BD Elience™ POC instrument front view

No.	Description
1	Sliding lid
2	LED status bar
3	Power button
4	USB port
5	Touch screen
6	Cartridge insertion port and heater port

BD Elience™ POC instrument back view

No.	Description
1	Sliding lid
2	DC power supply port
3	Service port - reserved for BD use only
4	Ethernet network port
5	Three USB accessory ports (printer, barcode scanner)
6	Mini USB port - reserved for BD use only
7	Cap detection sensor

2.2.2 Instrument specifications

Feature	Description
Cartridge Type	BD Elience™ POC instrument Cartridge
Data Storage	999 patient specimen and 999 QC test results can be stored on the instrument. Memory allows search and retrieval. Archive and export via USB.
Color Touch Screen	109.22 mm (4.3") LCD capacitive touch screen
Communications	10/100 Mbps Ethernet network connection 2.4 GHz, 5 GHz, dual-band Wi-Fi with WPA2-PSK and WPA3 Four USB 2.0 ports
Power	12 V DC from external AC/DC supplied plug pack DC Voltage fluctuation ±10% DC Current consumption: 12 V DC, 3.0 Amp Power supply adapter is configured for different regions.
Dimensions (approximate)	Width 185 mm (7.28") , Depth 200 mm (7.87") , Height 155 mm (6.10")
Weight	Approximately 2.3 kg (5.1 lb)
Operating Environment	Indoor Use 15–30 °C 20–80% RH (non-condensing) Altitude: Evaluated for safety to 2,000 m Ambient lighting: 20–5,000 LUX Installation Category II and Pollution Degree 2 per IEC 60664
Storage Environment	2–45 °C 20–80% RH (non-condensing)

12 V Power Supply

The BD Elience™ POC instrument shall be operated using only the specified and supplied AC/DC power adapter to ensure both the EMC and safety compliance of the product. This includes four plug types that fit Australia type I, UK type G, US (Europe) type A, and China type C.

Feature	Description
Rated input voltage	100–240 VAC ±10%
Rated input frequency	50/60 Hz +/-3 Hz
Rated input current	1.0 Amp maximum
Operating environment	0–40 °C 10–95% RH (non-condensing)
Storage environment	−20 °C to 70 °C 10–95% RH (non-condensing)
Output voltage	12 V DC
Output current	3.5 Amp

2.2.3 Optional accessories

The instrument supports the following accessories:

USB drive

The instrument includes four USB ports to which a USB drive can connect. The USB drive must meet the following requirements:

- FAT32-formatted
- At least 1 GB and only one partition
- Does not require proprietary software to run

A USB drive can be used to perform the following:

- Install software and assay definition updates onto the instrument
- Export test results and instrument data from the instrument

NOTE

The instrument only recognizes one USB drive at a time. Do not plug in multiple USB drives simultaneously.

Barcode scanner

The instrument accepts input from a USB-connected Datalogic QuickScan™ QD2430 barcode scanner. The barcode scanner must be configured in RS-232 over USB mode. Refer to the barcode scanner user's manual for configuration instructions. This scanner is not sold by BD and can be ordered through Datalogic.

Receipt/label printer

The BD Elience™ POC instrument supports printing test results using a USB connected printer.

The BD Elience™ POC instrument supports the following printer models:

- Epson® TM-T20III Thermal Receipt Printer
- Epson® TM-L90II LFC Thermal Label Printer
- Epson® TM-M30II POS Thermal Receipt Printer

For unpacking and setup instructions, or information about ordering replacement paper, refer to the instructions provided with the printer.

Ferrite cores

The instrument includes clip-on ferrite cores to support the optional printer and barcode scanner. Two clip-on ferrite cores and a tool for opening the clip are packaged with the instrument.

The clip is opened by pushing the key into the two open slots.

Once unlocked the housing can be opened, exposing the slot in the core where the peripheral cable can be placed.

The peripheral cable is placed in the slot and the housing is closed to lock the ferrite core on to the cable.

