Clarity®
DIAGNOSTICS

Clarity Platinum Urine Analyzer
Operator's Manual

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Clarity Platinum Urine Analyzer
OPERATOR'S MANUAL

1. Introduction

The introduction explains how to unpack, install, and begin using the Clarity Platinum Urine Analyzer. The introduction also includes an overview of the analyzer and its key features.

The Clarity Platinum Urine Analyzer Test System is for CLIA Waived Use and only to be used with Clarity Diagnostic's Urine Reagent (CLA-10P) Strips. This test is waived under the CLIA '88 regulations. This test is only waived for urine specimens, and 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 test. 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.

Intended Use

The Clarity Platinum analyzer is a benchtop analyzer designed to read Clarity's proprietary urinalysis strips (CLA-10P). The instrument is intended to be used together with Clarity Diagnostics' Urine Reagent Strips as a system for semi-quantitative detection of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes in urine. These measurements are used to aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections, and liver function.

Tests performed by the Clarity Platinum analyzer are intended for *in vitro* diagnostic use only.

Getting Started

Unpacking the Clarity Platinum

The Clarity Platinum analyzer is delivered in one box. To unpack the analyzer, carefully remove all components from the box and inspect for any signs of damage. If the analyzer appears to be damaged, immediately contact your shipping carrier and Clarity Diagnostics. Even if the box appears to be damaged, the device can be preserved due to the internal packaging. Verify that you have each of the following components:

- Clarity Platinum Analyzer
- Thermal Printer Paper (preloaded in analyzer)
- Power Supply Adaptor with AC Power Cord
- Clarity Platinum Manual
- Quick Start Operator's Manual
- Barcode Reader

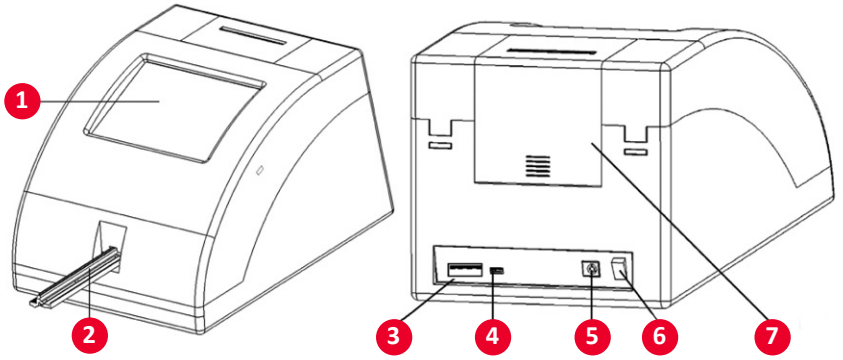
If you are missing any components, please contact Clarity Diagnostics immediately at (877) 485-7877, Monday-Friday, 8am-6pm EST.

Clarity Platinum Urine Analyzer Hardware Overview

The Clarity Platinum consists of the following hardware components:

- Touch Screen Display
- Test Strip Bed
- Printer
- Power Cord
- Connection Ports

Figure 1. Clarity Platinum

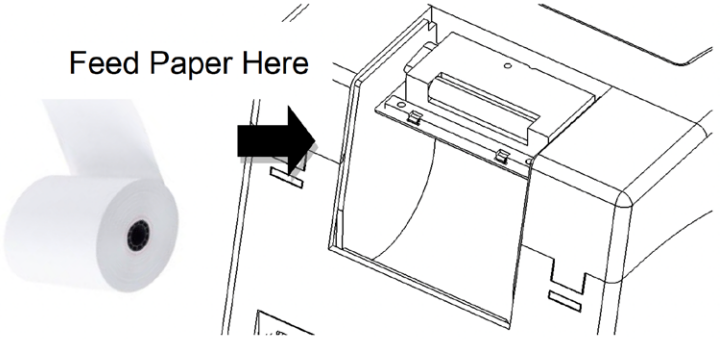


1. **Touch Screen Display**
2. **Test Strip Bed**
3. **USB-A Port, Barcode Reader**
4. **USB-C Port, Data Transfer**
5. **Power Cord (DC IN)**
6. **Power Switch**
7. **Printer Cover**

Assembling the Clarity Platinum

1. Place the Clarity Platinum analyzer on a level surface away from sources of heat and liquids. The Clarity Platinum analyzer performs optimally between 59°- 86 °F (18 – 30 °C).
2. Remove the barcode reader from the box and connect it to the USB-A Port on the back of your analyzer where it is labeled 'Barcode Reader'. (Figure 1, number 3)
3. Plug the power supply adaptor cord into the back of the analyzer where it is labeled 'DC IN'. (Figure 1, number 5)
4. Connect the power supply adaptor cord into a 120V AC wall outlet.

