Document History:

Title: Clinitek Status Connect System Operator Manual **Site(s): Shared Health**

Document #:	**110-50-19**	**Version #:**	**07**
Section:	**Clinical Biochemistry**	**Subsection:**	**Urinalysis**

Approved by:	H Malvern	**Date:**	15 April 2013

Approved by:	H Malvern	**Date:**	20 April 2021
Signature:	(Signature on File)		
		Effective Date:	20 May 2021

#	Details of Revisions:	Approval:	Date:
1	New document	H Malvern	13-MAY-2013
2	Added instruction for setting up a loaner instrument. Referred daily QC to SOP 110-50-06, Troubleshooting section. Reference range for SG, CAP EPT reporting guide	H Malvern	07-APR-2015
3	Corrected Ketone EPT reporting, Revised step 10 under Patient Testing	H. Malvern	04-Jan-2019
4	Included reference to SOP 110-50-20 for reagent principles and sample requirements	U. Uddayasankar	17-Jan - 2019
5	Created appendices for System Configuration Settings and Loaner Instrument Setup (ps.8/9). Moved LIS Downtime/EPT/QC reporting to separate Appendix 3; updated CMP reporting values, added URT reporting values (ps.10/11). Minor reformatting throughout.	H Malvern	28 April 2020
6	Removed reference to incorrect steps in QC section. (p.4).	H Malvern	27 Aug 2020
7	Removed CMP Reporting Values from Appendix 3. Report CAP results according to individual challenge options.	H Malvern	20 April 2021

1.0 PRINCIPLE:

The Clinitek Status Connect Urinalysis analyzer is a bench top analyzer. Clinitek Status connector and Clinitek Status analyzer together are the Clinitek Status Connect system. Clinitek Status analyzers and the connector provide the capability to communicate with remote Hospital and Laboratory Information Systems (HIS/LIS) and interface with Electronic Medical Records (EMR). The connector also supports importing certain information using an optional bar code scanner. It is designed to read Siemens Healthcare Diagnostics Reagent Strips for Urinalysis, such as, MULTISTIX® 10 SG. The analyzer 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.

Siemens Strips contain reagent areas for testing glucose, bilirubin, ketone (acetoacetic acid), specific gravity, occult blood, pH, protein, urobilinogen, nitrite, and leukocytes. Scientific principle of reagent pads and results interpretation guide is found in Shared Health document # 110-50-20.

2.0 SAFETY:

Follow Routine Laboratory safety procedures.

CAUTION: Do not use anything hard or pointed on the touch screen. It may damage the screen.

3.0 MATERIALS:

Clinitek Status Connect System
Siemens Multistix 10 SG

4.0 CALIBRATION:

The Clinitek Status®+ analyzer will perform an automatic calibration each time a test is run.

5.0 DAILY MAINTENANCE:

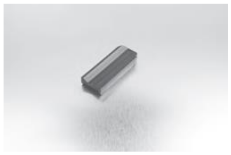
5.1 Clean the outside of the analyzer & screen:

- Always keep the outside of the Clinitek Status+ analyzer clean and free of dust.

CAUTION: Care should be taken to avoid liquid from entering the printer compartment.

1. Turn the analyzer off by pressing the on/off button for 2 seconds.
2. Wipe the outside (including the display) with a damp (not wet) cloth and a mild detergent.
3. Using 70% Isopropyl alcohol wipe monitor screen and allow to remain for 10 minutes. Wipe clean using a clean cloth dampened with water, then dry.

5.2 Cleaning of Test Table Insert:



1. Remove insert and thoroughly clean.
2. Rinse both sides of the table insert under running water.
3. Dry and replace insert.

5.3 Cleaning of Test Table when Required:

1. Remove the test table by pulling it slowly out of the analyzer. Lift the test table insert from the test table,
2. Wet a cotton-tipped stick with water and carefully clean test table (except for white calibration bar).
3. Dry the test table thoroughly (except for the white calibration bar) with a soft cloth or lint-free tissue.
4. Reinsert the test table into the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upwards. Push the test table firmly but slowly, just over halfway into the analyzer.

CAUTION: Care should be taken not to scratch the white calibration bar.

5. Replace the test table insert.

6.0 WEEKLY MAINTENANCE:

6.1 Check and Clean the White Calibration Bar:

The Calibration bar on the test table should be regularly checked and always check it after a strip jam.

1. Remove the insert from the test table.
2. Remove the test table by pulling it slowly out of the analyzer.

3. Check the white calibration baron the test table for dirt or discoloration.

White Calibration Bar

4. **If** the white calibration bar is clean and unmarked, replace the table into the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upwards. Push the test table firmly but slowly, just over half way into the analyzer.
5. Replace the test table insert.
6. **If** the white calibration bar is dirty or discolored, gently wipe and clean it with a new cotton tipped stick or lint-free cloth wetted with distilled water.