3 Controls and indicators

This section describes the meaning and use of the controls and indicators on the BD Elience™ POC instrument.

3.1 Power button

The instrument has a front mounted power button. After connecting power to the rear of the instrument, press the power button for 1 second to power on the instrument. To shut down the instrument, press and hold the power button for at least 3 seconds.

3.2 Audible alerts

The instrument employs an audible cue when user attention is required during a sample processing workflow. Audible alerts can be adjusted during the admin initial setup within the Start Up Wizard or from the User preferences menu.

3.3 Instrument status bar

The instrument has a front panel LED bar that indicates the instrument's status.

LED bar state	Instrument status
No light	No power; instrument powered off
White, steady	Powered on; idle, self-test, or software update in progress
White, slow flash	Starting; heaters not at temperature*
White, fast flash	Instrument heater fault*
Blue, breathing	Test workflow in progress; normal instrument operation
Green, steady	Patient specimen or QC test complete
Yellow, slow flash	Instrument warning message present
Red, fast flash	Instrument error message present
*Instrument heating/cooling and heater fault LED status override all other LED statuses except warnings and errors.	

4 Installation

4.1 Unpacking

The BD Elience™ POC instrument package contains the following:

- Instrument
- Instrument User's Manual
- 12 V power supply and region-specific power adapters
- Ferrite cores (for more information, refer to section **2.2.3 Optional accessories**)

WARNING

UNPACK THE INSTRUMENT AND SET UP ON A STABLE, LEVEL SURFACE, IN A CLEAN OFFICE OR LAB-TYPE ENVIRONMENT OUT OF DIRECT SUNLIGHT.

Set up the power supply for your region by attaching the appropriate adapter pin configuration.

Connect the 12 V power supply to the instrument.

4.2 Initial setup

After connecting the 12 V power supply, plug instrument into appropriate outlet and power on the instrument by pressing and holding the power button for approximately 1 second.

The instrument Start Up Wizard will walk the user through the instrument's basic configuration steps if this is the first time the instrument is booted following initial install or a system settings reset.

5 Admin configuration

Most admin functions are configured when using the Start Up Wizard. However, Admin settings can be changed later and additional settings configured.

Admin users have access to the same functionality as Standard users as well as access to configure the Admin settings. To access the Admin settings, navigate to the login screen and log in with the admin password. To access Admin settings when logged in as a Standard user, go to Settings. Select  , then input Admin password.

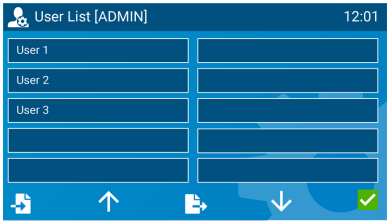
> NOTE
>
> The default password following a system reset is "admin." The user is prompted to change this password upon initial log in.

- From the home screen, select  to navigate to settings, then  to access Admin settings.
- Select  or  to navigate between the admin menu screens.
- Select  to return to the Settings screen.
- Select  to return to the Home screen.

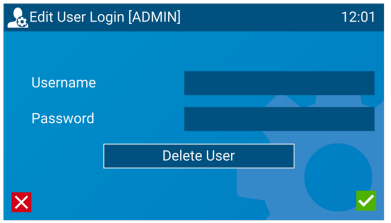
Standard User Settings	Admin User Settings
• Run patient specimen and QC tests • Review results • Print a single result • Export results to a USB drive (and optionally delete the results at completion of export if this function is enabled by an Admin) • View the instrument "About" information • Adjust the instrument audio settings • Configure the LCD screen brightness level • View the instrument legal information • View the connectivity/informatics status • Change their own password one time each day	Standard user settings plus the following: • Configure the user list • Configure login and auto logout settings • Change the Admin password • Set the clock, including time and date • Enable and disable individual assays • Change language settings • Configure LAN settings • Configure Wi-Fi settings • Export instrument log file • Configure connectivity/informatics settings • Configure Standard user export settings • Configure password expiration setting • Configure user lockout setting • Update instrument software and import assay definition files • Run a self-test to check instrument functionality • Restore the instrument to default settings

5.1 User List

1. To create or add a user to the User List, select **User List**.
2. Tap on an empty box.



3. Enter username.
4. Enter a temporary password.



5. Select ✓

On the first login, the user will input the temporary password. They will then be prompted to change to a new password.