Figure 2. Printer



Loading the Printer Roll

1. Open the printer cover by gently lifting the external tab located at the back of the analyzer upward and lifting the front pins out of their slots in the front. Set aside the cover.
2. Make sure the Clarity Platinum is plugged in for the automatic paper feed to function.
3. Place the roll of thermal paper in the cradle at the back of the machine, with the shiny side of the paper facing the front of the machine.
4. Feed the end of the thermal paper roll into the bottom of the black roller until it is caught by the auto-feed and pulled into the roller.
5. Gently replace the printer cover by hooking the plastic front pins first, with the Clarity Diagnostics logo facing the front of the machine. Feed the paper from the black roller through the slot with the perforated edge on the cover, and then push the external tab down the back of the machine until the cover is back in place.

Powering On/Off

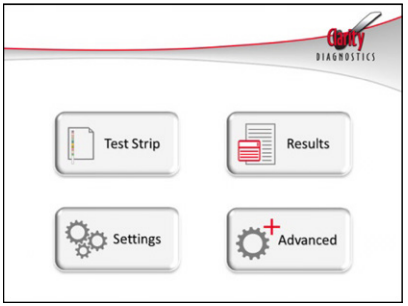
To Power On the Clarity Platinum Analyzer:

1. Press the power switch located on the back of the unit. (Figure 1, number 6)
2. The Clarity Platinum will perform system diagnostics each time the unit is powered on, which checks that the optical, electronic, and mechanical systems are performing as expected. If the system diagnostics are successful, the printer will automatically print: 'System Diagnostics OK. Ready to Use', and the main menu screen will appear.
3. If an error occurs during initialization, the analyzer will display a 'System Calibration Failed' error message and two options will appear on screen, 'Recalibrate' or 'Technical Support.'
4. Press the recalibrate button to rerun system diagnostics. If the error persists, please contact Clarity Diagnostics Technical Support at (877) 485-7877, Monday-Friday, 8am-6pm EST.

To Power Off the Clarity Platinum Analyzer:

1. Ensure that the strip bed is empty and that no tests are in progress.
2. Use warm water and a cotton swab to clean the strip bed.
3. Press the power switch located on the back of the unit to turn off the analyzer. Pressing the power switch will also automatically retract the strip bed into the machine. (Figure 1, number 6)

Figure 3. Clarity Platinum Main Menu



Accessing the Main Menu

After turning on the Clarity Platinum analyzer, the system diagnostics will run automatically, and the machine will bring you to the main menu.

From the main menu, you may select:

1. **Test Strip**
   This will bring you to the urine sample test.
2. **Results**
   From the **Results** page you, can recall previous results and search stored test results based on Date, Patient ID and Test ID.
3. **Settings**
   In this section, you can access settings for strip type, display language, date & time, and enable/disable the automatic printing feature and format. You can also view system information.

   The **Restore Default Setting** function is for Clarity Diagnostics administrators only and requires a valid administrator password for access.
4. **Advanced**
   The **Advanced** settings menu is accessible to all operators. The CLIA Waived operator can perform functions like quality control testing, system diagnostics, and strip bed maintenance. More advanced features, like adding authorized operators, modifying operator permissions, modifying quality control settings, selecting test mode, and enabling or disabling barcode scanning, are intended for Clarity Diagnostics administrators only and require a valid administrator password for access.

Note: *The strip bed can be retracted from the* ***Strip Bed Device Maintenance*** *section of the* ***Advanced*** *settings menu. Retracting the strip bed can prevent damage to the Platinum while not in use. Full instructions can be found in* ***Section 6: Removing/Replacing Strip Bed.***

Clarity Platinum User Interface

The Clarity Platinum analyzer uses a touch screen to display user options, results, settings, and diagnostics. The touch screen is used for all user input. The barcode reader attachment can also be used for inputting barcodes from the test strip or control bottles, as well as patient IDs. (See **Section 4.2: Advanced Settings**)

Do not use any sharp or pointed objects on the screen, as they may damage the display.