CAUTION: DO NOT scratch the white calibration bar. DO NOT use solvents to clean the calibration bar.

7. Allow the calibration bar to air dry and then inspect the surface for dust, foreign material, scratches or scuffs. If the calibration bar cannot be cleaned or is still marked, obtain a new test table.
8. Reinsert the test table as described in step 4.

7.0 AS REQUIRED MAINTENANCE:

1. Changing Batteries
2. Disinfecting the Test Table and Insert

Refer to instruction in the Manufacturer's operator manual

8.0 QUALITY CONTROL / EPT:

Two levels of Biorad qUAntify Plus controls are run after daily maintenance in accordance with Shared Health policy 110-10-21, QC Monitoring, review and Troubleshooting. QC data must be either submitted to Biorad for external comparison or recorded on the appropriate Urinalysis Control Log sheets. All QC records must be retained for two years. Refer to Shared Health Policy, Laboratory Records and Material Retention Policy [100-10-05].

- Refer to SOP 110-50-06, QC of Urinalysis Test Strips for type of controls required and handling of materials.
- Do not proceed with patient specimens if QC results are outside allowable ranges.

8.1 External Proficiency Testing:

- Each site should subscribe to CAP – CM and CMP (Clinical Microscopy Survey)

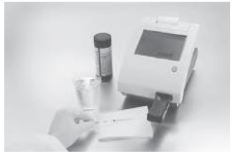
8.2 Performing QC analysis:

1. Materials:
   - Siemens Multistix 10 SG test strip
   - BioRad qUAntify Plus Controls Level 1 & 2 - Prepare the controls according to the manufacturer's instructions.
   - Paper towel

2. Preparation:
   - At the *Select Ready* screen, select **QC Test Strip due**. The *QC Test* screen displays.
   - Select **QC Strip Test Required**.
   - The *Name of Control* screen displays. Enter the control name. Use the alpha keyboard to enter text. To enter numeric text, select **123**.
   - Select **Enter**. The *Name of Control Level* screen displays. Enter the control level.
   - Select **Enter**. The *Control Lot* screen displays. Enter the control lot.
   - Select **Enter**. The *Control Expiration* screen displays. Use the arrow keys to indicate the control lot expiration date.
   - Select **Enter**. The *Strip Lot* screen displays. Enter the strip lot.
   - Select **Enter**. The *Strip Expiration* screen displays. Enter the strip expiration date.
   - Select **Enter**. The *Prepare Test* screen displays.
   - Select **Start**.

3. Procedure:
   CAUTION: Do not dip the automatic identification band or color band in the urine sample.
   NOTE: You have 8 seconds after pressing **Start** (step 10 above) to complete the following four steps:

   a. Dip the reagent strip into the urine sample, wetting all pads. Immediately remove the strip from the urine.
   b. Drag the edge of the strip against the side of the sample container as you remove it.
   c. Blot by touching the edge of the strip to the paper towel to remove excess urine.



   d. Place the reagent strip in the channel of the table with the test pads facing up. Slide strip to end of the channel.
   e. At the end of the 8 second countdown, the test table and strip will automatically be pulled into the analyzer.

   CAUTION: Be sure not to move or bump the table while the instrument is calibrating.

   f. After calibration, a timer will count down the time remaining in analyzing the strip results.

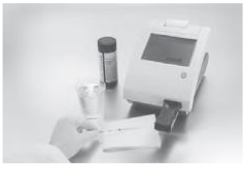
g. When testing is complete the *Results* screen displays the results. To print the results, select **Print**.
h. Repeat steps 1 to 7 for QC level 2
i. Evaluate and document the QC values.

9.0 PATIENT TESTING:

9.1 Materials:

- Patient Urine sample (urine sample requirements: Shared Health document # 110-50-20)
- Siemens Multistix 10 SG test strip
- Paper towel

9.2 Procedure:

Step 1			**Then**
	If	**Using the Specimen ID Without a Loadlist**	1. At the SELECT screen, select **Strip Test**. 2. Enter /Scan the ID number for the specimen you are about to test. 3. Select **A-Z** to enter alphabetic characters. 4. If needed, enter or scan the color and clarity. 5. When this information is correctly entered, select **Enter** The display changes to allow entry of the next ID number, and the push bar moves to the left so you can place a strip on the loading station. **NOTE:** If another ID is entered without a strip being detected, the analyzer automatically creates a loadlist.
	If	**Downloading a worklist from LIS**	1. The analyzer is at the SELECT screen 2. No IDs from an earlier loadlist are still stored in the analyzer 3. Download worklist from LIS 4. For the Specimen ID displayed
Step 2	Completely immerse all of the reagent pads **(Except the CHECK BAND**) on a Siemens Reagent Strip into the specimen.		
Step 3	Immediately remove the reagent strip.		
Step 4	While removing the strip, run the edge against the side of the container. This removes excess liquid.		
Step 5	Blot by touching the edge of the strip to the paper towel to remove excess urine. 		
Step 6	Place the reagent strip in the channel of the table with the test pads facing up. Slide strip to end of the channel.		

