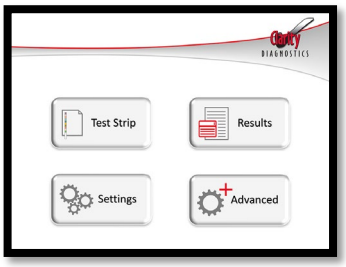
Quick Start Guide

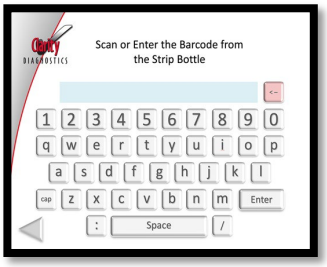
RUN A URINE SAMPLE TEST

1. Have a collected urine sample for processing, a urine test strip, paper towel and the analyzer turned on 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.

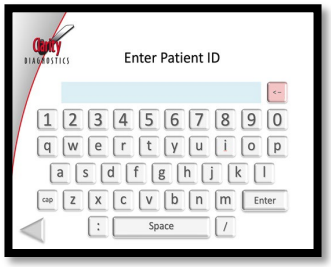
Biohazard: Wear personal protective equipment when handling patient specimen and performing the test. Use universal precautions for any biohazard materials.



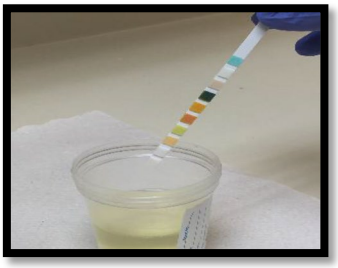
2. Turn on the device. Select ***Test Strip*** from the Main Menu.



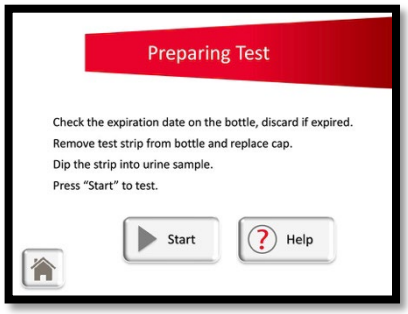
3. Scan or enter Barcode from the urine reagent strip bottle and press ***Enter.***



4. Enter or scan patient ID.

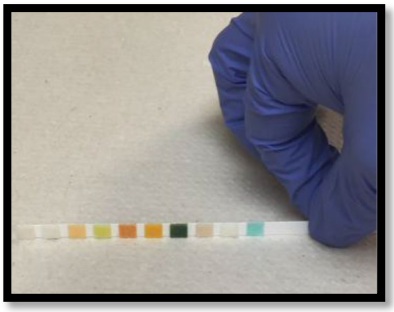


5. Dip the test strip (only once) in the urine sample. Be sure that all pads are fully covered with the urine sample. Dipping should not exceed 10 seconds.



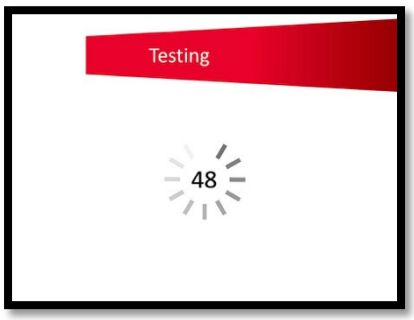
6. Once you follow the instructions listed on the display screen which includes dipping test strip from Step 5. then, press ***Start***.

7. Device will run auto-calibration. You will have 10 seconds to prepare the test.

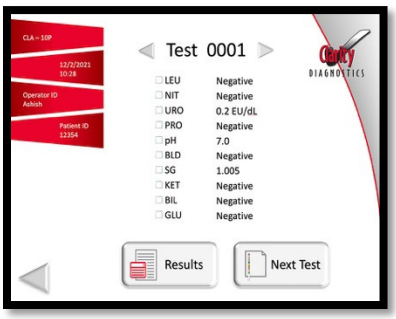


8. Touch the long edge of the strip onto a paper towel to remove the excess urine.

9. Place the test strip, with the pads facing upward, on the strip bed. Be sure that the test strip is inserted fully to the back of the strip bed.



10. A timer will count down until the end of the test.



11. 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.

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CLIA WAIVER INFORMATION

This Quick Reference 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 bed with a clean cotton swab.

For weekly maintenance:
1. Select the ***Advanced*** function on Main Menu and then select ***Strip Bed Maintenance***. To remove the strip bed, press the ⇩ button and the strip bed would automatically come out.

2. Wipe the strip bed with an alcohol swab/pad available in every clinic or doctor's office. Please ensure that the strip bed is thoroughly cleaned and **avoid wiping the White color block on the strip bed**. Dry the strip bed with a lint free tissue.

