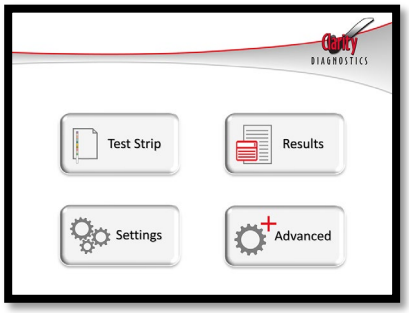
Quick Start Guide

PERFORMING A URINALYSIS TEST

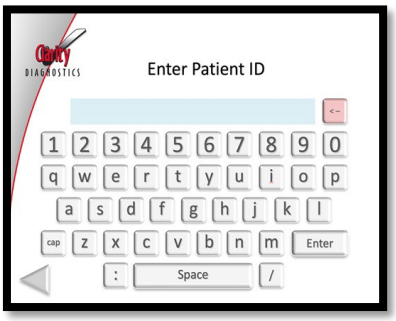
1. Have a urine sample, a Clarity Diagnostics urine reagent test strip, paper towel, and the analyzer turned on and ready for use. **The use of urine preservatives is not recommended.** If testing cannot be done within an hour after collection, refrigerate the specimen immediately and let it return to room temperature before testing.

Biohazard: Wear personal protective equipment when handling the patient specimen and performing the test. Use universal precautions for any biohazard materials.

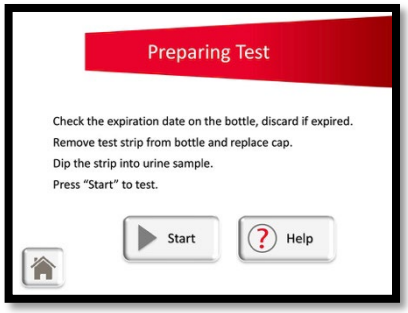


2. Turn on the device. Select ***Test Strip*** from the main menu.

3. Scan or enter the barcode from the urine reagent strip bottle and press ***Enter.***

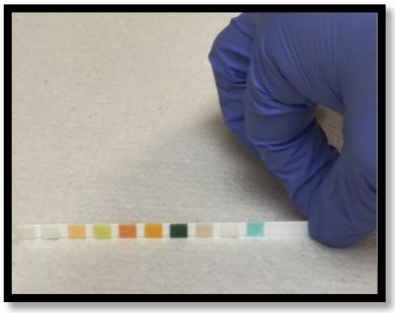


4. Scan or type in the patient ID and press ***Enter***, or press ***Enter*** to skip entirely.



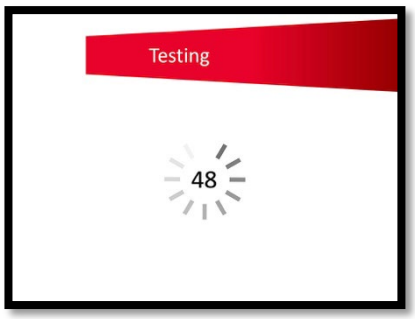
5. Follow the instructions listed on the display screen. Dip the strip into the urine sample one time, and remove it immediately. Ensure that all the pads on the strip are saturated with the urine sample. Dipping should not exceed 10 seconds. Then, press ***Start***.

6. After pressing the ***Start*** button, the analyzer begins 10 seconds of self-calibration. You will have 10 seconds to complete steps 7 and 8.

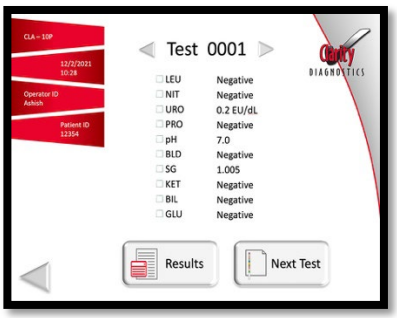


7. Touch the long edge of the strip onto a paper towel to remove the excess urine.

8. Place the strip on the strip bed with the test pads facing up. Ensure that the test strip is inserted fully into the back of the strip bed.



9. When calibration is completed, the analyzer retracts the strip bed with the strip, and it will begin analysis. A timer on screen will count down the time remaining in the strip analysis process.



10. The test result will be displayed on screen and printed. Select ***Results*** to go to the result menu. Select ***Next Test*** to perform the next test.

