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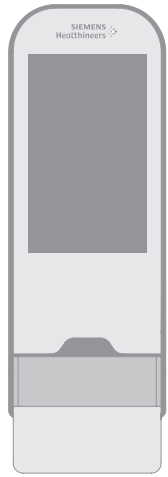

Atellica® VTLi

Immunoassay Analyzer

User Guide

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Atellica® VTLi Immunoassay Analyzer

User Guide

Contents

CHAPTER 1
Exploring the Atellica VTLi Immunoassay Analyzer

About this User Guide

This user guide describes the Atellica® VTLi Immunoassay Analyzer features and explains how to operate and maintain it. You should carefully read this user guide before using the device and its consumables. Make sure to keep this user guide for future reference.

The following conventions are used throughout this guide:

Symbols Description	
ⓘ	Indicates additional information about a feature or screen.
⚠	Indicates important operations or safety information.
☣	Indicates a potential biohazard danger. Always follow standard safety practices and your local laboratory guidelines when working with biohazard materials.
Next > Finish	In instructions, indicates a series of commands you tap to reach a screen.

Intended use

The Atellica® VTLi Immunoassay Analyzer is intended to be used by healthcare professionals in clinical laboratories and point-of-care settings, to measure the concentration of biomarkers in whole blood or plasma using disposable cartridges.

The Atellica® VTLi Immunoassay Analyzer is a solution for the quantitative evaluation of immunoassays using Magnotech® technology.

General warnings and precautions

Always observe these safety and usage guidelines when testing patient samples using the analyzer.

- Always follow your facilities established safety guidelines and standard procedures.
- Wear personal protective equipment such as safety glasses, gloves, lab coats, or aprons when working with possible biohazard contaminants.
- Dispose of contaminated materials according to your laboratory's biohazard control procedures.
- Do not use the analyzer in the proximity of a strong magnetic field.
- This device contains sensitive components. Handle with care, prevent shocks and sudden changes in temperature and humidity.

ⓘ For more information, see *Safety Information*, on page 14.

Cleaning the analyzer

You should clean the analyzer using the Siemens Healthineers recommended cleaning guidelines.

ⓘ For more information, see *Cleaning and disinfection*, on page 33.

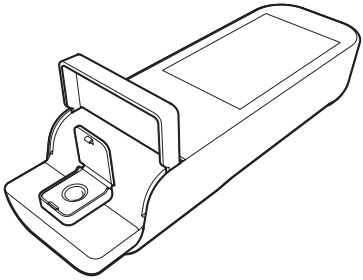
Getting to know the Atellica VTLi system

The Atellica VTLI system consists of the following components:

- Analyzer
- Docking station
- Service Software
- Test cartridges

VTLi Immunoassay Analyzer

The analyzer is a handheld point of care device that performs a test on a sample.



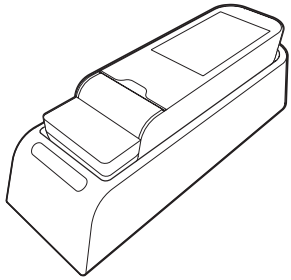
After inserting a new, unused cartridge into the analyzer, the analyzer instructs the user to apply the sample at the appropriate time. The analyzer then performs the test and displays the test results. The analyzer will not perform a test if a sample is applied to the cartridge before the cartridge is inserted into the analyzer. The analyzer also provides 2.4GHz or 5GHz WLAN functionality for data transfer.

ⓘ A best practice is to ensure at least 1 LAN connection is available in case of WLAN network issues.

Docking station

The analyzer can be docked in the docking station to:

- Perform a test
- Cool the analyzer
- Charge the battery
- Configure the analyzer via the service software
- Upload data or test results (via middleware software) to hospital information systems if applicable.



One docking station can support multiple analyzers.

Service Software

The Service Software allows you to do the following:

- Configure the analyzer
- Monitor the analyzer status

ⓘ For more information, see the *Atellica VTLi Immunoassay Analyzer Advanced User Guide*.

Test cartridges

The analyzer uses disposable cartridges to test patient samples. Each cartridge is for single use only; never perform a test with a previously used cartridge. For each test, refer to the Instructions for Use supplied with the cartridges. The sample material depends on the test that is to be performed. The sample can be whole blood or plasma. Consult the Instructions for Use of the test for the definition of the sample.

Setting up the Atellica VTLi Immunoassay Analyzer

Materials Provided

Atellica VTLi Immunoassay Analyzer

Special Materials Required (Not Provided)

- Atellica VTLi hs-cTnI Reagent Cartridge
- Quality Control Materials

What's in the Box?

Your Atellica VTLi system is contained in a single box, containing:

- Analyzer
- Docking station
- Power cords, AC power supply, Ethernet cable, battery, torx screwdriver
- Documentation pack (Users Guide, Quick Reference Guide)

ⓘ You must order the test cartridges separately.

Installation guidelines

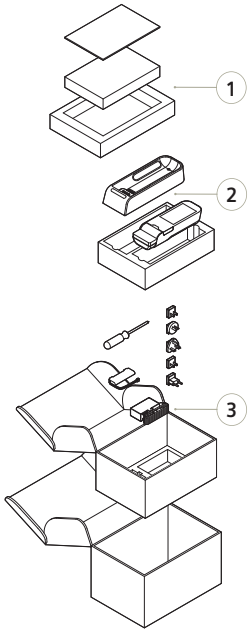
- The docking station requires a power connection.
- The docking station provides a connection to the local network or directly to a computer.
- A Windows-based computer, server, or virtual machine is required to install the Service Software, which manages the communication to and from the installed analyzer(s) for configuration and service purposes. The Atellica VTLi analyzer also connect directly to middleware software which manages data transfer to the hospital information system.
- Siemens Healthineers recommends using Windows NTP to implement the Consistent Time Integration (CT) profile. The PC should have this solution installed/enabled.
- Siemens Remote Service (SRS) is recommended for remote services.

ⓘ Contact your local Siemens Healthineers representative if connection to a laboratory information system is needed.

⚠ The electromagnetic environment should be evaluated prior to operation of the device. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these can interfere with the proper operation. This equipment complies with the emission and immunity requirements of the IEC 61326 series.

Unpacking and assembly

Follow these instructions to unpack and assemble the Atellica VTLi Immunoassay Analyzer.



Inspect the box and contents and notify your delivery representative if you notice any damage or missing items.

INSTRUCTIONS

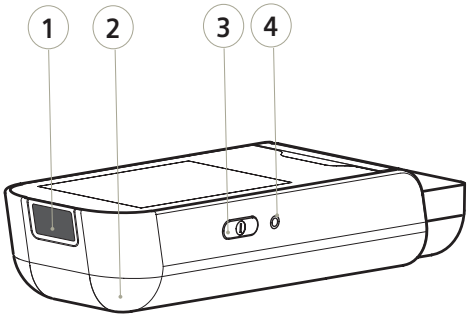
1. Carefully open the shipping box and remove the documentation pack from the top foam insert.

1	User documentation (User Guide, Quick Reference Guide)
2	Analyzer, Docking Station
3	Inner box with: Power supply, battery, power cords, torx screwdriver

2. Carefully open the inner box.
3. Remove the 2 plastic pouches from the foam insert. One contains the analyzer and the other the docking station.
4. Remove the empty analyzer/docking station foam insert.
5. Remove the accessory items from the accessories foam insert.
6. To remove the analyzer and docking station, carefully open each pouch.
7. To remove the user documentation, open the documentation pack and remove the contents.

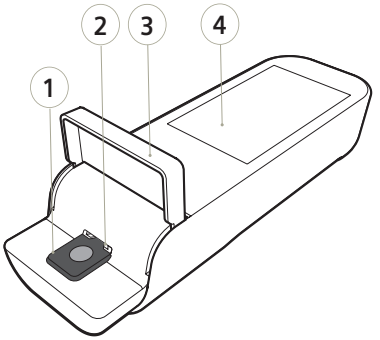
Identifying the analyzer controls

Side view



1	Barcode reader
2	Battery cover
3	On/Off button
4	Reset button

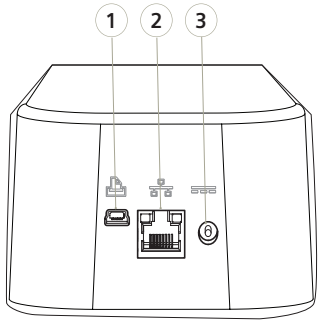
Top view



1	Cartridge insertion area
2	Cartridge slot
3	Analyzer cover
4	Analyzer screen

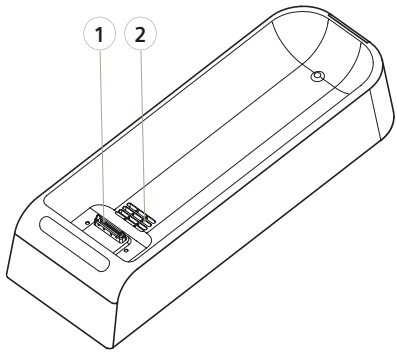
Identifying the docking station controls

Back view (connection ports)



1	Not used
2	Network connection
3	Power supply adapter connection

Top view



1	Analyzer connection socket
2	Cooling fan

⚠ Don't insert objects or spill fluids into the cooling fan area to avoid malfunction of the cooling system.

⚠ Avoid exposing the docking station to electrostatic discharge (EDS) as it may damage the unit.

Connecting the docking station

INSTRUCTIONS

1. Connect one end of the Ethernet cable to the docking station, and the other end either to a port on the local network or directly to the Service Software PC.
2. Connect the AC power adapter to the docking station and connect the AC power adapter to the power source using the power cord.

The docking station should be connected to the AC power source so that it can charge the analyzer battery and cool the analyzer with the cooling fan. If the docking station is not connected to the power supply with the analyzer docked, the analyzer battery will drain.