3. Return the strip bed into the device by holding it near the groove as depicted in the picture. Press the ⇧ button and the strip bed will be retracted.

4. The picture displays the strip bed automatically retracting inside the groove making it easier for the user. Press ➢ icon to go back to the Main Menu.

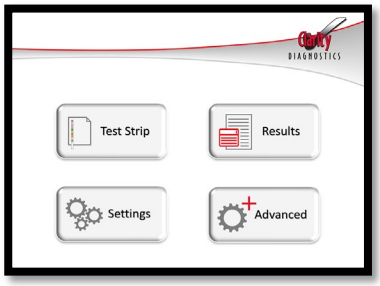
5. Before proceeding with patient sample testing, please perform the Quality Control Test as described below.

Quick Start Guide

STORAGE AND RECOMMENDED HANDLING PROCEDURES

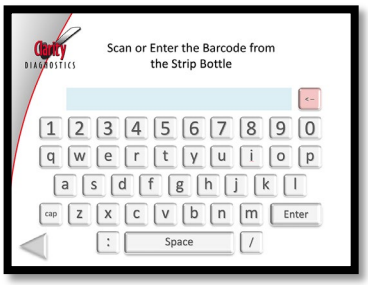
For the best performance, ensure the analyzer is operated under temperature 59°-86°F (15° - 30°C) and relative humidity (18 - 80%). Store test strips at room temperature between 59°-86°F (15°-30°C) and relative humidity (20%) and out of direct sunlight. Do not use after expiration date. Opened bottles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

Quality Control

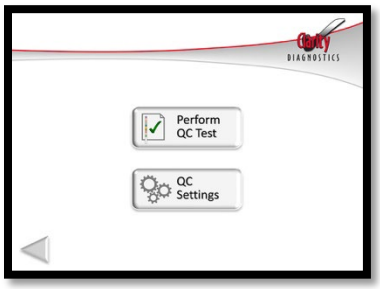


1. On the ***Main Menu***, select ***Advanced.***

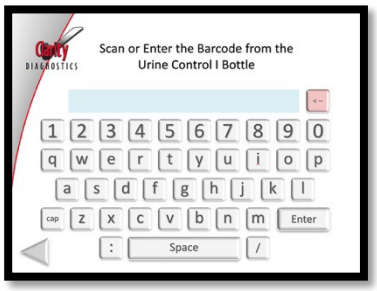
2. On the ***Advanced Setting screen,*** select ***Quality Control.***



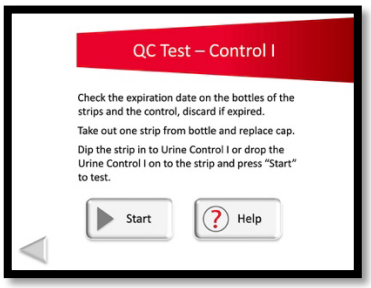
3. Scan or enter Barcode from the urine reagent strip bottle.



4. Select ***Perform QC Test***.



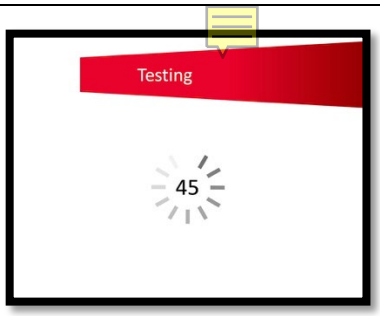
5. Scan or enter Barcode from the urine control I bottle.



6. Follow the instructions on the screen for performing QC with Control I. Either dip the strip in Control I tube or drop the Control I and press Start. The dipping step should not exceed 10 seconds.

7. Device will run 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 test strip, with the pads facing upward, on the strip bed. Be sure that the test strip is inserted fully to the back of the strip bed.



9. A timer will count down until the end of the test.

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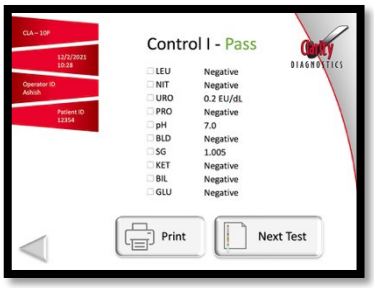
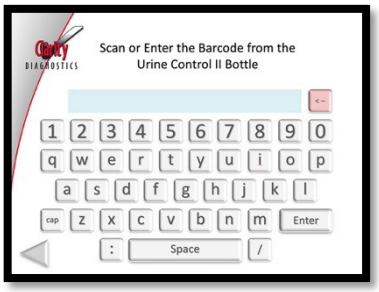
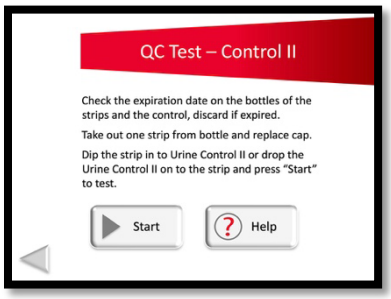
STORAGE AND STABILITY FOR URINE CONTROL:
The urinalysis control kit should be stored at 35–46°F (2-8°C) when not in use. Do not freeze. When stored at 35–46°F the controls are stable until the expiration date stated on the label. When stored at room temperature (64°–77°F), the controls are stable for 7-30 days depending upon the type of control being used.



