halfway into the analyzer.

As Needed Cleaning:

- *Cleaning the White Calibration Bar*
  - Remove the insert from the test table.
  - Remove the test table by pulling it slowly out of the analyzer.
  - Drain the drip tray, if necessary.
  - Examine the white calibration bar on the test table for dirt or discoloration.
  - If the white calibration bar appears clean and unmarked, perform the following steps:
    - Re-insert the test table into the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upward.
    - Push the test table firmly but slowly, just over halfway into the analyzer.
    - Insert the test table insert.
  - If the white calibration bar appears dirty or discolored, perform the following steps:
    - Wet a new cotton-tipped stick or lint-free cloth with distilled water and gently wipe and clean the calibration bar.
    - Allow the calibration bar to air dry.
  - Inspect the surface for dust, foreign material, scratches, or scuffs.

- If you cannot completely clean the calibration bar or if the bar has scratches, contact the Point of Care Coordinator.
- Insert the test table and table insert.

- *Disinfecting Table & Table Insert*
  - Prepare one of the following solutions in a tall, narrow container (such as an empty Multistix® bottle) to a depth of about 10 cm (or 4 inches):
    - Presept, Cidex, Theracide, or Amphyl solution prepare according to the product directions.
    - Household Bleach (5% sodium hypochlorite) use as full strength or dilute with water to as much as 1:20 (mix 5 mL bleach with 95 mL water for a total of 100 mL).
    - Isopropyl Alcohol (70% to 85%) use as full strength.
  - Remove the table insert from the test table.
  - Remove the test table by pulling it slowly out of the analyzer.
  - Drain the drip tray, if necessary.
  - Place the table insert and test table into the solution, with the white calibration bar on the test table above the liquid level.
  - Soak the test table and the table insert for a minimum of 2 minutes and a maximum of 10 minutes.
  - Rinse the test table and the table insert thoroughly with water.
  - Dry the test table and the table insert thoroughly with a soft cloth, except for the white calibration bar.
  - Insert the test table and the table insert in the analyzer.

QUALITY CONTROL:

QC Material:

- Quantimetrix Dropper Urine Controls

Frequency of Performance:

- Every time you open a bottle.
- Every 30 days.

Procedure:

1. On the Select Ready screen, select QC Test

2. Select QC Strip Test Required.

3. Select Enter New Operator Name.

4. Scan badge when prompted to enter operator name, then press Enter

5. Ensure that the level displayed is the level that you are using. Select Enter lot and expiration date.

6. Scan barcode on QC bottle, then press Enter.

7. Manually enter the control expiration date.

8. Select Enter new lot and expiration date.

9. Scan barcode on strip bottle.

10. Make sure reagent strip holder faces upward in the test table and have the urinalysis strip and paper towel ready.

11. Select Start. You now have 8 seconds to add your QC sample to the reagent strip and place the strip in the test table channel.

12. Add the QC liquid to the strip. Be sure *all* of the test pads are wet.

13. **Blot** the strip to remove excess QC material by **touching the edge** to a paper towel. Do not drag the strip across the towel; touch the edge only.

14. **Place** the Reagent Strip, **with the test pads facing up**, into the middle channel of the test strip table. Slide the strip along the table until it touches the end of the channel. Do not touch the pads on the strip

15. The table is automatically pulled into the instrument for reading. Results are available in one minute. Be sure not to move or bump the Analyzer.

16. Remove the used Reagent Strip after the table returns to start position. Discard the strip in the appropriate container. Wipe the test strip table with a damp, lint-free tissue.

17. Select print to print a copy of the results. Place printout on the log sheet, being careful not to place tape over the printed information as it can fade the print.

18. Select Done

Acceptable Limits:

- Refer to control package insert, included with controls, for acceptable ranges
- If any results are not within the expected range, DO NOT test patient specimens. Troubleshoot and rerun the controls. **ONLY** when control results are acceptable may a patient specimen be tested and reported.

Corrective Action:

- If any results are not within the expected range, DO NOT test patient specimens. Troubleshoot and rerun the controls. **ONLY** when control results are acceptable may a patient specimen be tested and reported.
- ***Troubleshooting: steps to consider when controls are out of acceptable limits:***
    - Was proper technique used while dipping and blotting strip?

- Was the proper control level tested? (Positive as positive and Negative as negative.)
- Does the test strip table need to be cleaned?
- Are the control solutions, or strips expired or discolored?
- Try a new test strip.
- Try a fresh control solution.
- Try a fresh bottle of test strips.
- Call Point of Care Coordinator at 815-599-6704.

Recording QC Data:

- Instrument will determine if QC passes.
- Place QC printout on patient log.
- If any results are not within the expected range, DO NOT test patient specimens. Troubleshoot and rerun the controls. **ONLY** when control results are acceptable may a patient specimen be tested and reported.