Installing the analyzer battery

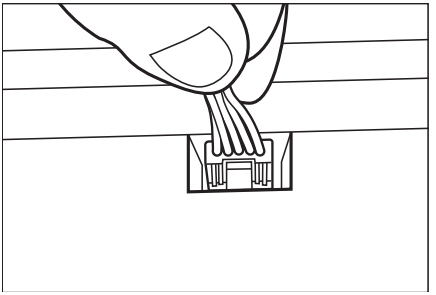
Before you can use the analyzer, you need to install the battery using the torx screwdriver included in the accessories box.

After installing the battery and prior to use, you must charge the analyzer battery for at least one hour to ensure that the analyzer can function correctly. A partial battery charge takes 2 hours; a full battery charge takes approximately 8 hours. Charge the battery with the analyzer docked and power on.

When undocked, the system is capable of performing at least one test after one hour of battery charging, but it is preferable to fully charge the battery before using for the first time.

INSTRUCTIONS

1. On the back of the analyzer, locate the small screw holding the battery cover in place.
2. Use the torx screwdriver to remove the screw completely and set it aside.
3. Slide the cover upward to remove it from the analyzer.
4. Insert the battery plastic wire connector into the analyzer. You should hear or feel it snap into place.



5. Fit the new battery into the battery compartment.
6. Position the wires before reattaching the cover.

Ensure that the wires are not crimped and will not interfere with reattaching the battery cover.

7. Slide the battery cover back into place on the analyzer.
8. Reinsert and gently tighten the battery cover screw.

For more information on battery care, see page 37.

Configuring the analyzer

The final step in setting up the analyzer is to use the Service Software to configure analyzer connectivity, users, and tests and workflow options.

Refer to the *Atellica VTLi Immunoassay Analyzer Advanced User Guide* for complete instructions on installing and using the Service Software.

Follow your hospital or laboratory procedures to ensure proper installation.

Turning the analyzer On/Off

Powering On the analyzer

INSTRUCTIONS

1. Press the Power button located on the side of the analyzer.
2. The analyzer starts and performs a self test to ensure correct operation. Progress of the self test is displayed on the analyzer screen.
3. Wait for the analyzer to finish the self test before continuing to operate it. The Home screen displays when the self test is finished.

The analyzer self test is performed dependent on "time passed since last performed self test" and dependent on "number of tests done since last performed self test."

Powering Off the analyzer

1. Do one of the following:
   - To shut down the analyzer, press and hold the Power button for several seconds.
   - To put the analyzer into standby mode, briefly press the Power button.

The analyzer cannot be shut down when a test is in progress. After the patient has been identified, a test is considered in progress from the time the cartridge insertion screen is shown until the test result has been accepted or rejected.

Working with the docking station

Docking the analyzer

Docking allows the analyzer to charge, cool down, and transfer data.

INSTRUCTIONS

1. Place the analyzer in the docking station so that the docking station connectors are engaged.
2. Gently push the analyzer to connect the analyzer to the docking station.

Undocking the analyzer

INSTRUCTIONS

1. Lift the analyzer out of the docking station.
2. If necessary, the analyzer automatically performs a self test, depending on the frequency configured when the analyzer is undocked.

When the analyzer is undocked, it:

- Runs on battery power alone
- Is not cooled down by the docking station

Docking station status indicators

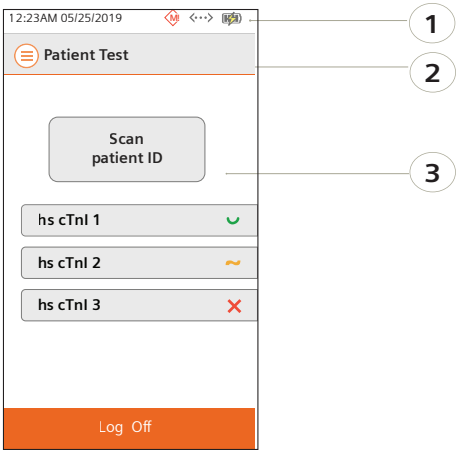
The indicators on the docking station a visual operational status.

Status Indicators	
	The analyzer is docked correctly.
	The analyzer is not docked or not docked correctly. Try docking the analyzer again. Press the analyzer gently after docking to help secure the connection.
	Power On/Off

Exploring the user interface

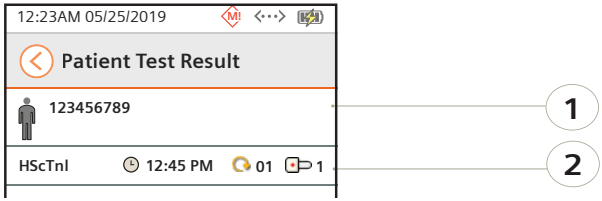
The touchscreen user interface allows you to interact with the analyzer to perform testing, quality control, and other tasks. It also displays messages, status information, and other details about the analyzer or task.

The Home screen



1	**Status bar** - contains indicators for time, date, memory usage, connectivity status, and battery level. Tap the status bar to display the **System Status** screen. Tap ⟨ to return to the **Home** screen.
2	**Navigation bar** - contains the main menu button ☰ and screen title (for example, Patient Test).
3	**Main display** - provides information about analyzer status and next steps, provides guiding illustrations, displays system messages, shows results, and serves as a location for data input, when applicable.

Test result screen



1	**Sample identification bar** - contains patient information for a patient test or information about the quality control (QC) for a QC test
2	**Test information bar** - displays the: – test name and version – test end time (if applicable) – repeat indicator – cartridge symbol – test sequence number If the test is a repeat test, the repeat icon appears next to the test number.

Common icons and buttons

Icons and Buttons			
	Display main menu		Display on-screen keyboard
	Go back		Scan a barcode
	Battery is fully charged		The battery is almost empty. Dock the analyzer to recharge the battery. An undocked test is still possible, but recharging the battery is strongly advised.
	Battery is charged (75%)		Battery is empty. A test can only be performed on the docking station.
	Battery is charged (50%)		Shows when the battery is charging. The current battery level is also indicted during charging.
	Memory Low. The analyzer has reached the low storage limit. Only a limited number of tests can be performed with the available memory.		Analyzer memory is full. No more tests can be stored. Free up memory by uploading results or contact your local administrator for assistance.

Icons and Buttons			
	The analyzer is connected to the LAN network, but there is currently no data transfer.		Quality control lot status indicator. All lots are up-to-date.
	The analyzer is connected to the wireless network, but there is currently no data transfer.		
	The analyzer is connected to the network, and there is active data transfer.		Quality control lot status indicator. A lot is about to expire.
	The analyzer is not able to establish a network connection.		Quality control lot status indicator. A lot has expired.
	Move down or up in a list or page	POS NEG	Positive or Negative qualitative result indicator
	Move left or right in a list or page	Pass Fail	Pass or Fail QC test result indicator
	Indicates a patient test.		
	Indicates a QC test.		

Entering information

You can enter information, such as a Patient ID, on the analyzer in 2 ways:

- Barcode reader
- Touch screen keyboard

When the analyzer requires information, such as a Patient ID (PID), it prompts you to use the barcode reader. The barcode reader enables you to easily scan important information directly into the analyzer.

Operating the barcode reader

INSTRUCTIONS

1. Aim the barcode reader at the item you want to scan.

   The red and green lights help you to aim the scanner on the barcode. Center the aiming beam over the barcode.

2. Tap  to activate the scanner.

   The screen changes when the barcode is accepted.

Tips for scanning

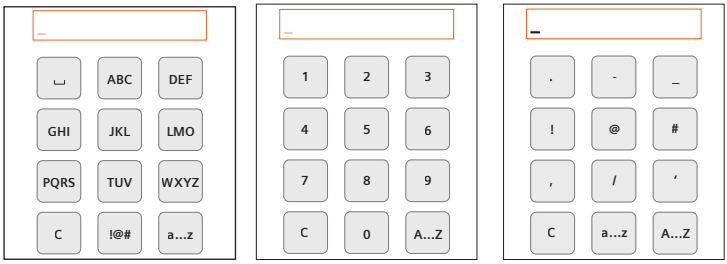
- Hold the item in the center of the scan window, not too close or too far away
- For items with more than one barcode, make sure you scan the intended barcode.
- Ensure proper lighting.
- If the code being scanned is on a highly reflective surface (for example, a laminated surface), tilt the barcode slightly to reduce reflection.

Using the on-screen keyboard

The on-screen keyboard is another way you can enter information.

INSTRUCTIONS

1. Tap .



2. Do one of the following:
   - To enter uppercase letters, tap a..z and then tap the key that corresponds to the letter you want.
   - To enter a space, tap ␣.
   - To enter numbers, tap 0..9 and then tap the key that corresponds to the number you want.
   - To enter special characters, tap !@# and then tap the key that corresponds to the character you want.
   - To delete the previous character you entered, tap C.
   - To enter lowercase letters, tap a..z and then tap the key that corresponds to the letter you want.

When entering sensitive data, such as a password, the selected character appears briefly in the entry field and is then hidden by a concealing character.

Logging on and off

You can enter your User ID on the analyzer using the barcode reader or on-screen keyboard.

INSTRUCTIONS

1. Aim the analyzer barcode reader at the User ID you want to scan.
2. On the **User Login** screen, tap **Scan User ID**.

   You can also tap **Keyboard** to enter your User ID using the on-screen keyboard.

If the **ID not found** message displays, tap **Try again** to rescan. Or tap to enter using the on-screen keyboard.

Your user information displays if the login is successful.

Logging off the analyzer

1. On the main display, tap **Log out**.

   The **Logout user** prompt displays.
2. Tap **Yes**.

   The **User Login** screen appears.

Learning more about the Atellica VLTi Immunoassy Analyzer

Refer to the following for additional information about Atellica VLTi Immunoassay Analyzer.

Instructions for Use

Read the Instructions for Use (IFU) that shipped with your test cartridge and quality controls. The IFU contains important information about your kits and their contents. Keep the IFU for future reference.

Advanced User Guide

Refer to the *Atellica VLTi Immunoassay Analyzer Advanced User Guide* for additional configuration settings including Service Software configuration and setup. The guide is located on the Siemens Healthineers Document Library at:
https://doclib.siemens-healthineers.com/home

Quick Start Guide

Graphical reference guide provides quick details on performing patient and quality control tests.