> NOTE
>
> A maximum of 20 users can be configured.

To delete a user from the instrument:

1. Select the username in the **User List**.
2. In the Edit User Login screen, select **Delete User**.

5.2 Export User list

To export a user list from the instrument to a USB drive:

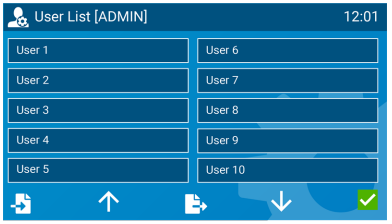
1. Select to export the user list to a USB drive.
2. Insert the USB drive into a port on the instrument and select ✓.

5.3 Import User list

A user list can be set up on one instrument, exported to a USB drive, and then loaded onto additional instruments.

To import a user list onto the instrument from a USB drive:

1. Select .

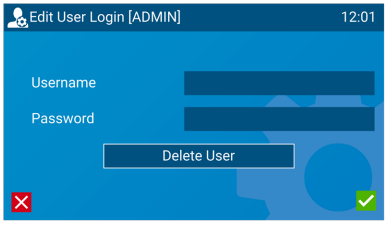


2. Insert the USB drive into a port on the instrument and select .

5.4 Change username or password

To change a username or password:

1. Select or to navigate through the User List screens.
2. Select the username in the User List.
3. In the Edit User Login screen, select the Username or Password field.
4. Edit the field by entering the new information.
5. Select to confirm your changes.



NOTE

A password must not be identical to the previous 8 passwords used by that user profile, and cannot include:

- Less than 4 characters or more than 20 characters (minimum password length required is based on Admin setting. See **5.19 Minimum Password** for details).

- Two identical characters in succession (if password length is 4 characters).

- Three identical characters in succession (if password length is greater than 4 characters).

- ASCII characters in sequential order, including reverse sequential order.

5.5 User Login

To change user login requirements, select **User Login** repeatedly to switch between the following options:

- Password: Requires username and password to log in.
- Username: Requires username only to log in.

5.6 Auto Logout

To set how long a user can remain idle before the instrument logs the user out, select **Auto Logout** repeatedly to switch between the following options:

- Never: The instrument will not auto logout.
- 5 min: Auto logout after 5 minutes of being idle.
- 10 min: Auto logout after 10 minutes of being idle.
- 30 min: Auto logout after 30 minutes of being idle.
- 60 min: Auto logout after 60 minutes of being idle.

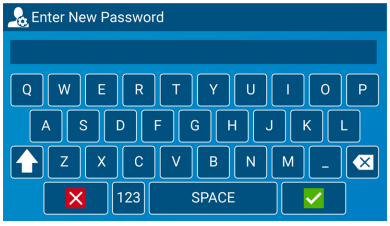
NOTE

Auto logout does not occur during a test run or active export event.

5.7 Set Admin Password

To change the admin password select **Set Admin Password**. The default password is "admin."

1. Enter a new admin password using the on-screen keyboard.
2. Select ✓ to confirm.
3. Re-enter the same new password.
4. Select ✓ to confirm.

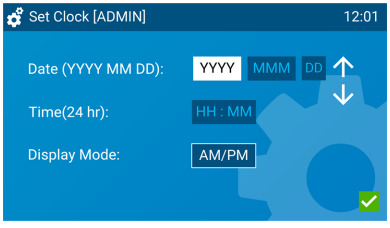


5.8 Set Clock

To change the time on the instrument select **Set Clock**:

1. Edit the Date, Time, or Display Mode.
   Select ↑ or ↓ to adjust the selected value.

   Tap the Display Mode field to select 24 hour (24 hr) or 12 hour (AM/PM) time format.
2. Select ✓ to confirm the settings.