To Operate the Clarity Platinum Analyzer:

- Press the **Test Strip** icon 

displayed on the screen to run a Urine Test Strip.
- Scan or enter the barcode from the strip bottle and press enter.
- Scan or enter the Patient ID, or skip it by pressing enter.
- Follow the instructions in the Quick Start Guide to perform a test.
- Press the back/return button ◀ on the bottom left of the screen to return to the main menu.

2. Operations

By pressing the Test Strip button on the main menu screen, you can perform a urinalysis test.

Note: *The Barcode Reader feature has been enabled (default configuration) and you will be prompted to scan or enter the barcode on the test strip bottle prior to reaching the Test Preparation screen.*

Entering Strip Barcode Information

To enter the Strip Barcode information, perform the following steps:

1. After pressing the **Test Strip** button, use the keypad on the screen or the Clarity Platinum barcode scanner to enter the barcode from the CLA-10P bottle.
2. After entering the barcode, press **Enter** to proceed to the next step.

Note: *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 the following conditions:*

- *When a new canister of strips is opened OR*
- *Test results appear to be inaccurate OR*
- *A new operator uses the analyzer OR*
- *Each new day of testing OR*
- *After performing maintenance or service on the analyzer. (See **Section 4.2: Advanced Settings, Quality Control**)*

2.1 Performing a Urinalysis Test

Pressing the Test Strip button on the main menu screen will bring you directly to the main testing screen.

Note: *You will be prompted to scan or enter the barcode on the test strip bottle prior to reaching the test preparation screen.*

Preparing a Urinalysis Test

1. Collect a urine sample, a CLA-10P urine test strip, a paper towel, and have the analyzer ready.
2. After pressing the **Test Strip** button, use the Clarity Platinum scanner or the keypad on the screen to enter the barcode from the CLA-10P urine reagent strip bottle.
3. Next, the analyzer will prompt you for a Patient ID. You can use the scanner or keypad to input that information, followed by **Enter**, or select **Enter** to skip.
4. The **Preparing Test** screen will appear and prompt you to perform the following actions before pressing the **Start** button:
    - Check the expiration date on the test strip bottle. Discard if it is expired.
    - Remove the test strip from the bottle and replace the cap.
    - Dip the strip into the urine sample.
- Press **Start** to begin the test.
5. Press **Help** to access more detailed instructions. At any time, you may return to the main menu by pressing the  button.

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

Performing a Urinalysis Test

1. Dip the strip into the urine sample and remove it immediately. Ensure that all pads on the strip are saturated with the urine sample. While you are doing this, press the **Start** button.
2. After pressing the **Start** button, the analyzer begins 10 seconds of self-calibration. During this time, touch the long edge of the strip onto a paper towel to remove the excess urine, and 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. The dipping step should not exceed 10 seconds.
3. When calibration is complete, the analyzer retracts the strip bed with the strip, and it will begin analysis.
4. A timer on screen will count down the time remaining in the strip analysis process.

Note: *You cannot cancel a test before the analyzer finishes the test.*

Caution:
DO NOT push or pull the strip bed or move the analyzer during the test. It might cause the analyzer to fail calibration.

Viewing the Urinalysis Test Result

1. After the countdown ends, the analyzer displays the test result on the screen.
2. Press the **Results** button to access the stored results, or press the **Next Test** button to perform another test.

Printing the Urinalysis Test Result

Once the test is completed, the test result is printed automatically if the machine is in the default setting. The test results printout could include any of the following information, depending on the settings:

- Operator ID
- Patient ID
- Test ID

You can change the printer setting to manual or the print options in the **Printer Setting** menu, as described in **Section 4.1: Basic Settings**.

Completing the Urinalysis Test

1. Remove the test strip from the strip bed and dispose the strip according to your local, state, and federal guidelines.
2. Clean the strip bed using a solution of sodium hypochlorite 525-615 ppm (dilution 1:100 of 5.25-6.15% sodium hypochlorite) or 70% isopropyl alcohol with a cotton swab.
3. Select **Results** to view the stored results, or select **Next Test** to perform the next test.
4. You may return to the main menu by pressing the ◀ button.

3. Test Result Management

Press the **Results** button on the main menu screen to access up to 2,000 previously stored results. You may search results by ID or test date, or delete all results.