Safety Information

Read the following safety information to protect yourself in the hospital or laboratory.

Protecting Yourself from Biohazards

The established guidelines for handling laboratory biohazards are based on the guidelines developed by the Centers for Disease Control, the Clinical and Laboratory Standards Institute, and the Occupational Safety and Health Administration.

Use these safety guidelines for general information only. It is not intended to replace or supplement your laboratory or hospital biohazard control procedures.

By definition, a biohazardous condition is a situation involving infectious agents biological in nature, such as the hepatitis B virus, the human immunodeficiency virus, and the tuberculosis bacterium. These infectious agents may be present in human blood, blood products, and other body fluids.

Recognizing Sources of Contamination

When you handle potentially infectious agents, keep in mind the following major sources of contamination:

- Hand-to-mouth contact
- Hand-to-eye contact
- Direct contact with superficial cuts, open wounds, and other skin conditions that might permit absorption into subcutaneous skin layers
- Splashes contact with skin and eyes

Preventing Contamination

To prevent accidental contamination in a clinical laboratory, strictly adhere to the following procedures:

- Wear gloves while servicing parts of the analyzer that have contact with possible biohazard contaminants.
- Wear facial protection when splatter or aerosol formation is possible.
- Wear personal protective equipment such as safety glasses, gloves, lab coat, or apron when working with possible biohazard contaminants.
- Dispose of contaminated materials according to your laboratory's biohazard control procedures.

References

Centers for Disease Control. Update: *Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings*. 1988. MMWR, 37:377-382, 387, 388.

Clinical and Laboratory Standards Institute (formerly NCCLS). *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline - Third Edition. Wayne*, PA: Clinical and Laboratory Standards Institute; 2005. CLSI Document M29-A3.
[ISBN 1 56238- 567-4].

Federal Occupational Safety and Health Administration. Bloodborne Pathogens Standard. 29 CFR 1910. 1030.

CHAPTER 2
Testing Patient Samples

General Warnings and precautions

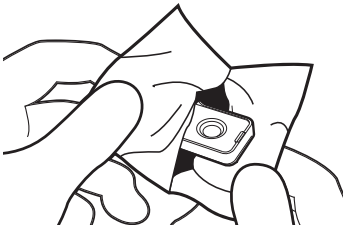
- Only store the patient sample at the prescribed storage conditions and time.
- Keep the reagent cartridges stored at the correct temperature noted in the Instructions for Use.
- Carefully follow the instructions and procedures described in the Instructions for Use that came with the reagent cartridges.
- Carefully follow the instructions and procedures in this user guide for system operation.
- Do not put reagent cartridges back into cooled storage after you remove them. Take out only what you plan to use.
- Keep the reagent cartridge in its sealed pouch until ready for use.
- Use the reagent cartridge within 15 minutes of removing from pouch.
- Do not use the reagent cartridge if the cartridge pouch is pierced or damaged.
- Do not use dropped reagent cartridges for testing.
- Only use the prescribed samples types for the test.
- Never touch the filter or the transparent optical area of the reagent cartridge.
- Always keep the analyzer in a horizontal position, and free from vibration, during testing.
- A patient test can be performed with the analyzer either docked or undocked.

Preparing for testing

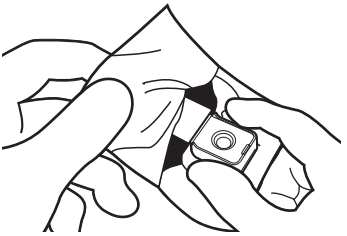
Working with reagent cartridges

INSTRUCTIONS

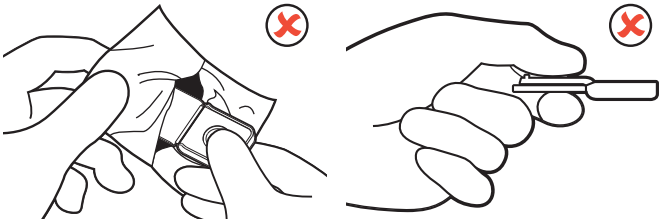
1. Open the pouch halfway by peeling back the corners.



2. Remove a reagent cartridge from the pouch by holding it on the sides of the housing (next to the filter), as specified in the instructions for use supplied with the cartridge.

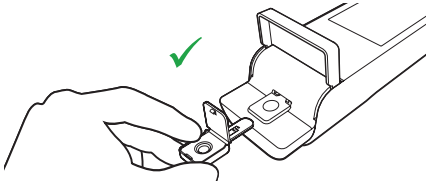


Do not touch the filter or hold the transparent area of the cartridge.

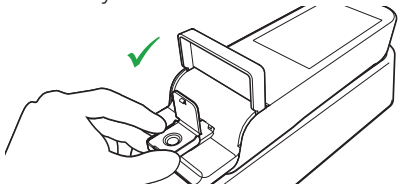


Guidelines for inserting the reagent cartridge

– Hold the reagent cartridge between your thumb and pointer finger to insert.

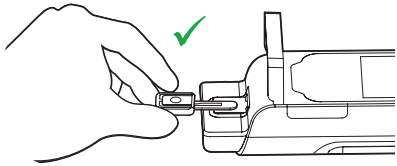


– Place one hand on the analyzer and line the reagent cartridge up with the insertion area of the analyzer.

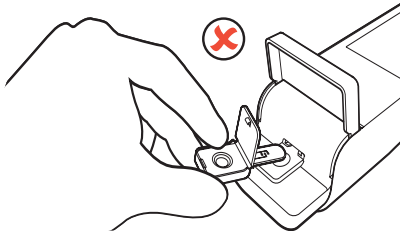


ⓘ Don't use one finger to insert the cartridge as it might not align correctly and lead to invalid results.

– Insert the reagent cartridge flat and aligned with the analyzer until it clicks in place.



⚠ Don't insert the reagent cartridge at a downward angle or crooked as this might damage the cartridge and the analyzer.



Collecting a sample

The following specimen types have been tested for use with the Atellica VTLi Immunoassay Analyzer:

- Venous whole blood or plasma (containing anticoagulant as noted in the Instructions for Use).
- Capillary whole blood.

For sample tube specimen collection, follow the sample tube manufacturer's recommended procedure. For capillary specimen collection, use a finger-stick method with a sample transfer device, according to manufacturers recommendations.

Refer to the Instructions for Use that comes with your Atellica VTLi Assay for information on storage and handling of samples.

Performing a test

Testing warnings and precautions

- If necessary, dock the analyzer in the docking station to reach the correct temperature.
- You can cancel a test at any time. Depending on the workflow step, you can tap to return to the previous workflow step. You can also cancel a test by opening the analyzer cover and removing the cartridge.
- Canceling a test in progress stops the current test and shows the **Results** screen from where you can continue.
- The analyzer must remain in a horizontal position after applying the sample and during the analysis processing. The analyzer displays a warning message when it detects a non-horizontal position.
- If a sample is spilled, make sure to clean the analyzer, but only after the complete test has finished.
- Do not drop, shake, or bump the analyzer after applying the sample or during testing.
- The sample type (venous or capillary blood, plasma) and the anticoagulant can affect the test result. Make sure you follow the guidance in the workflow and adhere to the indicated sample types .
- Do not use samples types other than the ones supported (venous or capillary blood, plasma).
- Make sure that the sample type you use matches the sample type you select on the **Select Sample Type** screen during the testing process. Applying an unsupported sample type may produce unexpected test results.

If you drop the analyzer, visually inspect for signs of damage to the device. Do not use if you observe any damage. Contact your technical support representative.

Basic test workflow

- (Optional) Scan your User ID
- Scan or enter the Patient ID
- Open reagent cartridge pouch
- Insert reagent cartridge into analyzer
- Select the sample type
- Confirm the sample type
- Add the patient sample to the reagent cartridge
- Close reagent cartridge lid and analyzer cover to begin test
- Review results
- Remove and dispose of reagent cartridge

Identifying the patient

For information on configuring the analyzer patient identification settings, see *Atellica VTLi Immunoassay Analyzer Advanced User Guide*.

INSTRUCTIONS

1. Tap **Scan Patient ID**.
2. Do one of the following:
   - Aim the scanner on the front of the analyzer at the patient barcode.

   To conserve the battery, the scanner turns off if no barcode is detected and displays a message. Tap **Scan Patient ID** to try again.

   - Tap to open the on-screen keyboard and enter the patient information.
   - Tap **Skip** to perform an anonymous test without patient information. The analyzer displays *Anonymous* as the patient name in the sample identification bar. The Patient ID field is left blank.
3. The analyzer displays the patient ID on the screen.

Inserting a cartridge (Insert Cartridge screen)

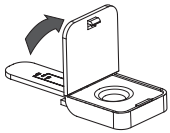
Make sure you properly insert the cartridge following the *Guidelines for inserting the reagent cartridge* on page 19.

INSTRUCTIONS

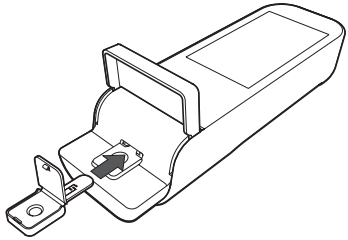
1. Open the analyzer cover.
2. Remove the cartridge from the pouch as described in *Working with reagent cartridges* on page 17.

Do not touch the filter or hold the transparent area of the cartridge.

3. With the filter pointing upward, hold the cartridge by one hand and bend the cartridge lid upward about 90 degrees with the other hand before inserting into the analyzer.



4. Position the reagent cartridge horizontally in front of the cartridge slot and press and slide the reagent cartridge straight into the cartridge slot until you hear and feel a click.



The analyzer automatically validates the reagent cartridge on proper insertion, using the information stored in the cartridge RFID tag. The reagent cartridge assay type displays on the screen.

The analyzer automatically checks whether the analyzer temperature is within the correct range to perform a test and displays an error message if the temperature is out of range.

Selecting the sample type

On the **Select Sample Type** screen, tap the sample type you are testing.