	 At the end of the 8 second countdown, the test table and strip will automatically be pulled into the analyzer.
Step 7	*The Clinitek Status®+ analyzer will perform an automatic calibration each time a test is run.* **DO NOT move or bump the table while the instrument is calibrating.** 
Step 8	Repeat steps 2 to 8 for each additional specimen
Step 9	If the printer is set to On, the results are printed, stored in memory or Automatically uploaded to the LIS with the positive bilirubin comment when applicable.
Step 10	Review results for flags and take appropriate action **Extremely dark colored or highly turbid sample may give error codes and not produce a dipstick result.** **Action:** Test add “UR2’ for urine microscopy and report the results. Attach a comment specific to the reason the dipstick result is not available. Remove the non-resulted urine dipstick test codes.

10.0 RESULTS REPORTING:

Manually report on a requisition (Refer to reporting chart) or if connected to an LIS results will automatically upload.

If the specimen is positive for Bilirubin report the following comment on the patient report manually. If connected to Delphic LIS the comment will attach automatically.

"A positive bilirubin result is not diagnostic, as a false positive test can occur in some urine samples; confirmation by a serum bilirubin test should follow if clinically warranted in this patient."

11.0 REFERENCE:

Clinitek Status Connect System Operators Manual (REF 10379682)

APPENDIX 1

CLINITEK STATUS CONNECT SYSTEM CONFIGURATION SETTINGS

Menu Options	Settings
Startup Wizard	
Language	English
Date	Current
Time	Current
Preferred test sequence	Quick Test
Type of Urinalysis Strip	MULTISTIX 10 SG
Result format	S.I.
Instrument Set up	
Language	English
Set Password	User defined (use to save setting)
Input settings	Quick Test
Operator ID	Disabled
Keypad Priority	Numeric
Patient ID	Enabled
Date	Day/Month/Year (05/03/13)
Time	24 hour (07:30 AM)
Preferred test sequence	Quick Test
Computer Port	OFF (if no LIS)
Printer	Internal: ON, 2 blank lines between patient results
Display contrast	Adjust for brightness if required
Result Units	S.I.
Plus System	OFF
Strip	MULTISTIX 10 SG
Alternative strip	None
Test to report and their order	GLU, BIL, KET, SG, BLD, pH, PRO, UBG, NIT, LEU
Mark positives	ON
Positive levels for tests	GLU-5.5, BIL-Small, KET-Trace, PRO-Trace, UBG-33, BLD-Trace L, LEU-15
Normal range for SG/pH	SG-1.005 to 1.030, pH-5.0 to 8.0
Color	OFF
Color choices	OFF
Clarity choices	OFF
Use default COL/CLA during run	OFF
Flags for microscopic	PRO, BLD, LEU
Set QC options	Compulsory regular QC test (Every 24 Hours)
Computer port options:	
Port	ON (OFF for non LIS sites)
Baud	9600
Data, Parity	May be analyzer/connection specific
Output format	May be analyzer/connection specific
Checksum	May be analyzer/connection specific
Handshake	May be analyzer/connection specific
Network settings	May be analyzer/connection specific
Subnet mask	May be analyzer/connection specific
Gateway	May be analyzer/connection specific
Restore Default Settings	N/A (DO NOT TOUCH)
System Information	Shows all inputted settings

APPENDIX 2

SETTING UP THE LOANER INSTRUMENT

Requirements:

- Manufacturer's Operator manual; Clinitek Status Connect - Chapter 6 System Configuration
- Print out of Menu settings from Site analyzer

Procedure:

1. Setup instrument according to instruction in the manufacturer's operator manual under system configuration.
2. Using the menu settings from your site analyzer, program the loaner instrument with the same parameters.
    - **Note:** Except for the LIS settings. All other setting should be the same (if not, reprogram according to the Shared Health sop instructions and your site's LIS settings)
3. If connected to LIS - Program a dummy patient in the LIS and test the connectivity of the instrument to the LIS
    - If connectivity does not work:
        a. Recheck the LIS settings
        b. Call e-Health for support – 204-940-8500
4. Perform daily maintenance and record in the Loaner instrument's maintenance log.
5. Calibrate if required and run quality control according to SOP 110-50-06 QC of Urinalysis Test Strips
6. Evaluate and document QC in the loaner instrument's QC log
7. Resume operations with the Loaner instrument
8. Indicate in the Loaner instrument's equipment log the date the instrument was put into service at your site and the date it is removed from service.