Note: *When the results list reaches 2,000 tests, the analyzer deletes the oldest test from the list. You cannot recall the deleted test.*

Recall All Results

1. On the result screen, select **Recall Result** to review all the stored test results arranged in chronological order.
2. The screen will display the most recent test result, including the strip type, test date & time, patient ID and test result.
3. Select **Print** to print the test result using the analyzer's built-in thermal printer.
4. On the result screen, select **Send** to send the test result to a PC, host computer, or LIS, if configured for this option.
5. On the result screen, press the ◀ or ▶ icon next to the test ID to view the previous or next result.
6. Press ◀ at the bottom of the screen to return to the results main menu.

Search Results by ID

1. On the result screen, select **Search by ID** to search the stored test results based on ID information.
2. If you select **Patient ID**, enter the patient ID using the keypad on the screen and press **ENTER**. All the matching results will be listed. Select the desired test result to review on the screen.
3. If you select **Test ID**, enter the test ID using the keypad on the screen and press **ENTER**. The matching results will be displayed on the screen.

Search Results by Date

1. On the result screen, select **Search by Date** to search the stored test results based on the test date.
2. Enter the date using the keypad on the screen and press **ENTER**.
3. All the matching results will be listed. Select the desired test result to review on the screen.

Delete Results

You may want to delete all the test results under the following circumstances:

- A complete download of all the stored results to a host computer has occurred.
- To protect patient confidentiality and comply with HIPAA regulations when the analyzer is moved to another clinical site.
- To repair or discard the analyzer.

1. On the result screen, select **Delete** to delete all the stored test results.
2. A prompt will say "Delete All Results?" Press ✓ to delete all results.
3. You can select ✗ to return to the result main menu.

Caution:
Selecting the delete function will delete all the stored test results. The system does not allow the deletion of a specific test result for data security reasons. Once results are deleted, you can no longer recall them from the database. If you want to keep all the data from your analyzer, please transfer the data to a host computer before you proceed with this function.

4. System Configuration

You can configure the analyzer's settings and review the system information with the settings and advanced menus.

4.1 Settings

Press the **Settings** button on the main menu screen to access the settings menu. From this menu, you may review the current settings and select the type of strip to be used, the display language, date & time, enable or disable the automatic printing function, and view system information for the Clarity Platinum. The **Restore Default Setting** and **Units Displayed** options are intended for Clarity Diagnostics administrators only and require a valid administrator password to login.

Strip Type

Note: *The device will set by default for testing Clarity Diagnostics' CLA-10P strips.*

1. On the settings menu, press the **Strip Type** button to review the current setting. The Clarity Platinum is only compatible with Clarity Diagnostics' proprietary strips.
2. Press ◀ to return to the settings menu.

Language

1. On the settings menu, press the **Language** button to review the current setting. The Clarity Platinum uses English as the default language. The user may choose Spanish for the operation language.
2. Select the desired language to change the display language.
3. Press ◀ to return to the settings menu.

Date & Time

1. Review the date and time, located on the top right of the screen. From the settings menu, press the **Date & Time** button to review the current setting.
2. Use the keypad to program the date & time exactly as shown in the following format: MM/DD/YYYY HH:MM am or pm (Please note: am/pm need to be lowercase). Press **Enter** to save.
3. Press ◀ to return to the settings menu.

Unit Setting

1. The Clarity Platinum urine analyzer uses C1 (conventional units) as the default unit setting.
2. The **Unit Setting** function is intended for Clarity Diagnostics administrators only and requires a valid administrator password to login.

Printer Setting

1. On the settings screen, press the **Printer Setting** button to review the current setting.
2. Select **Automatic** or **Manual** for the analyzer to print the result automatically or manually after each test.
3. Modify the printing format by selecting the following information to be included in the result printout:
   • Operator ID • Patient ID • Test ID
4. Press ◀ to return to the settings menu.

System Information

1. On the settings screen, press the **System Information** button to view the serial number of the analyzer, the current Clarity Platinum software version installed, and technical support contact information.
2. Press ◀ to return to the settings menu.

Restore Default Setting

1. The **Restore Default Setting** function is intended for Clarity Diagnostics administrators only and requires a valid administrator password to login.

4.2 Advanced Settings

Press the **Advanced** button on the main menu screen to access the advanced settings menu. From this menu, it is possible to perform quality control testing, strip bed maintenance, and system diagnostics on analyzer hardware.

Operator

The operator menu is only accessible for Clarity Diagnostics administrators.

