

Title: Clinitek Status Connect Plus Procedure

Cross References: Clinitek Status Connect Plus Training and Competency Record
Clinitek Status Connect Plus Problem Checklist
MGH POCT QC Storage Ordering and Documentation Guide

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Purpose

This document outlines policies and procedures that deal with automated urine dipstick testing. In an effort to be concise some information may be excluded from the manufacturer's recommended procedure. It is recommended that operators familiarize themselves with the manufacturer's product information that accompanies each package and their manual if one exists.

Scope

Level of Personnel: All RN's, NP's, PCA's, and MA's, who have successfully completed initial training and maintained annual competency

Testing Site: All sites approved and on file with the Pathology Service POCT Division.

Policy and Procedure Statement

The CLINITEK Status Connect Plus Analyzer is a waived instrument for in-vitro diagnostic screening using the Siemens Multistix Reagent Urinalysis Strips.

Test Principle

The optical system consists of six light emitting diodes, a light guide, a mirror, a lens and a detector. Light from the LEDs travels along the light guide and is reflected off the calibration bar, strip or cassette onto the mirror. It is then directed through an aperture plate onto the lens, from where it is focused onto the detector. The light intensity detected is converted into electrical impulses, which are processed by the instrument's microprocessor and converted into clinically meaningful results.

Regulatory Requirements

1. Each testing site must have a documented quality control program, which is developed in collaboration with or has been approved by the MGH Pathology Service.
2. All test results must be maintained in patient records with all required information for four years

Required information:

1. Patient's name
2. Medical Record Number
3. Patient's gender
4. Patient's age or date of birth
5. Date & time test collected, performed and reported
6. Ordering Physician
7. Responsible physician (if not 6)
8. Reference or Target Range
9. Test Performed
10. Test units
11. Lab name

3. Additional information that must be retained for four years:

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1. Testing personnel records
2. Quality control results
3. Product information (i.e. serial number, lot numbers, expiration dates, etc.), information on quality control and any remedial action
4. QC charts, maintenance sheets, reference and critical ranges

4. Other

1. Universal precautions must be observed when handling any patient specimen.
2. A physician's order or standing order is required prior to performing test.
3. The Hospital Hand Hygiene policy must be adhered to at all times.

Competency Assessment

All operators must read the procedure manual and complete the "Clinitek Status Connect Plus Training and Competency Record" during initial training. Competency is assessed at orientation and annually using at least two of the following methods:

1. Performing a test on a blind specimen.
2. Supervisor observes performance of routine work.
3. Each user's quality control performance is monitored.
4. Written testing specific to the method.

The name and operator ID of newly documented operators trained on the Clinitek STATUS Connect Plus must be provided to the POCT program for entry into Telcor to allow instrument access. Only approved operators are allowed to use the machine.

Expired Operators:

Operators who fail to meet competency requirements within 365 days will be locked out of the system. They will be required to undergo retraining and competency assessment according to above.

Limitations/Interferences

Place the instrument on a level work surface, where the temperature and humidity are fairly constant. The best temperature for using the instrument is between 18°C - 30°C (64°F - 86°F). The instrument should not be placed near open windows, ovens, hot plates, open burners, radiators and dry ice baths.

1. The CLINITEK Status Connect Plus Analyzer calibrates before each new specimen using the white plastic bar on the side of the test strip.
2. Do Not Push or Pull the Test Table.

Test Kit/Supplies/Equipment

Products	Distributor	Manufacturer #	People soft #	Storage
Siemens Multistix 8SG Test Strips	Owens & Minor	Siemens #AM-2164 2164phc	PS#028143 (only POCT approved strip type may be ordered)	Room Temp

Quantimetrix: The Dipper UDC Set 6x15ml (Levels 1 and 2) QC	Fisher Health Care	Quantimetrix Ref # 1440-01 Vendor Item ID: NC9728698	Use Special Request tab to order. Add in comments: Give order to Fisher Onsite to process.	2 - 8° C: until manufacturer's expiration date if unopened. Opened, 3 months or 20 dips. No room temp storage allowed.
Fisher Brand thermal paper 2-1/4 in. W x 70 ft. L 6 rolls/pk	Fisher Health Care	22-044296	Order through Fisher punch out website in eBuy	Room Temp

Specimen Collection

Collect FRESH urine specimen in a clean, dry container. Label with PACE label which includes 2 patient identifiers per hospital policy. Mix well before testing. Urine should be tested immediately.