PROCEDURE:

1. The urine specimen should be fresh, well mixed, and uncentrifuged.

2. On the Select Ready screen, select Strip Test

3. On the Operator Name screen, scan your badge.

4. On the patient information screen, enter the patient first and last name then select Enter.

5. Enter the patient ID as patient Account Number (A number) select Enter.

6. Scan bottle of test strips to enter strip lot number and expiration date.

7. Make sure reagent strip holder faces upward in the test table and have the urinalysis strip and paper towel ready.

8. Select Start. You now have 8 seconds to dip the reagent strip in the urine sample and place the strip in the test table channel.

9. **Dip** the strip into the urine. Be sure *all* of the test pads are wet.

10. **Remove** the test strip immediately: while removing drag the edge of the entire length of the reagent strip against the side of the urine container to remove excess urine.

11. **Blot** the strip to remove excess urine by **touching the edge** to a paper towel. Do not drag the strip across the towel; touch the edge only.

12. **Place** the Reagent Strip, **with the test pads facing up**, into the middle channel of the test strip table. Slide the strip along the table until it touches the end of the channel. Do not touch the pads on the strip

13. The table is automatically pulled into the instrument for reading. Results are available in one minute. Be sure not to move or bump the Analyzer.

14. Remove the used Reagent Strip after the table returns to start position. Discard the strip in the appropriate container. Wipe the test strip table with a damp, lint-free tissue.

15. If results are not interfaced, results are printed as soon as they are available. If results are not interfaced, place printout on the log sheet, being careful not to place tape over the printed information as it can fade the print.

16. Select Done

REPORTING RESULTS:

Reference Intervals:

- Glucose NEGATIVE
- Bilirubin NEGATIVE
- Ketone NEGATIVE
- Specific Gravity 1.001 to 1.035
- pH 5.0 to 9.0
- Protein NEGATIVE
- Urobilinogen 0.2 to 1.0 EU/dL
- Nitrite NEGATIVE
- Occult Blood NEGATIVE
- Leukocytes NEGATIVE
- Color YELLOW

Result Entry:

- Printout is to be placed on the urine log sheet
- Results are to be recorded in the patient chart.

LIMITATIONS OF PROCEDURE:

TABLE 1

MULTISTIX® 10 SG & Uristix 4		
Test Name	**False Positive/Increased Values**	**False Negative/Decreased Values**
Glucose		Ketones ≥ 40 mg/dL
Bilirubin	Indican interferes with interpretation Metabolites of Lodine	Indican interferes with interpretation
Ketone	Highly pigmented urine Large amounts of levodopa metabolites Compounds that contain sulfhydryl	

	groups (e.g. mesna)	
Specific Gravity	Presence of protein ≥ 100-750 mg/dL	Highly buffered alkaline urine (relative to other methods)
Occult Blood	Oxidizing contaminants (bleach) Microbial peroxidase	Captopril (Capoten®)
pH	Bacterial growth by certain organisms may cause a marked alkaline shift ≥ 8.0 due to urea conversion to ammonia.	
Protein	Proteins other than albumin	
Urobilinogen	p-amino salicylic acids and Sulfonamides (atypical color) High temperature	Formalin
Nitrite		Shortened incubation time in bladder Absence of dietary nitrate Presence of nonreductive pathological microbes
Leukocytes	Contamination with vaginal discharge	Urine glucose ≥ 3 g/dL Cephalexin Cephalothin Oxalic acid, Tetracycline

COMPETENCY REQUIREMENTS:

- Staff new to testing will be required to complete at minimum a return demonstration and assigned quiz.
- Existing staff will be required to complete an annual quiz AND one of the following:
  - Return demonstration
  - Blind Sample
  - Quality Control Test

PROCEDURE NOTES:

- Refer to the "Troubleshooting Clinitek for Urine Test Strips or Cassettes" document for how to troubleshoot error codes.
- **Thermal printed tapes** will fade with time. Make a copy of the result tape if records will be stored for a long period of time. Also, do not cover thermally printed results with transparent tape.
- **False Positives and Negatives** may occur in the presence of interfering substances. Refer to Table 1 in this document under "Limitations of the Procedure".

REFERENCES:

1. CLINITEK® Status+ Operator's Guide, Rev. C, 2019-08. Siemens Healthcare Diagnostics Inc., Tarrytown, NY 10591
2. MULTISTIX® 10 SG Reagent Strips package insert, Rev. A 7/2017. Siemens Healthcare Diagnostics Inc., Tarrytown, NY 10591

3. CLINITEK Status® Connector User Guide, Rev. A, 2020-06. Siemens Healthcare Diagnostics Inc., Tarrytown, NY 10591

10/26/22