Quick Start Guide

CLIA WAIVER INFORMATION

This Quick Start Guide is for use with the CLIA Waived Clarity Platinum Urine Chemistry Test System. This test is waived under CLIA '88 regulations. This test is only waived for urine specimens. Failure to adhere to the instructions for use will result in the test being considered high complexity and subject to all CLIA requirements. A CLIA Certificate of Waiver is required to perform this testing. A Certificate of Waiver can be obtained from the Centers for Medicare & Medicaid Services (CMS). Visit www.cms.gov to obtain an application (Form CMS-116). You must follow the manufacturer's instructions to perform tests. You should read the complete test procedure before performing the test.

Cleaning and Maintenance

For daily cleaning:
Wet a cotton tipped swab with warm water and carefully clean the strip bed. Dry the strip bed with a clean cotton swab.

For weekly maintenance:
1. Select the ***Advanced*** option from the main menu. Select ***Strip Bed Maintenance*** and press the top arrow ⇩ to unload the strip bed and remove it for cleaning.

2. Clean the strip bed with a 70% alcohol solution. **Avoid wiping the white color block on the top right side of the strip bed and avoid cleaning the groves on the left side of the strip bed.** Dry the strip bed completely with a lint free tissue or clean cotton swab.

3. Return the strip bed into the device by seating it back into the groove until you feel pressure and it stays in the machine by itself. Press the bottom arrow ⇧ on the screen and the strip bed will be retracted.

4. Press ➢ icon to go back to the main menu.

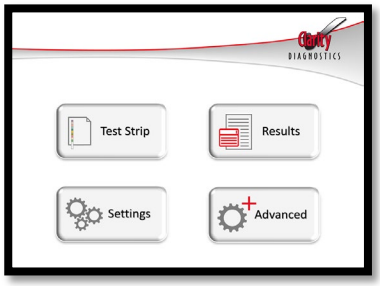
5. Before proceeding with patient sample testing, please perform a Quality Control test as described below.

Quick Start Guide

STORAGE AND RECOMMENDED HANDLING PROCEDURES

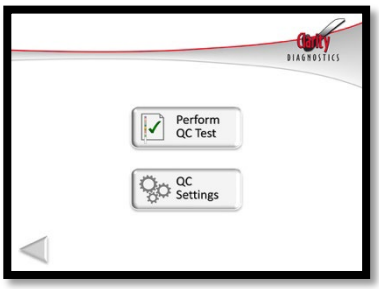
- ✓ *For the best performance, ensure the analyzer is operated between the temperatures of 59-86°F (15-30°C) and relative humidity of 18-80%.*
- ✓ *Store test strips at room temperature between 59-86°F (15-30°C), a relative humidity of 20%, and out of direct sunlight. Do not use strips after their printed expiration date. Opened bottles of test strips are stable and should be used within 3 months when stored at optimal conditions.*

Quality Control

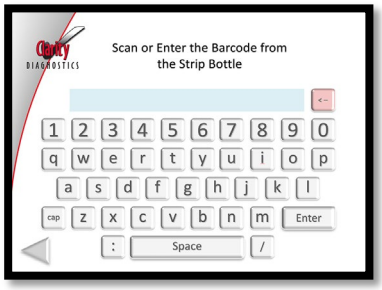


1. On the main menu, select ***Advanced.***

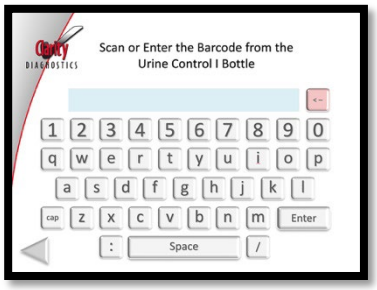
2. On the advanced setting screen, select ***Quality Control.***



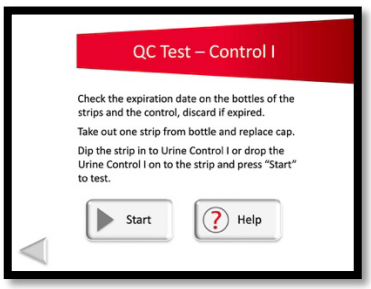
3. Select ***Perform QC Test***.