5.9 Test List

To import assay definition files onto the instrument from a USB drive:

1. Select **Test List**.
2. Select .
3. Insert the USB drive into a port on the instrument and select .

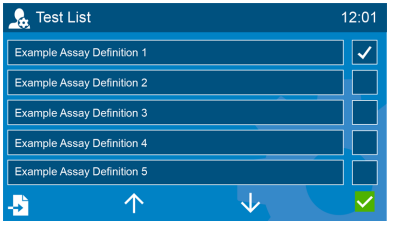
> NOTE
>
> Ensure there is only one assay definition file package available on the USB drive.
>
> Uploading a new assay definition file onto the instrument will overwrite the existing assay definition files.

To set the list of assay definition files that will be available to users:

1. Select the assay definition file(s) to appear in the Test menu.
   Select to enable or disable the assay definition file. An enabled assay definition file will be available to be run by all users.

   Select or to navigate through the Test List screens.

2. Select to confirm the setting



5.10 ID Type

To set the ID name used in the patient specimen test workflow, select **ID Type** to set one of the following options:

- Patient ID
- Accession No.

> NOTE
>
> This will change the ID names displayed for all patient specimen test workflows.

5.11 QC Method

The instrument can run QC tests with a known outcome for each assay type. When the expected result is generated, it confirms the Consumable lot, assay and instrument are working correctly.

Configuration

To set the QC Method that the instrument uses, select **Settings > QC Method** to cycle through the following options:

- Lockout: An error is displayed if the Consumable lot has not passed both positive and negative QC testing. Testing of patient specimens will be prevented.
- Warning: A warning is displayed before testing if assay QC for the lot failed or was not run. The user can proceed with testing.
- Not Required: The QC Test option is not required to perform a test.

> **CAUTION**
>
> **If QC lockout is enabled, using a Cartridge lot that has not completed QC testing will lead to a canceled run. A new patient specimen or aliquot and new test components will be required.**

5.12 Result Call

To set when the instrument reports the test results, select **Result Call** to cycle through the following options:

- Real-time: Positive or invalid test results will be displayed as soon as a result can be determined. All tests will run for the full test duration. Negative test results cannot be generated until test completion.
- End of test: Results are only displayed after the test has run to completion. The screen will display “in progress” until the test time count down completes, even if a positive result call can be made earlier. This option prevents the patient results from being displayed automatically.

> NOTE
>
> The Result Call selection will be applied to all test workflows.

5.13 Language

To set the language that the instrument uses on the touch screen and for reports:

1. Select **Language**.
2. Select the language by checking the box next to the language name.
3. Select to confirm the setting.

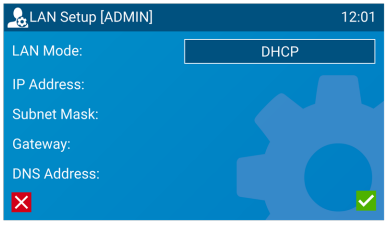
> NOTE
>
> Language change does not require the instrument to reboot to take effect.

5.14 LAN Setup

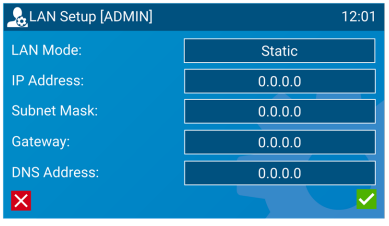
The Admin user can configure a Local Area Network (LAN) using a connected Ethernet cable on the rear port of the instrument.

To select the type of network connection, select **LAN Setup** repeatedly to toggle between one of the following options:

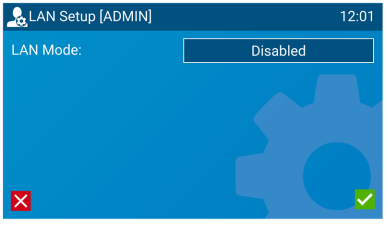
- DHCP: The network allocates the IP address and related settings for the instrument to use.



