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| **SUBJECT/TITLE:** | **UICC Microalbumin on the Clinitek Status+ Connect** |

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| **PURPOSE:****SCOPE:** | To provide a testing procedure for point of care microalbumin performed on the Clinitek Status+.All trained clinical staff within University of Iowa Community Clinics (UICC) who have demonstrated competency. |
| **DEFINITIONS:** | Not applicable.  |

**POLICY:**

1. Intended Use:
	1. For testing with associated EPIC order SPL705.
	2. The Clinitek Status+ is an analyzer 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.
	3. 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.
2. Supplies:
	1. Clinitek Microalbumin 2 Reagent Strips (product #2083)
	2. Lint free wipes such as Kimwipes ®
	3. Alcohol pads
	4. Urine controls (Quantimetrix Dropper Plus Levels 1 & 2 (product #1440-04))
	5. Bleach
	6. PDI Easy Screen cleaning wipes
3. Storage Requirements:
	1. Clinitek Status+
		1. Use between 18°C and 30°C.
		2. Use in places where relative humidity is between 18% and 80%.
	2. Clinitek Microalbumin 2 Reagent Strips
		1. Store between 15°C and 30°C.
		2. Do not use past the printed expiration date.
		3. Do not store the bottle in direct sunlight.
		4. Unused strips should remain in the original container with the lid tightly closed.
	3. Quantimetrix Dropper Plus Controls
		1. Store between 2°C and 8°C.
		2. Do not use past the printed expiration date.
	4. Urine Specimen
		1. May be stored at room temperature for 2 hours.
		2. If testing is delayed, store between at 0°C-8°C for up to 1 week or at -20°C for up to 1 month. Allow specimen to return to room temperature prior to testing.
4. Reference ranges
	1. See [Pathology Handbook](https://www.healthcare.uiowa.edu/path_handbook/?_ga=2.249625551.879073798.1554383905-2054287554.1550602127) for a list of reference ranges.
5. Quality Control (QC):
	1. QC should be performed:
		1. When a new bottle of reagent strips is opened.
		2. Every 30 days for the in-use reagent strip bottle.
		3. When training new users.
		4. Any time results do not match a patient’s clinical symptoms or there are concerns with the functionality of the analyzer.
	2. Record the lot number, expiration date, and passing ranges for a new lot of controls on the Quality Control Log (Form B). Retain package insert for 2 years.
6. Limitations:
	1. Substances that contain azo dyes, such as phenazopyridine will interfere with the test result. If a patient is taking phenazopyridine or has taken it within **24 hours** of their clinic visit, a point of care microalbumin **cannot be performed**. The patient sample must be sent to Medical Campus University (MCU) Specimen Control for processing. See #3 below for instructions on ordering.
	2. Specimen color can interfere with the test result. Only test specimens on the Clinitek Status+ that are one of the following colors: **Colorless, Light yellow, Yellow or Dark Yellow. For a specimen of any other color, a point of care microalbumin cannot be performed.** The patient specimen must be sent to MCU for processing. See #3 below for instructions on ordering.
	3. Instructions for placing order to send to MCU for processing:
		1. Place order **LAB646: Microalbumin, Urine Random.**
			1. For Sioux City: SPL599: Microalbumin, Urine
		2. See UIDL Handbook for processing instructions.
			1. For Sioux City: See LabCorp Procedure Catalog for processing instructions.
	4. Reference the reagent package insert for other possible limitations.