Confirming the sample type

Tap **Confirm** to verify your sample type selection.

⚠ Make sure that the sample type matches the one you select on the screen. Applying an unsupported or mismatched sample type may produce unexpected test results. Refer to the Instructions for Use for information on the sample type.

Adding the patient sample (Add Sample screen)

⚠ Do not add the sample until after inserting the reagent cartridge and the analyzer instructs you to do so.

Do not damage the reagent cartridge filter when applying the test sample.

INSTRUCTIONS

⚠ The guidance in this section on adding sample may vary depending on the test being performed. Read the test Instructions for Use for specific details on adding sample to the cartridge.

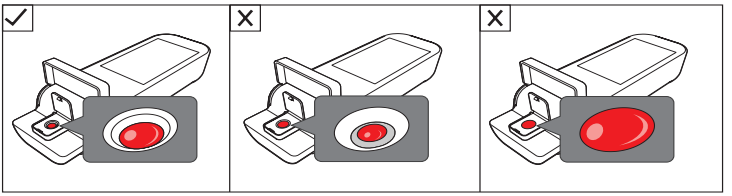
1. Apply sufficient sample, typically 2 to 3 droplets (30 µL), on the filter area of the cartridge as specified in the Instructions for Use supplied with the cartridge.

⚠ The sample must be added to the cartridge and detected by the analyzer within the defined time limit for the test being performed. Refer to the Instructions for Use of the test for the time limits on transferring the sample from the transfer device to the cartridge.

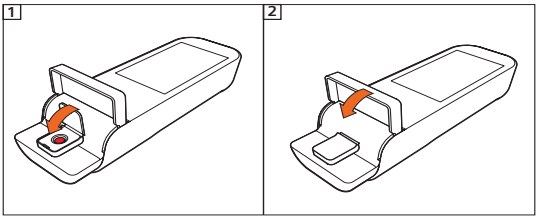
Plasma samples can be added to the cartridge using a pipette (30 µL).

2. Check to ensure you have added a sufficient amount of sample to the reagent cartridge.

   An under-filled cartridge filter looks dry, while an overfilled cartridge shows sample outside the filter area.



3. Close the cartridge lid as soon as the sample is added, and then close the analyzer cover.



When the analyzer detects the sample, it automatically begins the analysis.

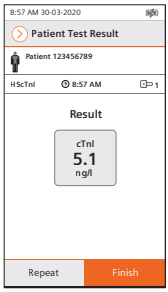
⚠ The analyzer cover **must** be kept closed during analysis. If the cover is opened, the analyzer cancels the current test.

4. The analyzer displays the test progress on the screen and when the test completes, the test results automatically display.

5. If there is any reason to doubt the test results, tap **Repeat** to perform the test again with a new cartridge.

Viewing results and result details

A result tile appears on the **Patient Test Result** screen.



INVALID displays if there is an error in determining the results.

– Tap the result tile for the indicated marker to view result details. Then tap **Back** to return to the **Patient Test Result** screen

– If there are multiple results on the screen, tap ◀ ▶ to view the result tiles.

Removing a cartridge (Remove cartridge screen)

INSTRUCTIONS

1. Open the analyzer cover.
2. Pull the cartridge out of the analyzer.
3. Dispose of the cartridge immediately as described in the instructions for use supplied with the cartridge.
4. Close the analyzer cover.

Close the analyzer cover after each use to protect it from dust and other foreign particles and substances.

Finishing a test (Finish screen)

INSTRUCTIONS

1. Tap **Finish**.

   The analyzer displays a confirmation message.

2. Do one of the following:

   – Tap **OK** to accept the results and finish testing.

   – Press **Cancel** to return to the previous screen.

   The analyzer displays “Remove cartridge.”

3. Remove the cartridge.

If the analyzer is docked and a LAN is connected to the docking station, the results are transferred via the LAN connection. If the docking station is not connected to a LAN, the results are transferred via WLAN if it is enabled. If the analyzer is undocked, and WLAN is enabled, the results are transferred via WLAN once within range.

Performing successive tests (Results screen)

Some tests support testing consecutive samples for the same patient.

INSTRUCTIONS

1. Follow the procedures described in the previous sections for performing a test.

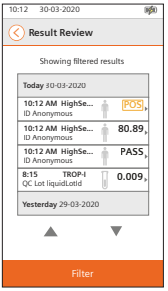
2. Do one of the following:
   – Tap **Next** to perform additional tests.
   – Tap **Finish** when all tests are completed.

Working with Patient Test Results

Viewing patient test results

INSTRUCTIONS

1. Tap ☰ **> Results Review.**
2. Do one of the following:
   – To review test results for a specific patient and view test details: Tap a patient result on the **Results Review** screen. Then tap the test result itself for additional details such as test date, Lot ID, and expiry date.
   – To navigate through the list of test results: Tap ▼ ▲.
   – To resend test results to the hospital information system: On the **Patient Test Results** screen, tap **Resend**. A confirmation message appears to confirm that the results are being sent.

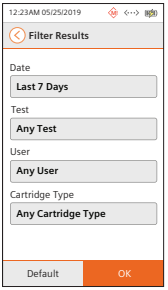


3. Tap ‹ to return to the Menu screen.

Filtering test results by date, test type, user, or cartridge type

INSTRUCTIONS

1. Tap ☰ **> Results Review > Filter**.
2. Do one of the following:
   – Tap **Date** to open the **Filter Date** screen.
   • Choose to view results for **Any Date**, **Today only**, **Last 7 Days**, or you **Specify Date Range**.



- For a specific date range, use the arrows on the **Date Selection** screen to select the date range. Tap **OK** to confirm your selection.

– Tap **Test** to choose whether you want to view all tests, patient tests, or QC tests.

– Tap **User** to select results from a specific user. Tap the user from the list, or select **Any User** to see all user results.

– Tap **Cartridge Type** to select results for a specific cartridge type. Tap a cartridge type from the list, or select **Any Cartridge** to see all cartridge results.

3. Do one of the following:

– Tap  to return to the **Results Review** screen.

– Tap **Default** to reset the filter to the factory setting.

CHAPTER 3
Performing Quality Control

About Quality Control

Quality control (QC) testing ensures that the Atellica VTLi Immunoassay Analyzer is working correctly and providing accurate results.

Refer to the quality control material package insert for proper handling and preparation instructions.

Siemens Healthineers recommends you run a quality control test:

- when you deploy a new Atellica VTLi Immunoassay Analyzer for testing
- at regular intervals determined by your hospital or laboratory regulations
- when using a new shipment of reagent cartridges or a new lot of reagent cartridges
- when an unexpected result is displayed
- when the analyzer is locked from testing due to QC lockout

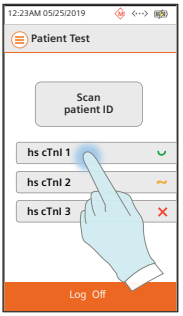
Guidelines when running a QC test

- Don't use control solution after the expiration date on the QC bottle.
- Always perform QC tests in accordance with local, state, and federal guidelines or national regulations.
- Follow the manufacturer's storage and handling instructions for quality control material. Improper storage and handling of control materials can cause erroneous results.
- QC test results are transferred to the hospital information system, if configured.

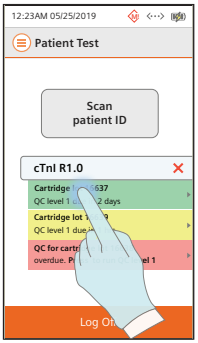
Performing a Quality Control (QC) test

INSTRUCTIONS

1. On the Home screen, tap the assay button to display the current lots.

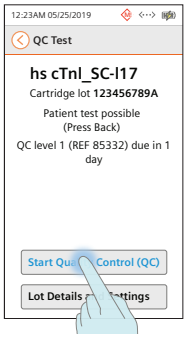


2. Tap the test lot you want to perform a QC test.



Cartridge lots are color coded for quick visual status indication. Green means lot is ready to use. Yellow means QC result for cartridge lot is about to expire. Red means a lot requires a successful QC test to be used.

3. Tap **Start Quality Control (QC)**.



4. Scan the QC vial barcode.

   The barcode contains the QC reagent lot ID and expiration date. The analyzer confirms the QC lot ID number.

   If an error occurs, tap Scan and try to read the vial barcode again.

5. When the **Insert Cartridge** screen appears, insert a cartridge from the corresponding cartridge lot.

   See *Inserting a cartridge* on page 21.

   If the cartridge is valid, the **Add Sample** screen appears.

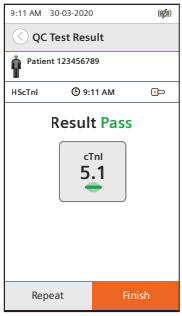
6. Add 1-2 drops of the QC sample for the level being tested.

7. Close the cartridge lid first and then the analyzer cover.

   The analyzer automatically detects the sample and begins the analysis.

   The screen displays “Analyzing” and estimated analysis time remaining.

8. After analysis, the analyzer displays the result as a quantitative value along with **Pass** or **Fail**.



9. Do one of the following:

   – Tap **Finish**.

   – Tap the **Result** tile to view the detailed test results and then tap **OK**.

10. On the **Finish** screen, do one of the following:

– Tap **OK** to accept the test results. The analyzer updates the cartridge lot locking status depending on the result and configured workflow option.

– Tap **Cancel** to not accept the test results.

11. Remove the cartridge and close the analyzer cover.

When QC guidance is turned on in the QC and Workflow settings dialog in the Service Software, failing to run an overdue QC test locks the cartridge lot, preventing patient testing on that lot only.

Working with QC Test Results

Viewing QC test results

INSTRUCTIONS

1. Tap ☰ **> Results Review.**
2. Do one of the following:
   – To review specific QC test results and view test details: Tap a QC result on the **Results Review** screen. Then tap the test result itself for additional details such as test date, Lot ID, and expiry date.
   – To navigate through the list of test results: Tap ▼ ▲.
3. Tap ‹ to return to the Menu screen.