- Static: Manually set and configure all network settings. You can edit all fields on this screen.



- Disabled: Disables the network function altogether.



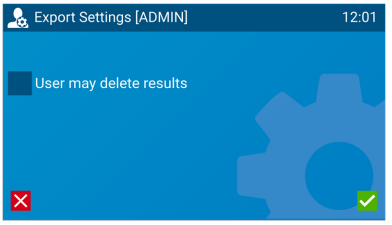
Select ✓ to confirm settings.

Select ✗ to cancel.

5.15 Export Settings

Select **Export Settings**.

To allow Standard users to delete all test results after exporting from the Results history list, select the box next to "User may delete results."



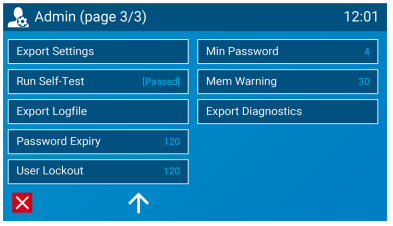
5.16 Export Logfile or Diagnostics

Select **Export Logfile** with a USB drive inserted into a USB port. This exports the instrument's log file.

The log file tracks the results of every Self-Test run, instrument details, calibration records, and other related information.

Select **Export Diagnostics** with a USB drive inserted into a USB port. This exports a file containing instrument diagnostics.

The diagnostic file tracks detailed instrument metrics collected during each test run.



The log and diagnostic files are encrypted and can only be read by a BD representative. These files are intended to be shared with BD representatives to support troubleshooting.

NOTE

See USB requirements in **2.2.3 Optional accessories** to ensure USB drive is compatible with the system.

5.17 Password Expiration

To select the number of days when the user's password will expire, select **Password Expiry** repeatedly to toggle through Standard user password expiration settings. Once a password is expired, the next time that user logs in they will be required to change their password.

- None: Standard user passwords do not expire.
- 30: Standard user passwords expire after 30 days.
- 60: Standard user passwords expire after 60 days.
- 90: Standard user passwords expire after 90 days.
- 120: Standard user passwords expire after 120 days.

5.18 User Lockout

To set how many times a Standard user can fail login and be locked out until the Admin user resets the user's password:

1. Select **User Lockout** repeatedly.
2. Select a number between 3 and 15.

5.19 Minimum Password

To set the minimum character length for a password:

1. Select **Min. Password** repeatedly.
2. Select a value of 4, 6, or 8.

NOTE

Password length is set at a maximum of 20 characters. This value cannot be changed.

5.20 Memory Warning

To set the number of tests reached before the instrument displays a memory capacity warning:

1. Select **Mem. Warning** repeatedly.
2. Select a value within the range of 5–30 tests.

If the number of test results memory capacity is equal to or less than the set value, the instrument displays a warning each time a test is run.

5.21 Restore Defaults

Restore Defaults is used to restore all the default settings. Restoring defaults will require the user to reinstall the user list and the latest assay definition files. If the QC method is set to lockout, the user will need to repeat QC controls on the reagent lot prior to running patient specimens.

Select ✓ to confirm returning to default settings.

Select ✗ to cancel.

CAUTION

Restoring defaults deletes all test results, user lists, and assay definition files, and resets LIS connectivity settings. Do not restore default unless you are prepared to reinstall assay definition files, and if necessary, run QC and reconnect the instrument to an informatics solution.

The following table shows all parameters that will be updated after restoring the default settings.