**PROCEDURES:**

1. Running Quality Control:
	1. Remove QC bottles from refrigerator and allow to come to room temperature for at least 15 minutes. Mix before use.
	2. Both levels of QC must be run as patient specimens, not in QC mode.
		1. This is because the instrument cannot support quality control ranges for two different tests at the same time. All Cliniteks are programed with the passing quality control ranges for urinalysis testing.
		2. Ensure that QC is not expired before use.
	3. Quality Control Testing:
		1. On the Select Ready screen, select STRIP TEST.
		2. Enter Operator ID by scanning the barcode on the back of the employee badge. Select ENTER.
		3. Touch ENTER NEW PATIENT.
		4. Scan the barcode on the Quantimetrix Level 1 bottle and touch ENTER.
		5. Touch ENTER NEW LOT AND EXPIRATION DATE and scan the barcode on the strip bottle. Select ENTER.
		6. Remove one strip from the Microalbumin 2 bottle.
		7. Select START. The next two steps need to be completed within 8 seconds.
		8. Quickly place a drop of control on each test pad, blot the edge of the strip on a paper towel to remove the excess control liquid.
		9. Place strip on the test table with the test pads facing upwards.
			1. Push or slide the strip to the end of the test table channel.
			2. Do not touch the pads on the strip.
		10. After the 8-second countdown ends, the analyzer pulls in the test table with strip and begins a calibration, humidity check on test strip, and testing.
		11. During analysis, a Select Appearancescreen appears.
			1. Select YELLOW AND CLEAR.
			2. This is the default selection for QC. The analyzer will not automatically print results until the color and clarity have been entered.
		12. A timer counts down the time remaining in the analysis of the strip. Once analysis is complete, the test table and strip will move out of the analyzer. Remove the used strip and properly dispose of it according to laboratory protocol.
		13. If needed, wipe the tray with a lint free wipe such as Kimwipes® dampened with water.
		14. Manually compare the results printout to the passing ranges from the package insert. Record QC results on the Quality Control Log and adhere the printout to the back of the form.
		15. Touch DONE.
		16. Repeat above steps a-o for level 2.
		17. Return QC bottles to the refrigerator.
	4. If either QC level results fail, do not test patient samples until the problem is resolved.
		1. Repeat quality control testing and/or try new strips.
		2. If controls still fail contact a supervisor, call UICC Lab Admin Team, or Siemens technical support at 877-229-3711.
2. Calibration:
	1. When a strip is placed on the test table, the analyzer automatically performs a calibration prior to analysis.
3. Running a Patient Specimen:
	1. Specimen requirements:
		1. Midstream clean catch urine sample. Refer to the [DN.P.DN.12.3 Urine Collection for Non-Catheterized Patients: Adult and Pediatric](https://uihealthcare.policytech.com/docview/?docid=6747&anonymous=true) for collection instructions.
		2. The specimen **must be** collected and received prior to testing because the instrument will require the user to scan the Beaker label. Please refer to [DN.P.DN.3.1 Specimen Collection and Transport](https://uihealthcare.policytech.com/docview/?docid=6232&anonymous=true) for instructions on specimen collection.
	2. Patient Testing:
		1. On the Select Ready screen, select STRIP TEST.
		2. Enter Operator ID by scanning the barcode on the back of your employee badge. Select ENTER.
		3. Touch ENTER NEW PATIENT and scan the barcode on the patient’s Beaker label to enter the Patient ID. Select ENTER.
		4. Touch ENTER NEW LOT AND EXPIRATION DATE and scan the barcode on the strip bottle. Select ENTER.
		5. Remove one strip from the Microalbumin 2 bottle.
		6. Select START. The next two steps need to be completed within 8 seconds.
		7. Dip the strip into the urine sample to wet all test pads. Immediately remove the strip from the urine. Blot the strip edge on a paper towel or other absorbent material to remove excess urine.
		8. Place strip on the test table with the test pads facing upwards.
			1. Push or slide the strip to the end of the test table channel. The end of the strip must be touching the white calibration bar.
			2. Do not touch the pads on the strip.
		9. After the 8-second countdown ends, the analyzer pulls in the test table with strip and begins a calibration, humidity check on test strip, and testing.
		10. During analysis, a Select Appearancescreen appears. Visually observe the urine and determine its color and clarity.
			1. If the sample is yellow and clear, select YELLOW AND CLEAR.
			2. If the sample is not yellow and clear, select OTHER.

Select a color option: COLORLESS, LIGHT YELLOW, YELLOW, or DARK YELLOW. Select NEXT.

For any other specimen colors, see LIMITATIONS and instructions for referring the testing to MCU.

For Sioux City: Send to Lab Corps

* + - 1. Select a CLARITY option, then select NEXT.
			2. Refer to color and clarity chart (Form A).
		1. A timer counts down the time remaining in the analysis of the strip. Once analysis is complete, the first page of results will display on the Results screen. If the analyzer is programmed to do so, the results will print automatically. **The results will not print until the color and clarity have been entered.**
		2. The test table and strip will move out of the analyzer. Remove the used strip and properly dispose of it according to laboratory protocol.
		3. If needed, wipe the tray with a lint free wipe such as Kimwipes ®) dampened with water.
		4. Select DONE to return to the Select Ready screen.
		5. Patient results should upload automatically to the EHR.. Add the results printout to the Daily Lab Log.
			- 1. If results do not interface to the EHR, contact the Pathology Point of Care Team at pathologypointofcareteam@healthcare.uiowa.edu and manually file the results in Epic.
1. Maintenance:
	1. The maintenance form is located in [DN.P.AC.38.11 UICC Clinitek Status + Connect](https://uihealthcare.policytech.com/docview/?docid=11247&anonymous=true). Only one maintenance form is needed per one machine.
	2. Weekly
		1. Cleaning the test table and table insert
			1. Remove the table insert from the test table.
			2. Remove the test table by pulling it slowly out of the analyzer.
			3. Drain the drip tray, if necessary.
			4. Wet a cotton-tipped stick with water and thoroughly scrub the test table and insert, except for the white calibration bar.
			5. Rinse both sides of the table insert and the test table under running water.
			6. Dry the test table thoroughly (except for the white calibration bar) with a lint free wipes such as Kimwipes ®.

Allow the calibration bar to air dry.

* + - 1. Examine the white calibration bar for dirt or marks.