Calibration

The instrument uses the white calibration bar on the test table to calibrate before a test is carried out. Before positioning the test table behind the shutter for analysis, the calibration bar is positioned under the reflected "read area" for calibration to be performed.

Connectivity and Downtime Procedure

1. The Clinitek Status Connect Plus analyzer is designed to work for a long period of time without any direct service. No preventative measurements are needed for the electronic components of the analyzer.
2. In the event of connectivity failure, document the results on the patient's chart with the units and reference ranges. Results can be re-transmitted in the "Recall Results" menu.
3. Contact the POCT program for assistance.(ext.6-1462, 3-5392 or 6-3858)

Quality Control Monitoring

Positive and negative control solutions are tested daily. This provides a check to ensure that the test strips are reacting correctly and the instrument is reading the strips properly. Testing controls also helps detect errors caused by incorrect user technique.

Controls must be tested at the following intervals:

- At the start of every day of patient testing.
- When you open a new bottle of test strips.
- Whenever test results are in doubt.
- When training instrument operators.

Note: Allow the controls to come to room temperature if refrigerated. New lots must have QC range verified, see next section.

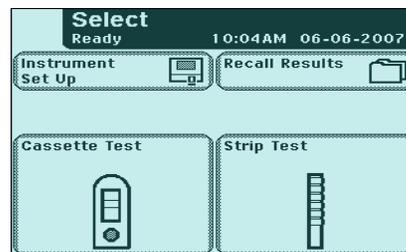
To perform a QC strip test when due, perform the following steps for each control level:

1. Follow hand hygiene protocols and put on gloves.
2. At the *Select Ready* screen, select **QC Test Strip due**.
3. Select **QC Strip Test Required**. Scan Operator ID and press **Enter**.
4. The *Control Lot* screen displays. Press "enter new lot and expiration date". Enter control lot number, press **Enter**.
5. The *Control Expiration* screen displays.
6. Use the arrow keys to indicate the control lot expiration date and press **Enter**.

7. The *Strip Lot* screen displays. Press “enter new lot and expiration date”.
8. Scan the urine strip lot number from side of bottle and press **Enter**.
9. The *Strip Expiration* screen displays
10. Use the arrow keys to indicate the strip expiration date and Press **Enter**.
11. The *Prepare Test* screen displays.
12. Remove a strip from the bottle and have the control solution ready.
13. Press **Start**. The operator has 8 seconds to apply control solution to the strip, blot off excess solution and place in testing tray.
14. The Results screen displays and the operator should press **Done**.
15. The *QC Test-Results Summary* QC result will display as Pass or Fail. If the result fails, the QC level in question must be repeated.
16. To repeat a failed QC test, select **Repeat failed QC test**.
17. Run second control following above steps.
18. Select **Done** to return to the *Select Ready* screen when all controls have passed.
19. If a QC result fails more than twice, the POCT program should be contacted (6-1462, 3-5392, or 6-3858).

Test Procedure

1. Follow hand hygiene protocol and put on gloves.
2. Touch “Strip Test” on the touch screen to perform a test.

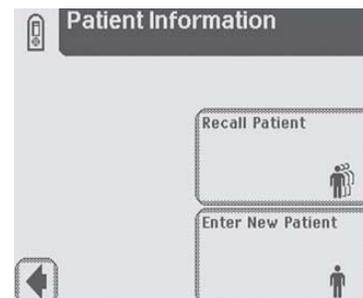


urinalysis

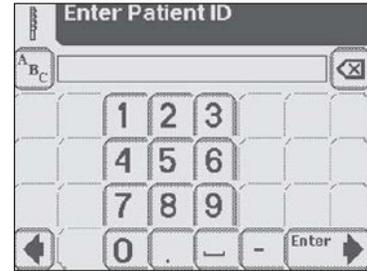
3. Scan Operator ID badge. Press Enter.