Test Mode

The test mode menu is only accessible for Clarity Diagnostics administrators.

Quality Control

On the **Advanced** settings menu, press the **Quality Control** button to access the quality control menu. From here, operators can perform Quality Control testing.

The QC settings option is only accessible for Clarity Diagnostics administrators. The frequency of QC prompts is preset to 30 days or 100 tests between QC, whichever comes first.

Note: *The Clarity Platinum analyzer will automatically lock the test strip function after 30 days or 100 tests have been performed to ensure the integrity of the urinalysis strips. In order to use the Clarity Platinum analyzer, CLIA Waived users are required to perform a successful QC test.*

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.

Note: *For CLIA Waived settings, only the QC controls produced by Clarity Diagnostics (CLA-UHCRL25) should be used, as the QC pass/fail criteria have been optimized for the Clarity Platinum analyzer.*

Perform QC Test

1. On the main menu, select **Advanced**. Then select **Quality Control**.
2. On the quality control screen, select **Perform QC Test**.
3. Scan or enter the barcode from the urine reagent strip bottle.
4. Scan or enter the barcode from Clarity's Urine Control Level I Bottle.
5. Follow the instructions on the screen for performing QC with Level I Control. Place one drop of Level I Control on each reagent pad, and press the **Start** button.
6. After pressing the **Start** button, the Clarity Platinum begins 10 seconds of self-calibration. During this time, touch the long edge of the strip to a paper towel to remove the excess quality control sample and 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.
7. When calibration is complete, the Clarity Platinum retracts the strip bed and starts analyzing the strip.
8. A timer on the screen counts down the time remaining in the strip analysis process.
9. Once the test is complete, the screen will display and print the QC test result for Control Level I. Once the QC test for Level I passes, perform a QC test with the Control Level II Solution. A QC pass/fail message will be displayed with the test result on the display screen.
10. Press **Next** to perform QC with the Urine Control Level II Solution. Scan or enter the barcode from Clarity's Urine Control Level II Bottle.
11. Follow the instructions on the screen for performing the QC test with Level II Control Solution. Place one drop of Level II Control Solution on each reagent pad and press the **Start** button.

12. After pressing the **Start** button, the Clarity Platinum begins 10 seconds of self-calibration. During this time, touch the long edge of the strip to a paper towel to remove the excess quality control sample and 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.

13. When calibration is complete, the analyzer retracts the strip bed and starts analyzing the strip.

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

15. Once the test is completed, the screen will display and print the QC test result for Control Level II. The QC Pass/Fail message will be displayed with the test result on the display screen.

16. Press ◀ to return to the QC main menu.

Note: *Water should not be used as a QC Level I low/negative control solution.*

Note: *Once the QC test is successfully performed, the test system will display the results on the screen. Passing the QC test enables the user to conduct patient sample testing. Failing the QC test will lock the system, and the user cannot perform any patient testing until the Quality Control test is performed successfully. If the problem persists, stop the test and call technical support at (877) 485-7877, Monday-Friday, 8am-6pm EST, or email us at techsupport@claritydiagnostics.com.*

Note: *In CLIA Waived settings, QC Prompts are enabled and required. The analyzer has to pass Quality Control testing before being able to resume patient urinalysis testing.*

4.3 Device Diagnostics

For use in CLIA Waived settings only when directed by Clarity Diagnostics' technical support team.

1. On the **Advanced** screen, select **Device Diagnostics**.
2. Select the individual options to perform diagnostic test:
   - **Display**
     After selecting **Display**, a screen will appear showing red, green, and blue panels. This allows you to verify the performance of the RGB LCD screen.
   - **Touch Screen**
     After selecting **Touch Screen**, a blue screen will appear. You can touch any part of the screen any number of times. Red spots will appear to verify that the touch screen is performing as expected. Press **Exit** to return to the previous screen.
   - **Printer**
     Selecting **Printer** runs internal diagnostics on the built-in printer. If the printer is performing as expected, 'Printer works OK' will be printed.
   - **Strip Bed**
     Selecting **Strip Bed** allows you to verify that the strip bed mechanics are working correctly by ejecting and retracting the strip bed once.
   - **Light Source**
     Selecting **Light Source** initiates an internal check. If the light source is performing as expected, the Clarity Platinum analyzer will display a message on the screen to notify the user that the light source is performing as expected.
   - **Electronics**
     Selecting **Electronics** initiates an internal check. If the electronics are performing as expected, the analyzer will display a message on the screen to notify the user that the electronics are performing as expected.
3. Press ◀ to return to the **Advanced** menu.