Do not touch the calibration bar while examining it or after it is cleaned. Fingerprints or lint on the bar could cause unreliable test results. When examining the white calibration bar, do it carefully and under good lighting.

* + - 1. If the white calibration bar appears clean and unmarked, perform the following steps:

Place 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.

Do not push the test table fully into the analyzer. The test table might jam and prevent you from using the analyzer.

Place the table insert onto the test table.

* + - 1. If the white calibration bar is dirty or discolored, perform the following steps:
		1. Wet a new cotton-tipped stick or lint-free cloth with distilled water and gently wipe and clean the calibration bar. **Do not use solvents of any kind to clean the calibration bar and do not scratch or mark the surface of the calibration bar.**
		2. Allow the calibration bar to air dry.
		3. Inspect the surface for dust, foreign material, scratches, or scuffs.
		4. Reassemble the test table and table insert as described in step 8 above.
			1. If the calibration bar cannot be cleaned of dust, discoloration, etc., or if the bar still has marks, contact the UICC Lab Admin Team.
	1. As Needed or every 6 months:
		1. Disinfecting the Test Table and Table Insert
			1. Approved disinfectants

**Household Bleach (5% sodium hypochlorite):** Prepare a 10% bleach solution (10 mL Bleach and 90 mL of water).

* + - 1. Disinfecting process

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 the test table into the solution with the white calibration bar above the liquid level. **Do not soak the calibration bar.**

An empty strip bottle can be used as a container for the solution.

Soak the test table and table insert for a minimum of 2 minutes but no longer than 10 minutes. Otherwise, damage could occur.

Rinse both sides of the table insert and the test table under running water.

Dry the test table and table insert thoroughly (except for the white calibration bar) with a lint free wipes such as Kimwipes ®

Allow the calibration bar to air dry.

Place 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.

Do not push the test table fully into the analyzer. The test table might jam and prevent you from using the analyzer.

Place the table insert onto the test table.

* 1. As Needed
		1. Cleaning the exterior of the analyzer
			1. Power off the analyzer.
			2. Wipe the exterior (including display) with a damp (not wet) cloth and a mild detergent.
			3. Wipe the display with a clean cloth dampened with water and dry the display with a clean cloth.

If the display is heavily soiled, use a PDI Easy Screen cleaning wipe.

1. Troubleshooting:
	1. If an operational or analyzer problem occurs, in most cases, an error number with an explanation of the problem displays on the Select Readyscreen. If a problem persists, write down the error number that displays and contact Technical Support at 877-229-3711.
	2. After an error occurs, power the analyzer off and on. Then, retest the sample that was in progress when the error occurred.
	3. Refer to the Operator’s Guide when error messages occur for troubleshooting information.

**RELATED POLICIES/DOCUMENTS:**

DN.P.DN.12.3 [Urine Collection for Non-Catheterized Patients: Adult and Pediatric](https://uihealthcare.policytech.com/docview/?docid=6747&anonymous=true)

DN.P.DN.3.1 [Specimen Collection and Transport](https://uihealthcare.policytech.com/docview/?docid=6232&anonymous=true)

DN.P.AC.38.11 [UICC Clinitek Status + Connect](https://uihealthcare.policytech.com/docview/?docid=11247&anonymous=true)

[UIDL Handbook](https://www.healthcare.uiowa.edu/path_handbook/rindex.html)

**REFERENCES:**

Quantimetrix. (2005). *Dropper Plus Point-of-Care Urinalysis Dipstick Control Level 1 & 2.*

Siemens (2022, May). *Clinitek Status® + Analyzer Operator’s Guide.*

Siemens (2017, Jul). *Clinitek Microalbumin 2 Package Insert.*

Source: University of Iowa Community Clinics and Pathology

Effective Date: 8/15/2024

Version Number: 1

Date Revised: 8/15/2024

Date Reviewed:

**APPENDICES:**

Form A: Urine Color and Clarity

Form B: Quality Control Log

8/12/2024 8/15/2024

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Date Date

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Michael Jung, M.D.

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MICROALBUMIN CLINITEK STATUS PLUS QUALITY CONTROL LOG

CLINIC: YEAR:

LOCATION of Clinitek: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ MONTH: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Directions:**

1. Begin a new page when the control lot number changes.
2. Carefully compare quality control results to package insert ranges to ensure the values fall within the passing ranges.

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| Control Levels | Control Lot Number | Control Exp Date | QC Range |
| Level 1 |  |  | Microalbumin |  |
| Creatinine |  |
| Level 2 |  |  | Microalbumin |  |
| Creatinine |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date | Initials | Reason for performing QC | Microalbumin 2 Lot # | Controls | Pass/Fail |
| New Bottle | Monthly (record date strips opened) |
|  |  |  |  |  | Level 1 |  |
| Level 2 |  |
|  |  |  |  |  | Level 1 |  |
| Level 2 |  |
|  |  |  |  |  | Level 1 |  |
| Level 2 |  |
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| Level 2 |  |