4. Scan or enter the barcode from the urine reagent strip bottle.



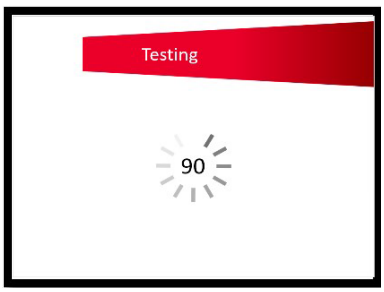
5. Scan or enter the barcode from Clarity's Urine Control Level I Bottle.



6. Follow the instructions on the screen for performing QC with Level I Control. Dip the reagent strip in Level I Control, or place one drop of Control on each reagent pad and press the ***Start*** button.

7. The analyzer will perform auto-calibration. You will have 10 seconds to prepare the test. Touch the long edge of the strip onto a paper towel to remove the excess Quality Control sample.

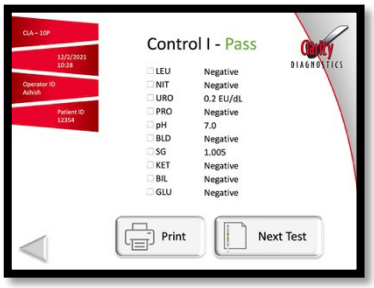
8. Place the strip on the strip bed with the test pads facing up. Ensure that the test strip is fully inserted into the back of the strip bed.



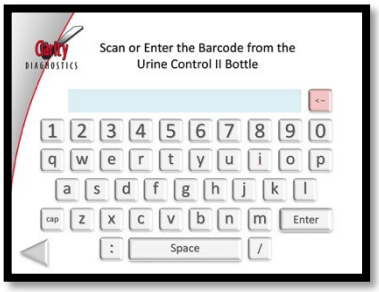
9. A timer on the screen counts down the time remaining in the strip analysis process.

Quick Start Guide

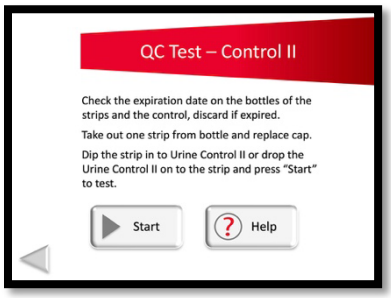
STORAGE AND STABILITY FOR URINE CONTROLS:
The urinalysis controls should be stored at 35–46°F (2-8°C) when not in use. Do not freeze. When stored at 35–46°F the controls are stable until the expiration date stated on the label. When stored at room temperature (64–77°F), the controls are stable for 7 days or until the expiration date stated on the label.



10. The QC Level I test results will display on the screen and print automatically, depending on your printer settings. If QC Level I fails, you will be prompted to repeat the test. Once QC Level I passes, press ***Next Test*** to run a QC test with Control Level II solution.



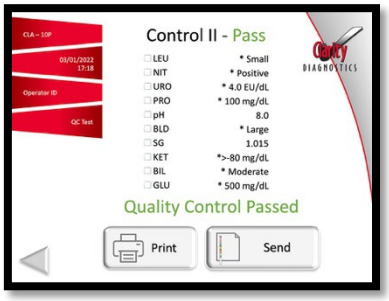
11. Scan or enter the barcode from Clarity's Urine Control Level II Bottle.



12. Follow the instructions on the screen for performing QC with Level II Control. Dip the reagent strip in Level II control, or place one drop of control on each reagent pad and press the ***Start*** button.

13. The analyzer will perform auto-calibration. You will have 10 seconds to prepare the test. Touch the long edge of the strip onto a paper towel to remove the excess quality control sample.

14. Place the strip on the strip bed with the test pads facing up. Ensure that the test strip is fully inserted into the back of the strip bed.



15. The QC Level II test results will display on the screen and print automatically, depending on your printer settings. If QC Level II fails, you will be prompted to repeat the test. Once QC Level II passes, press ◁ to return to the main menu.

Significance of QC tests and Consequences of Not Performing QC Procedures

Quality control testing is a process of detecting errors within the testing site to ensure both the reliability and accuracy of test results in order to provide the best possible patient care. Therefore, to ensure the accuracy and performance of the Clarity Platinum Test System, quality control procedures are incorporated into the Clarity Platinum analyzer. The purpose of including quality control procedures is to evaluate the reliability of the test system by assaying stable quality control material that resembles patient samples.