Parameter	Item	Default Setting
Settings	Touch Volume	60
	Alert Volume	80
	Brightness	80
Results	Test Results	None (all deleted)
Admin settings	User List	None (all deleted)
	User Login	Password (both username and password required)
	User Lockout	3
	Auto Logout Timer	5 minutes

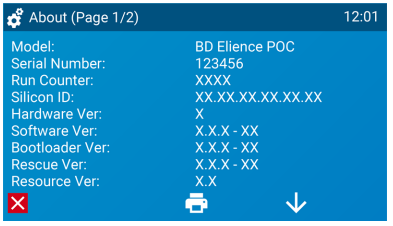
Parameter	Item	Default Setting
Admin settings (continued)	Admin Password	admin
	Assay Definitions Package	None (all deleted)
	Print Options / Printed Report Name	BD Elience
	Time	12 hour
	Language	English, US
	Network	DHCP
	LIS Settings	N/A
	QC test method	Warning
	Lot QC Status	Not run
	QC Status	None (all deleted)
	Specimen ID field terminology	Patient ID
	Export Settings, User may delete results	Disabled
	Password Expiry	120 days
	Minimum Password Length	4 Characters
	Memory Warning Threshold	30 result files remaining

6 User preferences

6.1 Viewing the instrument configuration details

The About screen displays the BD Elience™ POC instrument configuration details.

On the Home screen, select **Settings >About**.



Select or to navigate between the screens.

Select to print the information.

Select to return to the Settings screen.

6.2 Adjusting the instrument's volume

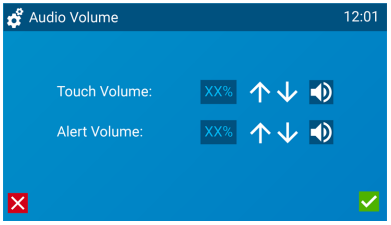
From the Home screen, select **Settings > Audio Volume**.

Select or to adjust the volume level.

Select to play a test sound.

Select to save the settings for this current session.

Select to cancel the audio settings.



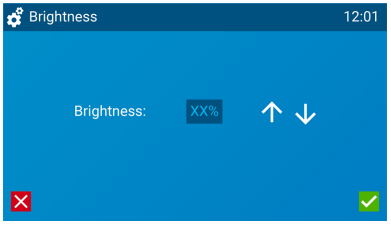
6.3 Configuring the LCD screen brightness level

From the Home screen, select **Settings > Brightness**.

Select or to adjust the LCD screen brightness.

Select to save the settings for this current session.

Select to cancel.



6.4 Displaying legal information

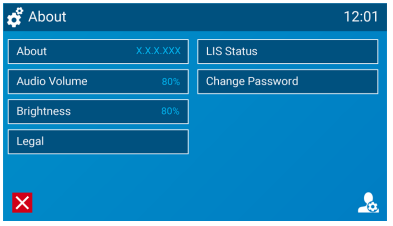
From the Home screen, select **Settings > Legal**.

The Legal screen displays the website for accessing licensing information.

6.5 Changing your password

From the Home screen, select **Settings > Change Password**.

A Standard user can change their password one time each day. The option to change the Admin password is accessible from Admin screens.



NOTE

A password must not be identical to the previous 8 passwords used by that user profile, and cannot include:

- Less than 4 characters or more than 20 characters (minimum password length required is based on Admin setting. See **5.19 Minimum Password** for details).
- Two identical characters in succession (if password length is 4 characters).
- Three identical characters in succession (if password length is greater than 4 characters).
- ASCII characters in sequential order, including reverse sequential order.

7 Operation

7.1 Power on

Ensure the BD Elience™ POC instrument is plugged into an electrical outlet, using the connected 12 V power supply adapter. Press and hold the power button for 1 second to turn on the instrument.

7.2 Self-Test

The instrument runs a self-test sequence at start up.

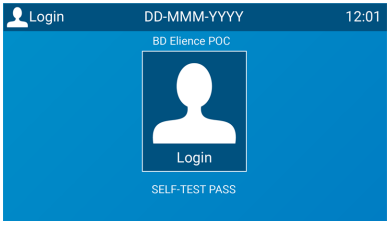
If all tests pass, the instrument displays the “User Login” screen.

If the self-test identifies a fault, the instrument displays an error screen. Select ✓ to acknowledge self-test results. See **10.3 Troubleshooting aids** Self-Test section for more information.

Some errors allow you to continue to use the instrument with limited functionality. See **10.1 Instrument service** for instructions.

7.3 User login

Select Login, then enter username and, if requested, password.