Filtering test results by date, test type, user, or cartridge type

INSTRUCTIONS

1. Tap ☰ **> Results Review > Filter**.
2. Do one of the following:
   – Tap **Date** to open the **Filter Date** screen.
   • Choose to view results for **Any Date**, **Today only**, **Last 7 Days**, or you **Specify Date Range**.
   • For a specific date range, use the arrows on the **Date Selection** screen to select the date range. Tap **OK** to confirm your selection.
   – Tap **Test** to choose whether you want to view all tests, patient tests, or QC tests.
   – Tap **User** to select results from a specific user. Tap the user from the list, or select **Any User** to see all user results.
   – Tap **Cartridge Type** to select results for a specific cartridge type. Tap a cartridge type from the list, or select **Any Cartridge** to see all cartridge results.
3. Do one of the following:
   – Tap ‹ to return to the **Results Review** screen.
   – Tap **Default** to reset the filter to the factory setting.

Adding new QC lots

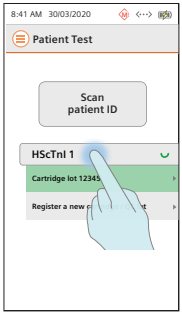
Once a new QC lot is registered, it can be released for use by performing a QC test on the analyzer.

Registering a new lot can be done by an Admin on the analyzer or by using the Service Software. Refer to the *Atellica VTLi Advanced User Guide* for details on using the Service Software.

INSTRUCTIONS

ⓘ Unless the lot is registered with the Service Software, only an Admin user can perform the procedure below.

1. On the **Home** screen, tap the assay button to display the current lots.
2. Tap the lot you want and then tap **Register a new cartridge/QC lot**.



3. Tap **Start Quality Control (QC)**.
4. Scan the QC vial barcode.

   The barcode contains the QC reagent lot ID and expiration date. The analyzer confirms the QC lot ID number.
5. Confirm the lot and level information and then tap **Scan**.

ⓘ Refer to the Instructions for Use included with the quality controls for the lot acceptance

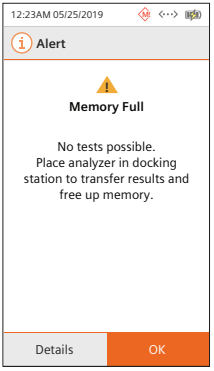
6. Follow steps 4 - 11 on page 29.

ⓘ If the Lot Management feature is enabled in the Service Software, the new registered QC lot is available for other analyzers in a group after synchronization.

CHAPTER 4
Troubleshooting and Maintenance

Analyzer messages and troubleshooting

The Atellica VTLi Immunoassay Analyzer displays messages to let you know of issues or errors. Messages typically explain the event, provide possible causes, and offer possible solutions.



An error code also displays on the screen.

For a complete listing of errors, see Appendix D.

Icon	Description
	Indicates a problem is detected but you can continue using the analyzer.
	Indicates a problem is detected that needs correction before continuing.

Some screens have a **Details** button you tap to get additional information on the issue.

General Troubleshooting

The following table describes some possible situations you might face and gives actions you can take to solve the problem.

Issue	You can...
Analyzer doesn't switch on.	Dock the analyzer in the docking station. Make sure the docking station is connected to a power supply. If the analyzer still won't switch on after docking, press the Reset button. Allow the analyzer to charge for a minimum of 2 hours and try to power on again.
Analyzer does not respond.	• Press the Reset button. • Check the analyzer battery for proper installation and connection. If necessary, replace the battery. • If the analyzer doesn't respond after charging, call your local administrator for assistance.

Issue	You can...
Analyzer does not connect to WLAN	• Ensure the analyzer is within range • If you manually enter an SSID, check if the correct SSID and a valid Password are entered. • Ensure the connected network matches with the supported security types as listed in *Appendix A Specifications*.
Results do not transfer from the analyzer to the hospital information system	• Verify that the analyzer is properly docked. • Verify that the Ethernet cable between the docking station and the LAN network is properly connected. • Check the connectivity status icon and details. If results still do not transfer, there may be a problem with the hospital network, or the analyzer. Call your local administrator for assistance.

Maintenance

General warnings and cautions

– If liquid spills inside the equipment or the product is immersed in liquid, do not operate the equipment before it has been tested and approved for further use.

– Disconnect the docking station from the power supply before cleaning and disinfection to prevent electric shocks.

– Strictly follow cleaning and disinfection guidelines to ensure that patients and users are not exposed to infections.

– Warranty does not cover damage caused by using unapproved substances or methods.

– Siemens Healthineers makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. See local regulations for further guidance.

– Never allow water or other liquids to enter the product, since these may cause electrical short-circuits or metal corrosion.

– Do not use colored detergents because they can leave lasting stains on the equipment surfaces.

– Always remove the analyzer from the docking station before cleaning and disinfection to prevent damage.

– Do not allow liquid to enter the analyzer or docking station.

– Do not immerse any part of the equipment or any accessories in liquid.

– Do not pour or spray liquid onto the system.

– Never use abrasive material (such as steel wool or silver polish).

– Keep your analyzer, docking station, associated cables, and any accessories free of dust and dirt.

– After cleaning and disinfection, check the equipment carefully. Do not use if you see signs of deterioration or damage.

Cleaning and disinfection

Cleaning and disinfection of this product is required periodically. Use only approved substances and methods listed in this chapter to clean or disinfect your equipment.

ⓘ Follow any local policies that apply within your hospital and country.

Cleaning and disinfecting the Atellica VLTi Immunoassay Analyzer

The analyzer does not require any special maintenance or extensive cleaning procedures, but disinfecting the entire exterior surface of the analyzer (including the touch screen and cartridge insertion area) is required after every test.

⚠ You must disinfect the analyzer after every test.

Siemens Healthineers tested and recommends Purell® Surface Disinfection wipes (EPA registration 84150-1) for cleaning and disinfecting the analyzer and docking station. See Appendix A for a list of recommended active ingredients.

⚠ Follow the recommended disinfecting instructions, contact times, and appropriate protection wear as indicated in the Purell Surface Disinfection wipes instructions for use.

Siemens Healthineers has tested cleaning and disinfecting the Atellica VTLi Analyzer and docking station using Purell Surface Disinfection wipes.

ⓘ Contact your local purchasing agent on how to buy Purell Surface Disinfection wipes.

⚠ **Caution**

- Always follow the cleaning instructions in this guide or damage to the analyzer can occur.
- Avoid using non-supported cleaning agents to clean and disinfect because they might damage the analyzer.
- Do not expose any analyzer or docking station electrical contacts to cleaning solutions. If that happens, the electrical contacts must be dry before docking the analyzer.
- Do not submerse the analyzer or docking station into any liquid as it could damage the system.
- Do not allow fluids to collect near the cartridge loading area or it could damage the system.
- Do not let fluids enter the analyzer hinge areas or it could damage the system.
- Do not apply liquids directly onto the internal or external areas of the analyzer or docking station.
- Do not attempt to clean the analyzer cartridge loading slot.
- Do not clean disposable cartridges.
- Do not sterilize or autoclave the analyzer or docking station.

Cleaning the analyzer and docking station

Siemens Healthineers recommends you disinfect the analyzer after every patient test. If visible blood or other contamination is observed, clean the surface with a recommended cleaning and disinfection wipe, prior to disinfecting. Discard the cleaning wipe and use a fresh wipe to disinfect.

Siemens Healthineers recommends to clean and disinfect the docking station if visible blood or other contamination is observed on the docking station surfaces, and after a soiled analyzer is placed on the docking station.

ⓘ Always follow your local cleaning and decontamination policies and procedures.

INSTRUCTIONS

1. Switch off the analyzer or remove the docking station from the power supply.
2. While wearing gloves, clean the surface of the analyzer or docking station, by wiping using a Siemens Healthineers recommended disinfection and cleaning wipe. Gently rub areas of dried blood with one or more wipes, until they are soft enough to remove.

   ⓘ Make sure the disinfection and cleaning wipe is damp, but not dripping.

   ⓘ Don't get cleaning liquid in the analyzer cartridge loading slot or hinges, or the charging ports of the docking station and analyzer.
3. Dispose of the used wipe in accordance with your local biohazard policies and procedures.

Disinfecting the analyzer and docking station

INSTRUCTIONS

1. Switch off the analyzer or remove the docking station from the power supply.
2. While wearing gloves, wipe the surface of the analyzer ,or docking station, using a Siemens Healthineers recommended disinfection and cleaning wipe, until wet.

   ⓘ Make sure the disinfection wipe is damp, but not dripping.

   ⓘ Don't get cleaning liquid in the analyzer cartridge loading slot or hinges, or the charging ports of the docking station and analyzer.
3. Allow the surfaces to remain wet for 30 seconds contact time, as listed by the wipes manufacturer.
4. Wipe dry with a clean cloth. A water rinse is not required.
5. Dispose of the used wipe in accordance with your local biohazard policies and procedures.

⚠ The 30 seconds contact time is listed on the EPA List N (COVID-19 disinfectant) and EPA List D (Effective Against Human HIV-1 and Hepatitis B Virus). Refer to the manufacturers instructions for the appropriate contact time for the removal of other microorganisms.

Battery care

If the docking station is not connected to the main AC power supply, the analyzer battery will drain when the analyzer is docked.

As a best practice, you should charge the batteries at least every six months.

During long periods of storage, remove the battery from the analyzer. In storage, the battery will drain over time. A full battery will drain completely in 18 months. Damage to the battery may result if it drains entirely.

ⓘ Store the battery in a well ventilated, dry, and cool location.

⚠ Do not store the battery in direct sun or locations where it's exposed to rain or moisture.

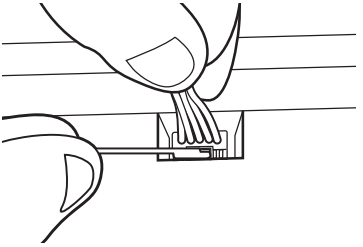
ⓘ Store battery in its original packaging.