The quality control function is designed to detect, reduce, and correct deficiencies in a laboratory's internal process prior to the release of patient results. Failure to conduct quality control testing or carry out QC procedures could lead to unreliable performance of the test system, which could result in misdiagnosis, delayed treatment, and increased costs due to retesting. It is of great importance to ensure all results are both accurate and reliable.

Clarity Diagnostics produces Quality Control Solution Levels I and II, which are used to perform quality control testing. For CLIA Waived settings, Clarity Urinalysis quality controls must be tested under the following conditions:
When a new canister of strips is opened OR

- ✓ 100 tests have been performed OR
- ✓ Test results appear to be inaccurate OR
- ✓ A new operator uses the analyzer OR
- ✓ Each new day of testing OR
- ✓ 30 days have passed since the previous QC Pass OR
- ✓ After performing maintenance or service on the analyzer.

If the QC tests do not provide the expected results, perform the following checks:

- ✓ Ensure the strips used are not past their expiration date.
- ✓ Ensure the strips are fresh from a new canister.
- ✓ Ensure the controls are not past their expiration date.
- ✓ Repeat the test to ensure no errors were made during the test.
- ✓ If QC testing still does not provide the expected results, call Clarity Diagnostics Technical Support: (877) 485-7877, Monday-Friday, 8am-6pm EST.

Once the QC test is successfully performed, the analyzer will display the results on the screen. A QC pass message will enable the user to proceed to patient sample testing. A QC fail message will cause a system lockout, and the user cannot perform any patient testing until the quality control test is completed successfully. If the problem persists, stop the test and call Clarity Diagnostics technical support at (877) 485-7877, Monday - Friday 8am to 6pm EST, or email us at techsupport@claritydiagnostics.com.

Failure Mode, Corrective Action for User and Error messages designed in Clarity Platinum Urine Analyzer

Failure mode	Error Message/ Alert displayed on the screen	Corrective Actions
Software system fails	'System Calibration Failed' Error	Restart the analyzer. If the problem persists, Contact Technical Support at (877) 485-7877 (Monday-Friday, 8am-6pm EST).
Optics fail (Broken LED),	'Optical System Fail' Error	
Electronics fail	'Electronic System Fail' Error	
Motor fails / strip bed jams	'Mechanical System Fail' Error	
Improper installation of strip bed	'Mechanical System Fail' Error	Remove the strip bed and insert it as per the instructions listed in Cleaning and Maintenance section.
Improper placement on the strip bed: tilted/ no strip/ upside down/ backwards	'Misplaced Strip' Error 'Incorrect Strip Type' Error	Repeat the test using a Clarity CLA-10P reagent strip. After placing the strip, ensure that the test strip is fully inserted to the back of the strip bed, and facing up.
Dry strip used / incorrect wetting of strips	'Dry Strip Detected' Error	Repeat the test with a new strip and ensure that the reagent pads have been completely wet with the urine sample.
Incorrect strip used	'Incorrect Strip Type' Error	Repeat the test using a Clarity CLA-10P reagent strip.

Usage of Improperly stored strips or reusing an already dipped test strip	'Strip Quality Issue' Error	Repeat the test with a new strip from an unexpired bottle.
Usage of Expired strips	'Strip Quality Issue' Error	
Expired strip bottle used	'Barcode Error'	Repeat the test with a new strip from an unexpired bottle.
Incorrect calibration (White block damaged), Gradual buildup of sediment (visibly detectable amounts)	'Optical system Fail' Error	Restart the analyzer. If the problem persists, Contact Technical Support at (877) 485-7877 (Monday - Friday, 8am-6pm EST).
Expired controls used /selection of incorrect controls / improperly stored controls used	'QC Test Fail' Error 'Barcode Error'	Repeat the test using unexpired Urinalysis Quality Controls. Only Clarity Urinalysis controls (CLA-UHCRL25) can be used.
Interference due to blood in urine specimen	Possible false positive results due to blood interference may occur for glucose, protein, bilirubin, urobilinogen, nitrite, leukocytes, ketone	User is alerted of possible false positive results. Submit the test result to the physician for interpretation.

The Clarity Platinum Operator's Manual can be found on our website or by scanning below:

We Support Better Outcomes™

Technical Support :1 (877) 485-7877
techsupport@claritydiagnostics.com.

Clarity Diagnostics LLC 1080 Holland Drive, Suite 1
Boca Raton, Florida 33487
www.claritydiagnostics.com