NOTE

The number of permitted login attempts is set by the Admin user. See **5 Admin configuration**. When the set number of failed login attempts is exceeded, that user will be locked out until an Admin resets the user’s password.

Test results

Select to print test result to a connected printer.

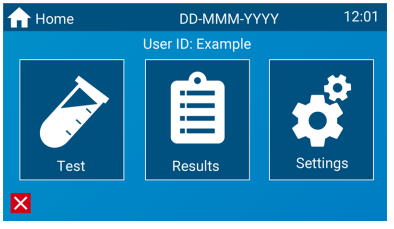
Select to export test result to a USB drive as a .csv file. See **7.8 Exporting results to a USB drive** for more details.

Select to return to the Home screen.

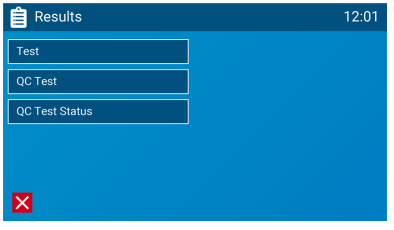
> NOTE
>
> Refer to the specific assay package insert for interpretation of results.

7.5 Reviewing and exporting results

1. On the Home screen select **Results**.



2. In the Results menu select **Test** or **QC Test** to view the saved results.

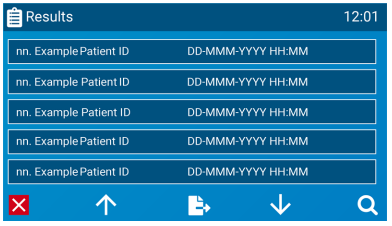


7.5.1 View results

The Results history screen displays a list of all available test results for the selected test category in order from newest to oldest.

Select  or  to navigate through the test Results history screens.

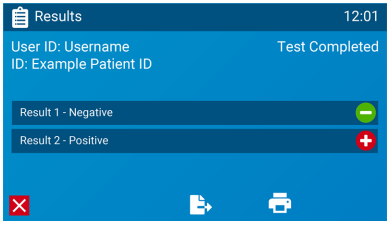
"nn" is the test number and starts with the most recent test run.



7.5.2 View and print individual result

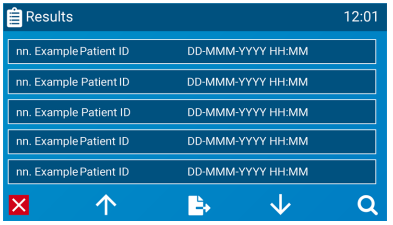
To print a single test result:

1. On the Home screen select **Results**.
2. On the Results screen, select the type of test category to view the saved results.
3. From the Results history, select a specific test to view additional result details.
4. Select  to print the test results.



7.6 Search test results

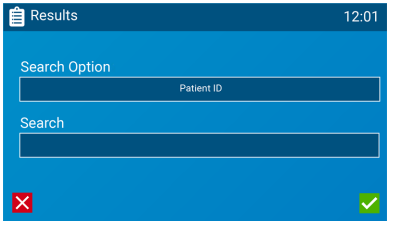
From the Results menu, select a test category to display the Results history. To search for a specific test result, select  to open the Search screen.



Select the Search Option field to toggle the searchable fields and select a field type. The following fields are available for each test type:

- Patient test: Assay Name, Patient ID/Accession No., Date Range, All
- QC test: Assay Name, QC Test ID, Date and Time, All
- "All" applies no filters to the search and displays all results.

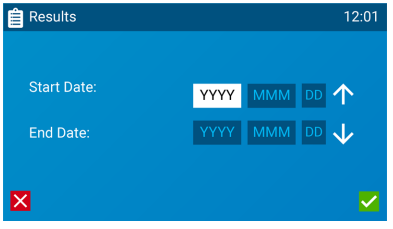
Enter the search criteria in the Search field.



Select to display the list of results that contain the text entered in the searchable field.