5. Troubleshooting

Your Clarity Platinum analyzer will function properly if you follow the instructions provided in this manual and maintain the instrument. If the Clarity Platinum analyzer detects a problem or an issue, error messages will be displayed on the LCD screen to alert the user.

There are two types of errors that could occur with the Clarity Platinum analyzer:

Errors That Disable the Instrument

If the error prevents the user from using the analyzer, the keypad will be disabled and the machine must be turned off. In the event of a disabling error, please contact Clarity Diagnostics Technical Support immediately at (877) 485-7877, Monday-Friday, 8am-6pm EST, or email us at techsupport@claritydiagnostics.com

Errors That Do Not Disable the Instrument

There are specific errors that need to be corrected prior to testing another sample, but the user is still allowed to operate the analyzer.

List of potential sources of error and various fail-safe and failure alert mechanisms designed to prevent the user from receiving an incorrect or false result:

POTENTIAL SOURCES OF ERROR	VALIDATION RESULTS
System failure (Includes software failure, motor failure, LED broken, strip bed jams, power disruption, and printer failure)	The system preforms hardware checks for mechanical, electrical, and optical components when the device is switched ON. The user is alerted with 'Mechanical System Fail,' 'Optical System Fail,' or 'Electronic System Fail' error message depending on the type of component fail and errors observed. Operators should perform device diagnosis for each hardware component in the **Advanced** menu.
Incorrect placement of strip	The user is alerted with a 'Misplaced Strip' error message which is generated due to improper positioning or incorrect alignment of the strip. Instructions for the correct testing procedure are provided on the display screen every time the user is performing a test. They are also found in the Quick Start Guide and Operator's Manual.
Dry strip detected	The user is alerted with the 'Dry Strip Detected' error message due to a partially saturated or unsaturated strip, and it suggests that the user ensures that the test strip is completely wet before placing a new strip on the strip bed. The instructions for correct testing procedure are provided on the display screen every time the user performs a test. It is also found in the Quick Start Guide and Operator's Manual.

POTENTIAL SOURCES OF ERROR	VALIDATION RESULTS
Incorrect strips used	The user is alerted with an 'Incorrect Strip Type' error message and is prompted to use the correct strip type. The Clarity Platinum Urine Analyzer must be used with Clarity branded strips.
Incorrect timing of test procedure or delayed test time	The strip bed is retracted once the 'Start' button is pressed. This is implemented to prevent users from delaying the test time or delaying placing the strip on the strip bed. The user is alerted with a 'Misplaced Strip' error message due to no strip being detected. Limited time is available for placing strips on the strip bed.
Use of improperly stored strips/ humidity compromised strips	The user is alerted with a 'Strip Quality Issue' error message and instructed to use a new strip from an unexpired bottle. If QC tests are performed with humidity compromised strips, then the user is alerted with a 'QC Fail' message generated after the Quality Control Test. Once the QC test fails, the system will go into a lockout function, and the user cannot perform any patient testing until the Quality Control testing is completed successfully.

POTENTIAL SOURCES OF ERROR	VALIDATION RESULTS
Interference with urine specimen testing due to presence of blood	Results are flagged when blood analyte has a high concentration block, which can create false positive readings for other reagent pads. The failure alert mechanism is employed to notify the user by flagging the test result with the warning message, 'Possible false positive results due to blood interference may occur for glucose, protein, bilirubin, urobilinogen, nitrite, leukocytes, ketones.' The message is displayed on screen, printed on the test results, and included in the data packet which is sent electronically (if applicable).
Use of expired strips	The product barcode feature will alert the user with a 'Barcode Error' message generated due to expired strip bottles. The system will lock out and will not allow users to perform tests until a new barcode is scanned.
Failure of device calibration	The Clarity Platinum Urine Analyzer performs a hardware check for mechanical, electrical, and optical components when the device is switched ON. The user is alerted with an 'Optical System Fail' error message if there is damage to the white calibration block and/or gradual buildup of urine sediment.