External Quality Control:

If an EPT challenge sample arrives while you are using the loaner analyzer:

1. Perform the challenge and submit results under your own Lab
2. Indicate the instrument serial number on all documents
3. If your results are non-compliant:
    - Perform all necessary follow up under your lab and submit non-conformance to Discipline team/Shared Health quality for reporting to MANQAP.
4. Make a photo copy of all documents: keep one for your site's record and place one in the Loaner instrument's EPT log book to follow the loaner instrument.

Trouble shooting:

- Refer to Manufacturer's Operator manual
- Call Vendor Hotline
- Document problem, actions taken and hotline reference number in Equipment action log
- Call e-Health from connectivity issues (Give the name of the Instrument)

APPENDIX 3

LIS DOWNTIME / EXTERNAL PROFICIENCY TESTING / QUALITY CONTROL REPORTING:

Analyte	Unit	Multistix 10 SG Reportable Range	LIS Reporting or Manual LIS Downtime	CAP - CMP Report from Analyzer Print out	Unity RealTime Reporting
Glucose	mmol/L	Negative	Negative	Use Method 2 UOM = mg/dL mmol/L / (divided by) 0.0555 = mg/dL	Negative
		5.5	5.5		5.5
		14	14		14
		28	28		28
		>55	>55		55
Bilirubin		Negative	Negative	Use Method 1	Negative
		Small	Small		Small
		Moderate	Moderate		Moderate
		Large	Large		Large
Ketones	mmol/L	Negative	Negative	Use Method 3 UOM = mg/dL mmol/L / (divided by) 0.0961 =mg/dL	Negative
		Trace	Trace		Trace
		1.5	1.5		1.5
		3.9	3.9		4
		7.8	>7.8		8
		>15.6	Report >7.8 for patients		16
Specific Gravity		<1.005	<1.005	<1.005	1.005
		1.010	1.010	1.010	1.010
		1.015	1.015	1.015	1.015
		1.020	1.020	1.020	1.020
		1.025	1.025	1.025	1.025
		>1.030	>1.030	>1.030	1.030
Blood	Ery/µL	Negative	Negative	Use Method 3 UOM = Ery/µL	Negative
		Trace-Lysed	Trace-Lysed		Hemolyzed Trace
		Trace-Intact	Trace-Intact		Non-Hemolyzed Trace
		Ca25	25		Small
		Ca80	80		Moderate
		Ca200	200		Large
pH		5.0	5.0	5.0	5.0
		5.5	5.5	5.5	5.5
		6.0	6.0	6.0	6.0
		6.5	6.5	6.5	6.5
		7.0	7.0	7.0	7.0
		7.5	7.5	7.5	7.5
		8.0	8.0	8.0	8.0
		8.5	8.5	8.5	8.5
		>9.0	>9.0	>9.0	
Protein	g/L	Negative	Negative	Use Method 2 UOM = mg/dL g/L x 100 = mg/dL	Negative
		Trace	Trace		Trace
		0.3	0.3		0.3
		1.0	1.0		1.0
		3.0	>3.0		3.0
		>10.0			20.0

Analyte	Unit	Multistix 10 SG Reportable Range	LIS Reporting or Manual LIS Downtime	CAP - CMP Report from Analyzer Print out	Unity RealTime Reporting
Urobilinogen	µmol/L	3.2	3.2	Use Method 2 UOM = mg/dL or µmol/L	3.2
		16	16		16
		33	33		33
		66	66		66
		>131	>131		133
Nitrite		Negative	Negative	Negative	Negative
		Positive	Positive	Positive	Positive
Leukocytes	Leu/µL	Negative	Negative	Use Method 3 UOM = Leu/µL	Negative
		Ca15	15		Trace
		Ca70	70		Small
		Ca125	125		Moderate
		Ca500	500		Large

Note: Ca on the analyzer printout represents approximately and does not need to be reported

Abbreviations for Slot entering results into Delphic LIS

Print Display	LIS Entry
Slot enter numerical values as they appear	
Negative	N
Positive	P
Small	S
Moderate	M
Large	L
Trace	T
Trace *(The Novus only prints (Trace) for Trace lysed Blood)*	TL
NHT	TI
<xxx (Less than)	Lxxx
>xxx (Greater than)	Gxxx