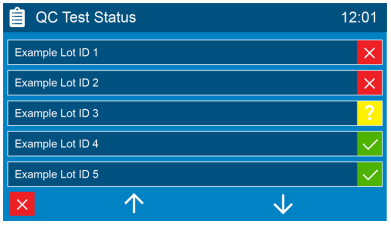
Select to cancel and navigate to the Results screen.

When filtering by the date range field, select the Search field to display the screen below. To edit the Start Date and End Date, select the up or down arrow.



7.7 QC test status

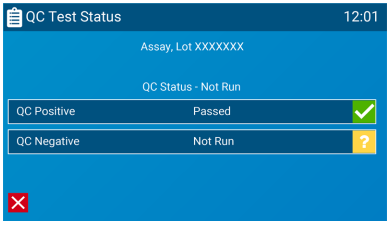
Access QC Test Status from the home screen by selecting **Results** followed by the applicable test. The QC status screen displays the latest result of all the associated QC tests and the overall QC status for each Consumable Lot. Scroll up and down through the screens to view the QC status for additional Consumable Lots.



The QC status for each Consumable Lot is indicated by an icon.

- Pass is shown when all associated QC tests have passed.
- Fail is shown when one or more of the associated QC tests have failed.
- Not Run is shown when one or more of the associated QC tests have not been run.

Select QC lot to view more information.



7.8 Exporting results to a USB drive

The instrument has an internal test result memory capacity of 999 patient tests and 999 QC tests. Warnings will display as the number of tests approaches capacity. See **5.20 Memory Warning** for more information on the setup of memory warnings.

It is recommended to export test results to an external USB drive and store this data separately from the instrument as a backup measure.

Each test result on the instrument can be exported as Summary Test Result File (.csv), which contains critical test details relevant to the instrument user. The summary will contain the critical details for all tests selected.

The file names are structured in the following format:

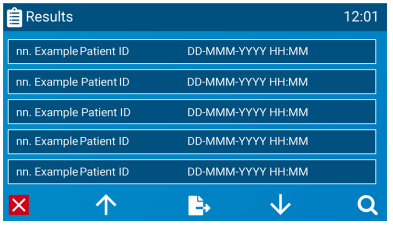
Patient Test	Serial number-year-month-day-hour-minute_T_summary
	Example: S041234-2022-11-14-11-58_T_summary
QC Test	Serial number-year-month-day-hour-minute_Q_summary
	Example: S041234-2022-11-14-11-48_Q_summary

You can export an individual test result or all test results.

Depending on the Admin settings, once all test results have been successfully exported, the Standard user may be able to delete all test results from the instrument. See **5.15 Export Settings** for details.

7.8.1 Exporting all test results

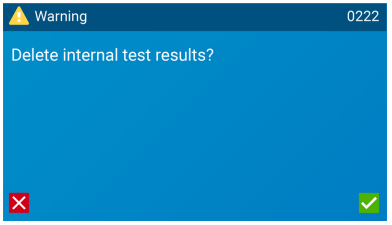
1. Navigate to the Results history screen.
2. Select .



3. Insert a formatted USB drive.
4. Select to export test results.
5. Select on the export success screen.
6. Choose whether to delete all test results from the instrument:

   To confirm deletion, select

   To keep the test results on the instrument, select .

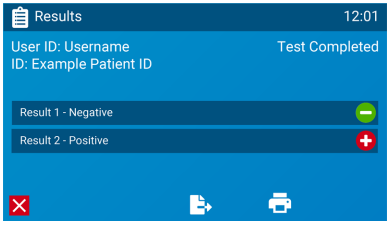


NOTE

The delete option is only available to Standard users if permitted in the Admin settings. See **5.15 Export Settings** for details.

7.8.2 Exporting an individual test result

1. Navigate to the Results history screen.
2. Select or to navigate through the Results screens.
   To search for specific test results, select .
3. Select an individual test result that you want to export.
4. Insert a formatted USB drive.
5. On the individual test result screen, select . The export will happen automatically.



NOTE

You can also select to print the test result to a connected label printer.

6. Select on the export success screen.