POTENTIAL SOURCES OF ERROR	VALIDATION RESULTS
Use of incorrect QC controls/ expired controls or improperly stored and handled controls	Users will receive a 'Barcode Error' message if they use the incorrect control level, or if they are using an expired bottle of controls. The system will not proceed to the Quality Control test, and the user will need to use an unexpired bottle of controls or the correct control level to get to the quality control test function. The user will be alerted with a 'QC Fail' error message if they select an improperly stored control that was compromised due to incorrect storage conditions. The system is locked out and the user cannot perform any patient testing until the Quality Control testing is completed successfully.
Unauthorized operator	The user will be alerted with an 'Operator Login Invalid' error message if the username or password is incorrect.

The following table provides the Failure Mode, Error Messages, and Corrective Action plan for the user to implement

FAILURE MODE	ERROR MESSAGE 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 the instructions explain in **Section 6: Removing and Replacing Strip Bed**.
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 is fully inserted into 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.

FAILURE MODE	ERROR MESSAGE DISPLAYED ON THE SCREEN	CORRECTIVE ACTIONS
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)	'Barcode 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.

Note: If you cannot troubleshoot an error or when an error continues to occur after the corrective action is taken, please contact Clarity Diagnostics Technical Support at (877) 485-7877, Monday-Friday, 8am-6pm EST, or email us at techsupport@claritydiagnostics.com.

6. Maintenance

Careful maintenance of the Clarity Platinum analyzer is important for it to operate properly. Routine cleaning of the Clarity Platinum analyzer helps to prevent contamination and bacterial growth. It is recommended that you clean the analyzer weekly, or more frequently if necessary.

Note: *Positive and negative controls should be tested after performing maintenance or service on the Clarity Platinum analyzer; with every new shipment and new lot of CLA-10P strips; when opening a new CLA-10P bottle; whenever test results appear to be inaccurate; with each new operator training; and every thirty days to check storage quality of the strips (see* ***Section 4.2: Advanced Settings, Quality Control****).*

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

Caution:
Make sure the analyzer is turned off before cleaning the outside of the unit.

Removing/Replacing Strip Bed

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 for cleaning.
2. Wait until the bed has been fully ejected from the analyzer and gently lift it away from the machine.
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 ⇧ and the strip bed will be retracted into the machine.

Daily/Routine Cleaning of Strip Bed

1. Wet a cotton-tipped swab with warm water and carefully clean the strip bed.
2. Dry the strip bed with a clean cotton swab.

Weekly Cleaning of the Strip Bed

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. Wait until the bed has been fully ejected from the analyzer and gently lift it away from the machine.
3. Clean the strip bed with a 70% alcohol solution, or bleach at a dilution of 1:100 of 5% sodium hypochlorite. 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.
4. Dry the strip bed completely with a lint free tissue or clean cotton swab.
5. 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.

Cleaning the Analyzer Case

1. Power off the analyzer.
2. Wipe the exterior plastic casing of the analyzer with a damp cloth. Bleach, at a dilution 1:100 of a 5.25-6.15% sodium hypochlorite (provides 525-615 ppm) can be used if needed. Do not use isopropyl alcohol or alcohol prep pads.
3. Dry the analyzer case with a clean cloth.

Cleaning the Touch Screen

1. Power off the analyzer.
2. Wipe the screen with a clean, soft, lint free cloth. If needed, you can use a small amount of non-ammonia, non-alcohol-based solution to avoid any damage to the screen. Do not wash the LCD Screen with glass cleaner or laboratory wipes, as they may damage the screen.
3. Dry the touch screen with a clean cloth.

Appendix A. Clarity Platinum Urine Analyzer Specifications

Methodology	Reflectance Photometer
Calibration Method	Automatic; white reflective check area
Entered Parameters	Urine color and clarity, operator ID, and patient ID
PC Port	USB- C
Interface Ports	USB
User Interface	Touch Screen Color LCD
Printer	Fixed head built-in printer using a roll of thermal paper
Power Source	100-240 VAC ±20%, 50/60 HzOutput +9V
Ambient Operating Temperature	59°F to 86°F (15°C to 30°C)
Weight	5.21 lbs.
Dimensions	10.5 (depth) x 7 (width) x 6.5 (height) inches

Appendix B. Clarity Platinum Urine Analyzer Default Settings

Date Format	YYYY-MM-DD	Strip Barcode	Enable
Urine Color	Disable	Authorized Operator	Disable
Urine Clarity	Disable	Operator Access to Strip Test	Enable
Strip Selection	Automatic	Operator Access to Recall Result	Enable
Language	English	Operator Access to Settings Menu	Enable
Unit Convention	C1	QC Prompts	Enable
Printer	Automatic	Type of Prompts	Required
Printing Format	Include Patient ID and Test ID	Number of days between QC test	30
Test Selection	Quick Test Mode	Number of tests between QC test	100