Replacing the Atellica VLTi Immunoassay Analyzer battery

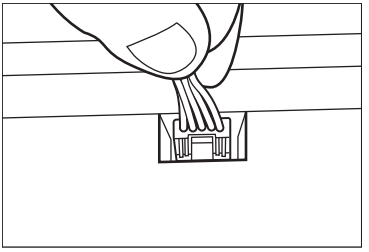
For continued optimal operation, the battery must be replaced when its capacity is reduced.

INSTRUCTIONS

1. On the back of the analyzer, locate the small screw holding the battery cover in place.
2. Use the torx screwdriver to remove the screw completely and set it aside.
3. Slide the cover upward to remove it from the analyzer.
4. Gently pull the battery from the battery compartment. Wires still connect the battery and the analyzer.
5. Using the screwdriver, gently press the wire connector release to disconnect it from the analyzer.



6. Pull gently on the wires and remove the connector from the analyzer.
7. Remove the new battery from its packaging.
8. Insert the battery plastic wire connector into the analyzer. You should hear or feel it snap into place.
9. Fit the new battery into the battery compartment.



10. Position the wires before reattaching the cover.

⚠ Ensure that the wires are not crimped and will not interfere with reattaching the battery cover.

11. Slide the battery cover back into place on the analyzer.
12. Reinsert and gently tighten the battery cover screw.

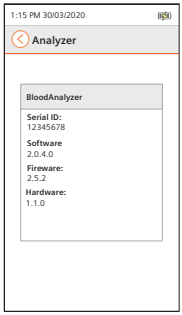
Dispose the battery according to local laws and regulations.

Displaying analyzer information

You can view the current serial number and firmware versions for the analyzer.

INSTRUCTIONS

1. Tap ☰ **> Analyzer Info.**



2. Tap ‹ to return to the Menu screen.

Viewing Connectivity settings

You can view the current IP information, WiFi network, middleware, and service software settings for the analyzer.

ⓘ Only Admin users can change these settings. Refer to the *Atellica VTLi Advanced User Guide* for details.

INSTRUCTIONS

1. Tap ☰ **> Connectivity Settings.**

2. Tap one of the options to view the current settings for the analyzer.
3. Tap ‹ to return to the Connectivity Settings screen.
4. Tap ‹ to return to the Menu screen.

Orderable Supplies

ⓘ Part numbers subject to change without notice.

Part Number	Description
11562209	Atellica VTLi Analyzer Starter Kit (US)
11555604	Atellica VTLi Immunoassay Analyzer Power Adapters
11555593	Atellica VTLi Immunoassay Analyzer analyzer cap
11556490	Atellica VTLi Immunoassay Analyzer docking station
11555590	Atellica VTLi Immunoassay Analyzer analyzer battery
11555594	Atellica VTLi Immunoassay Analyzer Battery Cover
11555592	Atellica VTLi Immunoassay Analyzer Service Software (USB)
11555609	Atellica VTLi hs-cTnI Test Cartridges (24 count)
11555717	SERO Pathonorm™ Cardiac Acute Liq L-1 (Liquid QC)
11555718	SERO Pathonorm™ Cardiac Acute Liq L-2 (Liquid QC)
11555719	SERO Pathonorm™ Cardiac Acute Liq L-3 (Liquid QC)
11555895	Minivette® POCT Capillary Transfer Device
11555893	Smearsafe™ Whole Blood Dispenser
11555894	Unistik® 3 Extra Lancet
11556042	QC Dropper Tips

Non-Orderable Items

Atellica VTLi Immunoassay Analyzer kit
Atellica VTLi Immunoassay Analyzer (11643345)
Atellica VTLi Immunoassay Analyzer Docking Station (11643347)

APPENDIX A
Specifications

Technical Specifications

This section summarizes the design specifications for the Atellica VTLi Immunoassay Analyzer and docking station.

Specifications	
Analyzer Length	25cm
Analyzer Height	approximately 5.2cm
Analyzer Width	8.5cm
Analyzer Weight (with battery)	approximately 780g
Analyzer Weight (without battery)	approximately 580g
Display	Color LCD touch screen with back light Size: 4.3 in.
Docking station Length	29cm
Docking station Height	approximately 6cm
Docking station Width	10cm
Docking station Weight	approximately 460g
Docking station Power supply	Input: 100–240 V AC, 50-60 Hz, 660 mA Output: 19 V DC, 1570 mA Classification: Class II
Analyzer tests per battery cycle	Approximately 60 tests on a fully charged battery
Analyzer internal protection rating	IP 20
Analyzer memory	(typically) 100 tests
WLAN Security Types	WPA-Personal, WPA2-Personal
Operating Temperature	5 °C to 27 °C
Operating Humidity	20 % to 80 % (non-condensing)
Air Pressure	70 to 110 kPa
Storage Temperature	-20 °C to 55 °C
Storage Humidity	5 % to 85 % (non-condensing)
Design Life	At least 10,000 cleaning and disinfection wipes
Cleaning & disinfecting wipes active ingredients	**RECOMMENDED**: Purell® Surface Disinfection wipes (EPA registration 84150-1) 20% Ethyl alcohol [(CAS: 64-17-5)] **NOT RECOMMENDED:** Healthcare bleach products as they can have corrosive properties. Healthcare Peroxide products containing additives that can affect the system labels.

Electromagnetic Compatibility (EMC)

This product complies with relevant international and national laws and standards on EMC (electromagnetic compatibility) for this type of product when used as intended. Such laws and standards define both the permissible electromagnetic emission levels from the product and its required immunity to electromagnetic interference from external sources.

Other electronic products exceeding the limits defined in such EMC standards could, under unusual circumstances, affect the operation of the product.

Medical electrical products need special precautions regarding EMC, and need to be installed and put into service according to EMC information provided in the accompanying documents.

The use of accessories and cables other than those specified, may result in increased emission or decreased immunity levels.

The product should not be used adjacent to or stacked with other products and that if adjacent or stacked use is necessary, it should be observed to verify normal operation.

Declaration of compliance

This device complies with United States FCC part 15 Rules and Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:

(1) this device may not cause interference, and

(2) this device must accept any interference, including interference that may cause undesired operation of the device.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Portable and mobile RF communications can affect medical electrical equipment. Use caution when using such communication devices within the specified range of medical electrical devices.

IT Security

See the product's Security White Paper and MDS2 for additional information about specifications for software, hardware, network characteristics, and security controls. This technical information is not part of the operator guide, and is intended for the information technology or security professional. Security White Paper and MDS2 can be found at siemens-healthineers.com/poc or contact your local technical service provider.

Disposal of the Analyzer

The instrument must be treated as biological contaminated hazardous waste. Proper disposal of old instruments (including its plastic parts, electrical components) prevents potential negative consequences for the environment and human health. All electrical and electronic products and other components of the analyzer should be disposed of separately from the municipal waste system. Final disposal must be organized in a way that does not endanger waste handlers. As a rule, such equipment must be sterile before it is passed for final disposal. For more information about disposal of such product, please contact your city office, waste disposal service, or your local safety officer.

Technical Assistance

For customer support, please contact your local technical support provider or distributor. siemens-healthineers.com/poc

Training

This guide describes the proper use and operation of the system. System operators and administrators should familiarize themselves with the applicable sections in the manual prior to conducting testing to assure safe and effective use of the system. As training requirements for this device vary by country and region, make sure you follow any training in accordance with local, federal, or country laws and regulations. If you require further information about training in the use of this product, contact your local Siemens Healthineers representative.

APPENDIX B
Symbols and Glossary

Symbols

This section describes the symbols that can display in the Atellica VTLi Immunoassay Analyzer documentation, on the analyzer, or the device packaging and labeling.

The symbols on the analyzer provide you with the location of certain components, with warnings for proper operation. The symbols on the packaging and labeling provide you with other important information.

Symbols			
	Indicates to not reuse the product.		Indicates that the product complies with the applicable directives of the European Union
	Indicates that you should consult instructions for use.		The name and location of the product manufacturer.
	This symbol is used for both Warnings and Cautions. A Warning indicates the risk of personal injury or loss of life if operating procedures and practices are not correctly followed. A Caution indicates the possibility of loss of data or damage to or destruction of equipment if operating procedures and practices are not strictly observed.		Indicates the use by or expiration date.
	Indicates useful product information.		The orderable material number of a part or product. This symbol indicates the revision letter of a part or product.
	This symbol alerts you to a potential biohazard.		Indicates an item can be recycled.
	Indicates an in vitro diagnostic device or an in vitro diagnostic medical device.		Keep the product dry.
	Indicates that the product has a temperature limitation.		Observe precautions for handling electrostatic sensitive devices.
	Indicates that the product has a humidity limitation.		Indicates to follow the appropriate procedures for disposal of electrical and electronic equipment.
	Identifies that this electronic information product does not contain any toxic or hazardous substances or elements, and is green and environmental. This system can be recycled after being discarded, and should not be casually discarded.		Product is fragile and you need to handle it with care.

Symbols			
LOT LOT	Product batch code.		Indicates that the instrument is safety tested by TUV SUD, a national certification body, for conformity to global markets, including Canada, US, and EU.

Glossary

Term	Description
analyzer	The analyzer is a handheld point of care device that receives a reagent cartridge and performs a test on a sample. It is intended for use in medical care settings.
application	A test or group of tests running on the system.
cartridge	The cartridge, constructed primarily from plastic components, has no moving parts or embedded electronics. The sample must be added to the cartridge after the cartridge has been inserted into the analyzer. The cartridge is disposable and can only be used once. Different cartridges are available to perform specific tests.
docking station	The analyzer can be docked in the docking station to charge the battery and to transfer anonymized service-related data to the service software. A single docking station can support multiple analyzers.
Magnotech	Magnotech is a biosensor technology that uses magnetic particles to measure picomolar concentrations of target substances in the sample.
middleware	Software that enables communication between the analyzer(s) and the hospital information system as well as monitoring of analyzer performance.
plasma	The fluid portion of the blood in which cells are suspended
self test	The analyzer starts and performs a self test to ensure correct operation. An error message will appear on the screen if the self- test detects that the analyzer is not functioning properly.
Service Software	The Service Software allows you to manage and configure one or more analyzers and exchange anonymized service-related data.