10. The screen will display and print QC test result after completion of test. Once QC test for Control I Passes, then you press Next to QC test with Control II solution.



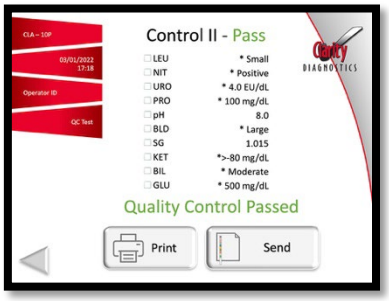
11. Scan or enter Barcode from the urine control II bottle.



12. Aliquot quality control solution II in a tube. Follow the instructions on the screen for performing QC with Control II. Dip the strip in Control II tube and press Start. The dipping step should not exceed 10 seconds.

13. Device will run 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 test strip, with the pads facing upward, on the strip bed. Be sure that the test strip is inserted fully to the back of the strip bed. A timer will count down until the end of the test.



15. The screen will display and print QC test result after completion of test. Once QC test for Control II Passes, then you can go back to Main Menu and start testing Patient samples.

Significance of Quality Control tests and consequences of not performing QC procedures

Quality Control testing is a process of detecting errors within the testing site to confirm the reliability and accuracy of test results in order to provide the best possible patient care. Hence, to ensure the accuracy and performance of Clarity Platinum Urine Chemistry Test System, quality control procedure is incorporated in the Clarity Platinum analyzer. The purpose of including QC procedures is to evaluate the reliability of the test system by assaying a stable QC 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. Failing to conduct Quality Control testing can lead to unreliable performance of the test system and possible misdiagnosis, delayed treatment and increased costs due to retesting. It is, therefore, of great importance to ensure all results provided are both accurate and reliable.

Clarity Diagnostics provides Quality Control Solution I and II for performing Quality Control testing. Each lab should establish its own standard and procedures for performance. Test known positive and negative specimens/controls at each of the following events in accordance with local, state, and/or federal regulations or accreditation requirements. For CLIA waived settings, Clarity Urinalysis Quality Controls must be tested under following conditions:

- ✓ When a new canister of strips is opened OR
- ✓ Test results seem inaccurate OR
- ✓ A new operator uses the analyzer OR
- ✓ Each new day of testing OR
- ✓ After performing maintenance or service on the analyzer

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

- ✓ Ensure the strips used are not past their expiration date.
- ✓ Ensure 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 expected results, call Clarity Diagnostics Technical Support at: 1(877)722-6339.

Once QC test is successfully performed, the test system will notify the results on the display screen. QC Pass message would enable the user to proceed for patient sample testing. If QC Fail message appears, the system is locked out and the user cannot perform any patient testing UNTIL the Quality Control testing is done successfully. If the problem persists, stop the test and call Clarity Diagnostics technical support at 1(877)722-6339(M-F: 8am-5pm EST) or reach 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 Clarity Diagnostics Technical Support at 1(877)722-6339 or email us at: techsupport@claritydiagnostics.com
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 New CLA-10P reagent strip. After placing the strip be sure that the test strip is inserted fully to the back of the strip bed.

Dry strip used / incorrect wetting of strips	'Dry Strip Detected' Error	Repeat the test with a new strip and ensure that the strip has been completely wet with the urine sample.
Incorrect strip used (Multistix 10SG, UAC)	'Incorrect Strip Type' Error	Repeat the test using a New CLA-10P reagent strip only.
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 using an unexpired New and non-expired CLA-10P reagent strip only.
Incorrect calibration (White block damaged), Gradual buildup of sediment (visibly detectable amounts)	'Optical System Fail' Error	Restart the analyzer. If the problem persists, contact Clarity Diagnostics Technical Support at 1(877)722-6339 or email us at: techsupport@claritydiagnostics.com.
Expired controls used /selection of incorrect controls / improperly stored controls used	'QC Test Fail' Error 'Barcode Error'	Repeat the test using unexpired Clarity Diagnostics Urinalysis Quality Controls.
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.

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