Appendix C. Clarity Platinum Urine Analyzer Unit Convention Table

Parameter	Value (C1)	Value(C2)	Value (S1)	Value (S2)
Leukocytes	Negative	Negative	Negative	Negative
	Trace	Trace	Ca 15 Leu/uL	Trace
	* Small	* 1+	Ca 70 Leu/uL	* 1+
	* Moderate	* 2	Ca 125 Leu/uL	* 2+
	* Large	* 3+	Ca 500 Leu/uL	* 3+
Nitrite	Negative	Negative	Negative	Negative
	* Positive	* Positive	* Positive	*Positive
Urobilinogen	0.2 EU/dL	0.2 EU/dL	3.2 umol/L	3.2 umol/L
	1.0 EU/dL	1.0 EU/dL	16 umol/L	16 umol/L
	* 2.0 EU/dL	* 2.0 EU/dL	* 32 umol/L	* 32 umol/L
	* 4.0 EU/dL	* 4.0 EU/dL	* 64 umol/L	* 64 umol/L
	* ≥8.0 EU/dL	* ≥8.0 EU/dL	* ≥128 umol/L	* ≥128 umol/L
Protein	Negative	Negative	Negative	Negative
	Trace	Trace	Trace	Trace
	* 30 mg/dL	* 1+	* 0.3 g/L	* 1+
	* 100 mg/dL	* 2+	* 1.0 g/L	* 2+
	* ≥300 mg/dL	* 3+	* ≥3.0 g/L	* 3+
PH	5.0	5.0	5.0	5.0
	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

* Denotes Positive Test Results observed and is printed on the test results.

Appendix C. Clarity Platinum Urine Analyzer Unit Convention Table

Parameter	Value (C1)	Value(C2)	Value (S1)	Value (S2)
Blood	Negative	Negative	Negative	Negative
	Trace	Trace	Trace	Trace
	* Small	* 1+	* Ca 25Ery/uL	* 1+
	* Moderate	* 2+	* Ca 80Ery/uL	* 2+
	* Large	* 3+	* C 200Ery/uL	* 3+
SG (Specific Gravity)	≥1.030	≥1.030	≥1.030	≥1.030
	1.025	1.025	1.025	1.025
	1.020	1.020	1.020	1.020
	1.015	1.015	1.015	1.015
	1.010	1.010	1.010	1.010
	≤1.005	≤1.005	≤1.005	≤1.005
Ketone	Negative	Negative	Negative	Negative
	Trace	Trace	Trace	Trace
	* 15 mg/dL	* 1+	* 1.5 mmol/L	* 1+
	* 40 mg/dL	* 2+	* 3.9 mmol/L	* 2+
	* ≥80 mg/dL	* 3+	* ≥7.8 mmol/L	* 3+
Bilirubin	Negative	Negative	Negative	Negative
	* Small	* 1	Small	* 1+
	* Moderate	* 2+	* Moderate	* 2+
	* Large	* 3+	* Large	* 3+
Glucose	Negative	Negative	Negative	Negative
	100 mg/dL	Trace	5.5 mmol/L	Trace
	* 250 mg/dL	* 1+	* 14 mmol/L	* 1+
	* 500 mg/dL	* 2+	* 28 mmol/L	* 2+
	* 1000 mg/dL	* 3+	* ≥55 mmol/L	* 3+

* Denotes positive test results observed and is printed on the test results.

Appendix D. Clarity Platinum Urine Analyzer Unit Convention Table

This section indicates the symbols that appear on the exterior packaging of the Clarity Platinum urine analyzer, the analyzer itself, the power adapter, and the urine reagent strips.

	Manufacturer
	European authorized representative
SN	Serial Number
	In vitro diagnostic device
	Consult instructions for use
	Caution
	Biohazard
	Indicates a power on/off button
	Temperature Requirements for Ambient Operation (59°F - 86°F / 15°C - 30°C)
	Quantity
	Expiration Date: YYYY-MM-DD
LOT	Lot Number
	This equipment is classified as Waste Electrical and Electronic Equipment under the European WEEE Directive. It must be recycled or disposed of in accordance with applicable local requirements.
REF	Catalog number

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