Abbreviations

Term	Description
CT	Consistent time integration profile
DHCP	Dynamic Host Configuration Protocol
DNS	Domain Name System
EMC	Electromagnetic compatibility
EMF	Electromagnetic fields
ESD	Electrostatic discharge
HIS	Hospital information system
IFU	Instructions for Use
IP	Internet protocol
IVD	*In vitro* diagnostic
LIS	Laboratory information system
NTP	Network time protocol
OS	Operating system
PC	Personal computer
PIN	Personal identification number
POC	Point of care
QRC	Quick reference card
RF	Radio frequency
RFID	Radio frequency identification
VPN	Virtual private network

APPENDIX C
Theory of Operations

Overview

The Atellica VTLi Immunoassay Analyzer is a portable instrument for patient-side immunoassay testing in combination with Atellica VTLi Reagent Cartridges. The main test functions of the analyzer are:

- Mechanical alignment of inserted cartridges
- Read test information from the inserted cartridge (via RFID technology)
- Detect application of sample to the cartridge filter
- Detect loading of the sample into the cartridge (i.e., filling of the reaction chambers)
- Maintain the temperature of the cartridge at 37°C (where applicable)
- Control the movement of magnetic particles within the cartridge using an electromagnetic system to bind analytes and particles to the detection surface within the assay cartridge
- Measurement of optical signals at the detection surface
- Calculate concentrations of analytes from raw signal data
- Perform data validity checks on measurement data
- Display test results with numerical values (where applicable)
- Maintain internal clock and calendar
- Store all test records, including quality control data

Analyzer

The Atellica VTLi Immunoassay Analyzer includes the major components described below.

- **Single board computer:** Manages all functions of the analyzer. It runs the embedded application software controlling the analyzer user interface and workflow. It provides memory storage for at least 100 patient test and QC test results and contains an antenna for WLAN connectivity.
- **Real-time data processing unit:** Consisting of an ARM processor and FPGA for the real-time test functionality such as the magnetic actuation of the electromagnets and the optical detection via the CMOS camera.
- **Optical mechanical unit:** Integrates the optical, electromagnets, mechanical alignment components, and the temperature control units.
- **Barcode scanner:** Used for patient, Quality control, and user identification.
- **Touchscreen:** Displays information to the user for testing, results review and device configuration. The touchscreen displays date and time, backed up by a coin battery and display. Also device connection status and memory are shown.
- **Battery:** The analyzer contains, a replaceable Lithium-ion battery pack to enable instrument portability. A full battery can be used for at least 60 tests.
- **Docking station:** Used for analyzer battery charging, wired LAN connectivity and analyzer cooling.

Analyzer VTLi Service Software

The Atellica VTLi Service Software facilitates the installation, configuring, monitoring, and updating of the Atellica VTLi Immunoassay Analyzer. The Service Software is installed on a Windows-based computer, server, or virtual machine on the same network as the analyzer.

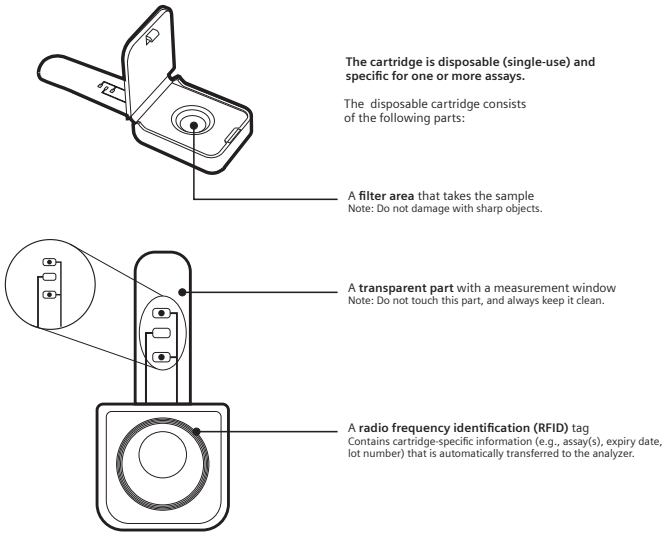
The Service Software consists of a server and one or more client installations to access the server, and connects one or more analyzers installed on the network. The Service Software can be accessed via the client and used to configure analyzer group settings. Analyzers can be assigned to user defined analyzer groups to synchronize common settings. In case of analyzer software updates, the Service Software is used to load software updates and apply

the updates to analyzer groups. The Service Software performs security and data integrity checks to ensure valid software updates are applied to the analyzers.

Reagent Cartridge

The Atellica VTLi Reagent Cartridge includes the following major components:

- **Molded plastic basepart** with microfluidic features: fluid channels, reaction chambers, fluidic stops, air channels. The fluid channels contain a hydrophilization layer The reaction chambers contain dried functionalized spots of antibodies and other reagents for the analyte to be tested. The basepart contains optical windows to interface with the analyzer optical system and thermal ribs to enable a constant cartridge temperature.
- **Plastic laminate foil** which seals the plastic basepart and holds the dried magnetic particles within the basepart reaction chambers.
- **Plastic molded blood-housing** with a closing lid, containing the filter where the sample is applied, and the radio frequency identification (RFID) tag.
- **Filter**, which is a blood-plasma separation membrane, that receives the sample fluid for the test
- **Radio frequency identification (RFID) tag**, containing cartridge information such as test type, lot information, expiry date, calibration information
- **Cartridge pouch**. The cartridge is stored in a labeled pouch containing desiccant to keep the cartridge dry and stable when stored.

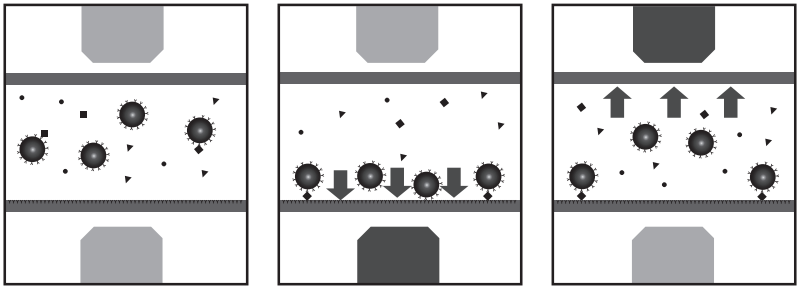


Measurement principle

The Atellica VTLi Immunoassay Analyzer uses Magnotech® technology. Magnotech is a biosensor technology that uses magnetic particles to measure picomolar concentrations of analytes in the sample in a matter of minutes.

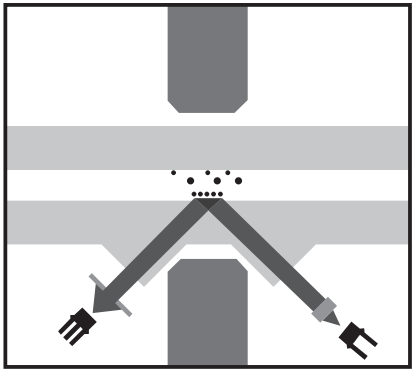
For a test, the analyzer uses a cartridge containing all the necessary analyte-specific reagents in dried format, including the magnetic particles. The cartridge is disposable and can only be used once. When the cartridge is inserted in the analyzer, the cartridge fills automatically after applying a few droplets of the sample. Once filled, no other fluid movement is required. As the reaction chambers within the cartridge fill with sample, the dried magnetic particles are dispersed in the sample fluid.

The entire test process within the cartridge is executed by controlled movement of the magnetic particles within the cartridge using magnetic fields generated by the analyzer. The magnetic particles are coated with appropriate ligand molecules to allow binding to the analyte molecules in the sample.



The analyte molecules which are captured by magnetic particles can then be pulled towards the detection surface of the cartridge using the electromagnets of the analyzer which are positioned below the detection surface[1]. The detection surface is also coated with ligand molecules which can bind to the captured analyte molecules on the magnetic particles. In this way, magnetic particles bind to the detection surface, depending on the presence of analyte in the sample.

After a certain reaction time, the electromagnets above the detection surface are used to pull unbound magnetic particles away from the detection surface. A very fast and controlled separation between bound and unbound magnetic particles is thereby achieved.



In the final phase, the number of magnetic particles at the detection surface is measured using an optical technique based on frustrated total internal reflection. This optical technique uses an LED light source to direct light from the bottom-side of the cartridge to the detection surface.

The light is incident to the detection surface at an angle, such that without the presence of the magnetic particles, the light reflects at the sensor surface, i.e. total internal reflection. Total internal reflection is achieved by refractive index differences between the cartridge plastic material and the sample fluid. In the presence of magnetic particles at the sensor surface, the refractive properties at the detection surface change, and lead to incomplete internal reflection of the light, i.e. frustrated total internal reflection.

The reflected light is guided to a CMOS camera and constitutes the raw optical measurement signal used for the test. The optical system is such that an optical image of the sensor surface is created. The measured optical signal depends on the amount of frustration to the light reflecting at the detection surface due to any magnetic particles present.

As the number of magnetic particles at the detection surface depends on the analyte concentration, the optical signals can be used to calculate the analyte concentration, using calibration curve parameters provided via the cartridge RFID tag.

Internal Quality Control (IQC)

During various operating stages, the Atellica VTLi Immunoassay Analyzer performs multiple monitoring tests (in the background) used to control the quality of the system and flag non-conformities. In case of non-conformities, the analyzer reports the error or warning on the touchscreen, with any relevant error code, and guidance on next steps. In the case of non-conformities that occur during a test, additionally, the test result are marked as invalid, and a 3-digit tag code provided with a reason for the invalid result.