4. Press Enter New Patient button, the next screen displayed is **Enter Patient ID**

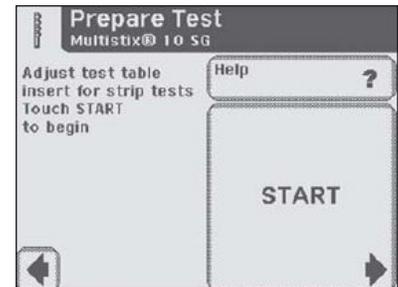


5. Scan Patient information from PACE label on properly labeled sample.



6. Select "Previous Lot" if using the same lot number of Multistix 8 SG strip.

7. Remove a reagent strip from the bottle and replace the cap tightly. Touch **START** and the display will change to the second **Prepare Test** screen. The time available for test preparation is counted down by the digital timer and the countdown bar. You have approximately 8 seconds to complete these 4 steps



- a. Dip the reagent strip into the urine sample, ensuring that all the test pads are wet.
- b. Immediately remove the strip from the urine, dragging the edge of the strip against the side of the sample container to remove any excess urine.
- c. Blot the edge of the strip on a paper towel. Do not drag the strip across the towel.
- d. Place the reagent strip, with the test pads facing up, into the strip holding channel of the test table. Slide the strip along the test table until it touches the end of the channel. Be sure not to move or bump the table. At the end of the 8 second countdown, the test table with strip will automatically be pulled into the instrument, stopping first to be calibrated then for the position of the strip in the test table to be checked. After these stops the test table will be retracted completely and the shutter will close.



8. When the urine results are ready, the Results screen is displayed. The first page of the test results are displayed on the screen and the test table and strip are automatically pushed out of the analyzer.

9. Press DONE to transmit results to electronic medical record.

10. Remove the used test strip and discard in the trash. Use a clean cotton swab to gently wipe the test table to prevent carryover to the next sample.



Reporting results

Results will post in the patient's electronic medical record if the analyzer is connected to the network. For analyzers not yet connected, staff must document the results in one of the following methods:

- (1) in the patient's record, or
- (2) on a patient log or
- (3) on another approved permanent record.

Note: All records must be retained and retrievable for 4 years. The thermal paper used by the printer will fade with time. All results must be documented elsewhere for permanent record retention.

Reference Intervals

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Glucose	Negative
Ketone	Negative
Specific Gravity	1.001 - 1.035
Blood	Negative
pH	5.0 - 9.0
Protein	Negative
Nitrite	Negative
Leukocytes	Negative

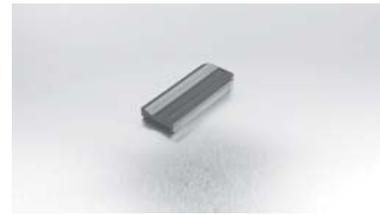
Maintenance

Cleaning

The test table and insert must be kept clean if the instrument is to provide accurate test results and operate correctly.

Routine Daily 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.



Periodic 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; drain the drip tray if necessary.
2. Wet a cotton-tipped stick with water and carefully clean the test table (except for the white calibration bar). Dry the test table thoroughly (except for the white calibration bar) with a soft cloth or lint-free tissue.
3. 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.



NOTE: 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. Replace the test table insert.



Disinfecting the Test Table and Insert:

1. Remove, clean and dry the test table and insert.
2. Hospital approved disinfectant solutions are safe to use on the table and table insert when the solutions are used for no longer than 10 minutes once a day.

CAUTION: Do not use any other solutions as they may damage the test table and table insert.

3. Fill a tall, narrow container to a depth of about 4 inches (10 cm) with the solution you have prepared. Place the test table into the solution, making sure the white calibration bar remains above the liquid level.

CAUTION: Be sure the solution does not come in contact with the calibration bar. Do not cover the container while the test table is soaking.

4. Soak the table for no longer than 10 minutes, and then rinse it thoroughly with water. Clean the table insert in the same way as the test table. Dry with a soft cloth and replace test table and table insert in the instrument.

To enable your Clinitek Status Plus analyzer to perform as intended and provide reliable test results, it is recommended that you regularly check the white calibration bar on the test table, and always check it after a strip jam.

In normal use, the white calibration bar should not become dirty or discolored.

Cleaning the White Calibration Bar:

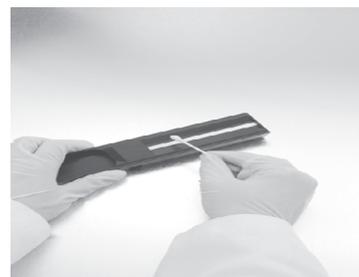
1. Remove the insert from the test table.
2. Remove the test table by pulling it slowly out of the analyzer.
3. Check the white calibration bar on the test table for dirt or discoloration.
4. If the white calibration bar is clean and unmarked, replace the table into the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upwards.
5. Push the test table firmly but slowly, just over halfway into the analyzer.