The analyzer performs the following internal quality control checks covering the entire testing process:

Self-test

The analyzer performs self-tests to check the main hardware and software functionality of the analyzer. Self-tests are done upon instrument activation (i.e. turn on, or wake up from deep sleep-mode), and repeated every 24 hours or 20 tests. The self-test consists of checking the battery level, reboot needs, database consistency, memory storage for user data, and tilt sensor calibration (the latter only when the analyzer is docked in the docking station). Additionally, during a self-test the measurement board is powered on and a hardware self-test is executed, i.e. checking the electronics, imaging (including camera), magnetic, and temperature control system.

Test initialization tests

During test initialization the analyzer performs a check on analyzer readiness for testing, as well as a check on the test information retrieved from the cartridge RFID tag. The analyzer readiness checks include checks on software version, memory space, battery level, electronics system, imaging system, magnetic system, temperature control system and analyzer orientation. Using the cartridge RFID information, which is obtained after inserting the cartridge, checks are performed on RFID version and data validity, cartridge type compatibility with analyzer configuration, and expiry date. On the inserted cartridge, the analyzer will also check cartridge position alignment, optical image quality (e.g. pollution), and cartridge filter state (i.e. no sample added yet).

Tests during sample measurement

When a test is successfully initialized, the analyzer will enable the start of the test upon sample application to the cartridge filter. The analyzer provides a 15 minute time-window to apply sample to the cartridge, before aborting the test and invalidating the cartridge to prevent any degradation of the unpacked cartridge.

A sample detector located below the cartridge blood-housing (when the cartridge is inserted in the analyzer) will detect the application of the sample to the cartridge filter and enable the

analyzer to start the test procedure. When sample is detected, the analyzer instructs the user to close the analyzer cap to prevent touching the inserted cartridge during the test.

The cartridge will fill with fluid, and the analyzer limits the cartridge filling time to 3 minutes. If the cartridge did not fill within this time (e.g., low sample volume), the analyzer cancels the test and invalidates the cartridge. Filling of the cartridge is detected by the analyzer using the processing of the images of the reaction chambers.

Once the reaction chambers fill with fluid and this is verified, the analyzer starts the assay procedure (i.e., the magnetic actuation protocol).

Through-out the assay procedure, the analyzer monitors the cartridge temperature, the analyzer orientation and movement, and the position of the analyzer cap.

At the start, halfway, and end points of the assay procedure, the analyzer takes optical images of the detection surface to enable checks on cartridge position, light intensity, and signal homogeneity.

At the halfway point of the assay procedure, before magnetic particles are pulled to the detection surface, the optical signal is measured, which serves as a calibration of the optical system to determine changes to the reflected light.

During the assay procedure, optical signals are measured inside and outside the assay spots. Too large deviations in signals (e.g., within spots) outside the spots and between spots are detected during result calculation and lead to test result invalidation.

Lastly all process steps are logged by the embedded application software and stored in service data packages which are sent for storage to the Atellica VTLi Service Software.

Analyzer calibration

The analyzer does not need any calibration procedures to be performed to enable cartridge tests.

Each cartridge contains on its RFID tag fit parameters corresponding to the dose-response curve calibrated at cartridge manufacturing site, as well as the expiry date of the cartridge. The expiry data of the cartridge is determined by the shelf-life of the cartridge during which the fit parameters are still valid.

The analyzer contains internal calibration procedures to calibrate the optical system during each test to ensure an accurate measurement of the change in reflected light at the detection surface.

The internal quality control checks ensure any device instability is detected and prevents test result outcomes in these cases.

Quality Control (QC) testing

The Atellica VTLi Immunoassay Analyzer supports QC testing using QC samples on reagent cartridges for each test application. QC tests, as recommended by the manufacturer for each test application, can be run in a dedicated QC workflow on the analyzer. QC tests using other QC liquids may be performed using the regular testing workflow on the analyzer.

In QC liquids that are not recommended by Siemens Healthineers, tests may fail due to matrix effects. The QC workflow functionality on the analyzer can be configured using the Service Software to provide additional guidance for QC testing, and to set required QC testing intervals and time-warnings when QC testing becomes due.

APPENDIX D
Error Codes

Listing of Error Codes

Patient Test Results	
Error Number	**Description**
150	Unexpected failure during test. Test failed.
350	Cartridge protocol invalid.
450	Analyzer cover not closed in time.
455	Sample was not added to cartridge within required time.
451	Temperature controller error.
452	Sample detector error.
453	Cartridge reader error.
454	Cartridge not recognized.
550	Unexpected failure during test. Test failed.
551	Analyzer cover opened during test. Test aborted.
552	Unexpected failure during test. Test failed.
553	Unexpected failure during test. Test failed.
554	Cartridge moved during sample addition or closing of cartridge lid.
555	Cartridge moved during closing of cartridge lid.
556	Cartridge moved during test. Test aborted.
557	Cartridge removed during test. Test aborted.
558	Insufficient sample or a blockage in cartridge.
559	No result available (data processing failed).
560	No result available (temperature (°C) out of range).
561 - 562	Detection error.
563	Cartridge hardware error.
564	Power button error.
565	Cover detector error.
566	Docking station connection error.
567	Battery or charging hardware error.
568	Cartridge error.
569	Cartridge moved during test. Test aborted.
570	Too much movement or analyzer not horizontal. Test failed.
571	Tilt sensor error.
572	QC result is out of range.
573	Test performance deviation detected. Test failed.
576	Detection error.
577	Test performance deviation detected. Test failed.

Patient Test Results	
Error Number	**Description**
578	Display hardware error.
579 - 581	Cartridge error.
650	Result calculation failed. Test failed.
651 - 662	Invalid result due to signal deviation.
950	Analyzer stopped working.
951	Service access failure.

General Errors	
Error Number	**Description**
1000 - 1018	Analyzer problem.
1200	Analyzer problem.
1202	Cartridge not removed or inserted too early.
1203	Analyzer not horizontal during self-test.
1400 - 1401	System update failed.
1402	Update failure due to too low battery level. Charge the battery and retry the update.
1403	Data Migration Failure
1600	Battery level too low for test. Dock the analyzer to charge the battery to about at least 15% and retry.
1601	The cartridge information for the cartridge/lot is corrupt. If the problem persists, the analyzer needs servicing. Contact your administrator or technical support representative.
1602	Firmware update required to read cartridge.
1603	Cartridge could not be read. Retry with another cartridge. If the problem persists, contact your administrator or technical support representative.
1604	Expired cartridge used.
1605	Cartridge already used.
1606	Cartridge could not be read by analyzer. Ensure the cartridge protocol for the test indicated on the cartridge pouch is installed on the analyzer.
1607	Incorrect cartridge type tested.
1608	Cartridge protocol failed to load.
1609	Sample added too early.

General Errors	
Error Number	**Description**
1610	Cartridge detection error. Possible causes are cartridge handling (touching transparent part, incorrect cartridge insertion), or the analyzer needs to be cleaned. If the problem persists, contact the your administrator or technical support representative.
1611	User removed cartridge during test
1612	Battery not charged in time.
1613	Cartridge failure.
1614	Initial cartridge insertion not correct.
1615	Cartridge lot not released for testing.
1616	Failed QC locked analyzer.
1617	QC not tested in time.
1618	Incorrect cartridge lot tested.
1619	Cartridge or QC lot is already registered.
1620	Cartridge lot already exists for another test. If the problem persists, contact your administrator or technical support representative.
1800	Sample not added in time.
1801	Sample added too early.
1802	Analyzer cover not closed in time.
1803	RFID incorrectly programmed.
1804 - 1805	Sample added too early.
2000	Analyzer cover opened during test.
2001 - 2002	Cartridge failure or handling error.
2003	Cartridge moved during measurement.
2004	Cartridge failure or handling error.
2005	Non filling cartridge/ Not enough sample.
2006 - 2007	Analyzer problem.
2008	Temperature out of range.
2009	Cartridge failure or handling error.
2010	Cartridge moved during measurement.
2011	Analyzer tilted out of range during test.
2012	Analyzer problem.
2015	Analyzer problem.
2016 - 2017	Cartridge error.
2200	Result is invalid.
2700	Analyzer not docked when requested.

General Errors	
Error Number	**Description**
2701	Hiding the only remaining cartridge lot is not allowed. Active a new lot first.
4001 - 4002	Incompatible barcode scanned
4051	No users have been send by SSW or MW.
4052	Invalid access code.
4053	Account not activated in SSW or MW.
4054	Expiration data in SSW or MW past.
4055	Training overdue in MW.
4056	Wrong password used.
4057	Wrong user permission.
4103 - 4104	Incompatible barcode scanned.
4105 - 4106	Incorrect QC sample.
4107 - 4108	System failure.
4109	Expired QC sample.
4110	Unknown QC lot .
4111	Incompatible barcode scanned.
4112 - 4114	Incorrect QC sample.
4115	Wrong QC barcode scanned. Scan the barcode from the QC vial.
4116	QC acceptance limits were not entered in Service Software or Middleware.
4117	The scanned barcode does not match the scanned barcode from the QC vial.
4118	Wrong barcode scanned. QC vial was scanned. Locate the barcode containing the QC acceptance limits; see the QC package insert.
4119	Product type/Lot ID do not match. Either a QC lot ID is registered as a cartridge lot, or a cartridge lot ID as a QC lot. Use the Service Software (or Middleware) to correct the lot registration.
9000	Fatal system problem.
9001 - 9003	System failure.
9004	Analyzer problem.
9005	Anonimise function used in SSW. Analyzer needs service.
9006	System failure.

Communication Errors	
Error Number	**Description**
1201	Memory storage full - memory can be freed by uploading results to Middleware or modifying the data overwriting setting in the Service Software.
2400	Memory low. Upload results to Middleware to free up space, or change memory settings in Service Software.
2600	Network error. Failed to communicate with Middleware.
2650	Network error. Failed to communicate with Service Software.
2699	Communications error.
4150 - 4153	HHA configuration changes in network settings.
4154 - 4157	HHA SSW configuration changes in settings.
4158	Analyzer Settings: Change WiFi Connection
4159	WiFi Settings: Invalid Ssid
4160	WiFi Settings: Invalid Security Type
4161	WiFi Settings: Invalid Encryption Type
4162	WiFi Settings: Invalid Password

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