NOTE: Do not push the test table fully into the analyzer as the test table may become jammed and prevent the use of the analyzer.

6. Replace the test table insert.
7. If the white calibration bar is dirty or discolored, gently wipe and clean it with a new cotton-tipped stick or a lint-free cloth wetted with distilled water.

NOTE: Care should be taken not to scratch the white calibration bar. Solvents of any kind must not be used to clean the bar.

8. 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.
9. Reinsert the test table as described in step 4.



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

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.

NOTE: Do not use any type of solvent, oil, grease, silicon spray or lubrication on the analyzer.

Do not spray the glass cleaner directly onto the screen. Do not use laboratory wipes, such as Kimwipes, since they may scratch the screen.

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

Loading the Printer Paper or Label Roll

Open the covers on the printer and paper roll compartment. Lift the gray paper holding arm towards the front of the instrument.

Place the new roll into the compartment beneath the printer with the paper unrolling from underneath. Insert the paper or labels under the printer roller until the edge appears above the roller.

Pull the end of the paper gently towards the rear of the instrument until enough paper roll is exposed to feed through the printer cover. Do not pull the paper straight up or towards the front as this will damage the printer. Push the paper holding arm back into position.

Feed the paper or labels through the printer cover. Do not tear the paper without the cover in place, as this will damage the printer. Close the covers on the printer and paper roll compartment.

Troubleshooting and Corrective Action

General Information

Your Clinitek Status[®]+ analyzer will operate properly if you follow the directions for using and cleaning the instrument.

Error Messages

Error messages will be displayed to help you when the Clinitek Status+ analyzer detects something which needs your attention. The format of this advisory information depends upon the importance of the problem and the mode in which the instrument is being used.

Errors which Disable the Instrument

If the error is one which prevents the instrument from being used, all selection areas on the screen will be disabled. Taking the corrective action shown will remove the error alert screen and allow you to use the instrument.

Other Errors

There are certain errors which need to be corrected to enable testing of samples but do not prevent other instrument functions from being used. You will need to carry out the corrective action to enable testing.

Advisory Messages

Errors of less importance will be presented via a message on the main **Select** screen when this screen is next displayed. When you have taken corrective action, the message will be removed from the display. If more than one of this class of error occurs, clearing one message will enable the next to be displayed in order of importance to a user.

Results Alert

If an error occurs during testing and the test cannot continue because of the error, this will be presented via the **Results Alert** screen. This will provide details of the error and show that the test has been cancelled. The test table will be extended so that the urinalysis strip or Clinitest[®] cassette can be removed.

Paper-out Icon

A paper-out icon appears in the top of the title bar when the printer paper/label roll needs replacing.

An advisory message will be displayed on the main **Select** screen. Replace with new paper or label roll as instructed in Section 1, Loading the Printer Paper or Label Roll.



Dashes in Displays

Dashes are displayed in the **Results** screens and on printouts when no text has been entered for a field enabled in **Instrument Set Up**. Dashes may appear next to Color and Clarity on test result printouts.

This occurs when the instrument is powered by batteries. Color and Clarity are selected in the **Instrument Set Up**, but no selections have been recorded on the **Select Appearance** screens before time-out. The time-out on these screens is designed to ensure that battery life is preserved. The Color and Clarity description may be added to the printout in writing if needed.

Irregular or Slow Movement of Test Table

If movement of the test table is irregular or slow, this may be caused by heavy buildup of dried urine on the test table. Clean the test table and insert as described in Section 9, Periodic Cleaning of Test Table.

Contacting POCT program

If your Clinitek Status+ analyzer is displaying corrective actions for a detected problem, please carry out the displayed instructions before calling for assistance. If this does not correct the problem or no instructions are displayed, complete the Problem Check List and contact the POCT program at 6-1462, 3-5392 or 63858.

References

Clinitek Status + Operators Manual, Siemens, 11-2009.

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Cross-References

Clinitek Status Connect Plus Problem Checklist; Clinitek Status Connect Plus Training and Competency Record

Clinitek Status+ Analyzer Quick List of Errors and Advisory Messages

Error Code	Description	Action
E02	Failure of calibration data	Contact POCT Program.
E10 or E48	Loss of test results	Switch the instrument off by pressing the on/off button for 2 seconds. Switch the instrument on again by pressing the on/off button. Repeat the test.
E11	Failure of test table	Make sure that the test table is in place. Move the test table in or out of the instrument slightly to reposition the test table. If the error remains, with the instrument powered on, unplug the power cord from rear of instrument and plug back in. Turn instrument on by pressing the gray power button. If the error remains with the test table in place, contact POCT program
E12	Failure of LED	Contact POCT Program.
E20	Failure of clock	Contact POCT Program.
E24	No printer paper	Replace the printer paper: See instructions on the inside of the printer paper compartment cover, or to view instructions on the display, touch the Error Report selection area
E25, E64 or E65	Failure of automatic calibration	Clean the calibration strip. If the error remains after cleaning, contact POCT program
E27	Set Up failure	Switch the instrument off by pressing the on/off button for 2 seconds. Switch the instrument on again by pressing the on/off button.
E28	Printer error	Lift the printer cover and push the paper holding arm back into position
E50	Incorrect strip type or tilted strip	Ensure that the strip type selected in Instrument Set Up is being used. Check that the strip is placed correctly on the test table insert. If the correct type of strip is being used and the strip is placed correctly, check the instrument operation by running another test using: a) a yellow and clear sample, or b) quality controls. Contact POCT program.
E52	Invalid barcode	Repeat the test using the correct Siemens cassette.
E53	Strip Test selected but cassette detected	Repeat the test using the Cassette Test routine.
E54	Cassette Test selected but strip detected	Repeat the test using the Strip Test routine.
E57	Missing strip or cassette	Repeat the test ensuring that the strip or cassette is positioned on the test table.
E58	Misplaced strip	Repeat the test ensuring that the strip is correctly positioned on the test table. If error remains and you are testing a urine dip strip, examine the test table insert to insure that the small, white line located near the tip of the strip (on strip side of insert) is present and not damaged. If this line is damaged or missing contact POCT program.
E59	Inverted strip positioned on the test table	Repeat the test ensuring that the strip is correctly positioned on the test.
E60	Tilted strip	Repeat the test ensuring that the strip is correctly positioned on the test.
E61	Dry strip	Repeat the test ensuring that the strip has been in contact with the sample.
E62	Light Ingress	Contact POCT program
E63	Failure to find end of strip	Repeat the test ensuring that the strip is correctly positioned on the test table.
E67 or E68	Insufficient sample	A sample flow issue with the cassette test may have been detected. One or more of the test indicator lines may be missing or indiscernible from the background, or not enough sample was applied to the cassette. Repeat the test ensuring the pipette is correctly filled and the correct volume of sample is dispensed into the well of the cassette
E69	Strip quality problem	When performing the quality check, the strip quality failed. This means that the strip was not shipped or stored in the proper humidity, temperature, or light conditions. 1. Remove the defective strip and discard. 2. Repeat the test ensuring the strip meets quality requirements. 3. Repeat the test using a new test strip.
E03, E04, E05, E06, E07, E08, E21, E22, E90, E91, E92 or E93	Failure of computer software	Contact POCT program

Urine Dipstick Result Correlation with Clinical Conditions

Test	Clinical Conditions
pH	Respiratory or Metabolic Acidosis Respiratory or Metabolic Alkalosis Defects in renal tubular secretion and re-absorption
Protein	Glomerular membrane damage Impaired tubular re-absorption Multiple myeloma Preeclampsia Orthostatic or postural proteinuria Diabetic nephropathy
Glucose	Diabetes mellitus, Stroke, Neoplasms, Uremia Impaired tubular re-absorption Pregnancy with possible latent diabetes mellitus.
Ketone	Diabetes ketoacidosis, Acute illness with vomiting, diarrhea Starvation
Bilirubin	Hepatitis Cirrhosis Biliary obstruction or hepatocyte dysfunction.
Nitrite	Cystitis Pyelonephritis Monitoring of patients at high risk for urinary tract infection Screening of urine culture specimens
Specific Gravity	Patient hydration and dehydration Loss of renal tubular concentrating ability Diabetes insipidus Identification of unsatisfactory specimens due to low specific gravity
Leukocytes	Urinary tract infection Screening of urine culture specimens

Reference:

Shu-Ling L. Fan and Lindsay Hardy, Contemporary Practice in Clinical Chemistry, AACC Press ed. William Clarke 2011. Taken from the text of the above reference