LumiraDx Platform User Manual Copy (Master)

LumiraDx

Confidential

Purpose of this document

This purpose of this document is to develop and control the master copy and section contents for the LumiraDx Platform User Manual.

This document will be used to populate the InDesign layout document which will be used for final formatting and printing purposes.

Platform User Manual

• The LumiraDx Platform is for use with SARS-Cov-2 IgG IgM Test Strips and SARS-Cov-2 Ag Test Strips, under the Food and Drug Administration's Emergency Use Authorization only. • For *In Vitro* Diagnostic Use • Rx Only	⚠

Contents

Symbols

On the packaging and on the identification plate of the Instrument you may encounter the following symbols, shown here with their meaning:

	Temperature limitation
	Manufacturer
IVD	In vitro diagnostic medical device
	This product contains electrical and electronic components that may contain materials which, if disposed with general waste, could be damaging to the environment. Residents of the European Union must follow specific disposal or recycling instructions for this product. Residents outside the European Union must dispose or recycle this product in accordance with local laws or regulations that apply
REF	Catalogue Number
SN	Serial Number
⚠	Caution - Consult Instructions for Use. Refer to safety-related warnings and precaution notes in the Instructions for Use accompanying this product, e.g. Platform User Manual, Test Strip Product Insert or Quality Control Pack Insert

☣	Indicates that the Instrument can be potentially infectious due to the samples or reagents used
⎓	Direct current - Indicates that the Instrument is suitable for direct current only and to identify relevant terminals
USB	Universal Serial Bus (USB) Port
(((•)))	Near Field Connectivity (NFC) – Indicates the presence of the Radio Frequency (RFID) reader
⏻	Identifies the power button to power on or power off the Instrument
📖i	Consult Instructions for Use

Instrument icons and buttons

The icons and buttons that appear on the touch-screen during normal operation of the LumiraDx Instrument are shown here, along with their respective meanings.

	Indicates the patient's biological sample
	Return to the home screen
	Info button - used to reveal additional information, such as test or patient information
	Indicates which fields barcode scanning is available as a means of data input When pressed as a button, displays barcode scanning instructions
	Indicates when the Instrument is connected to Connect Manager
'Cloud icons'	Indicates whether the Instrument has an active connection to an EHR
	Notification - Highlights an area which requires attention
	Caution - Highlights an error or precautionary statement which requires attention. Refer to safety-related warnings and precaution notes in the Instructions for Use accompanying this product, e.g. Platform User Manual, Test Strip Product Insert or Quality Control Pack Insert
	Indicates the status of the battery
	Displayed when the battery is in a charging state
	Icon which acts as a button - clears the text input field of all data
	Indicates the high end of the touch-screen brightness slider

	Indicates the low end of the touch-screen brightness slider
	Volume (high)
	Volume (low)
	Indicates a text field which can perform a search function
	Indicates confirmation of a completed action

Abbreviations

CDC   Centers for Disease Control and Prevention

EHR   Electronic Health Record

HCP   Health Care Professional

ID   Identification

QC   Quality Control

RFID   Radio-Frequency Identification

UK   United Kingdom

USB   Universal Serial Bus

WHO   World Health Organization

HIS   Hospital Information System

LIS   Laboratory Information System

DOB   Date of Birth

Important safety information

Healthcare professionals need to adhere to standard precautions when using the LumiraDx Platform [1,2,3]. All parts of the LumiraDx Instrument and LumiraDx Test Strips should be considered potentially infectious after use and are capable of transmitting pathogens between patients and healthcare professionals [4].

The Instrument should be disinfected after use with each patient [4]. The Instrument may only be used for testing multiple patients when standard precautions and the manufacturer's disinfection procedures are followed. Full cleaning and disinfecting procedures are described in the "Cleaning and Disinfecting" chapter in this Platform User Manual.

A clean pair of gloves should be worn before testing each patient. Wash hands thoroughly with soap and water before putting on a new pair of gloves and performing the next patient test. Only use auto-disabling, single use lancing devices. Dispose of all Test Strips used for patient or Quality Control testing safely in accordance with local regulations and procedures.	⚠

The LumiraDx Instrument contains a neodymium magnet. Although the risk of interference with implanted devices such as pacemakers is minimal, we recommend that patients with an implanted device should maintain a distance of at least 15 cm between the LumiraDx Instrument and their heart device.	⚠

Overview of the LumiraDx Platform

The LumiraDx Platform is a point of care system which is used for in vitro diagnostic tests. It comprises a portable LumiraDx Instrument and a LumiraDx Test Strip for the required test. This allows healthcare professionals to perform tests using small sample volumes and to view results quickly on the Instrument touch-screen. Information about test duration and test performance can be found in the LumiraDx Test Strip Product Inserts.

The LumiraDx Instrument is intended to be for multi patient use and should be disinfected after use on each patient.

The LumiraDx Instrument can be used in Standalone mode, providing test results on the touch-screen. Single or multiple Instruments can be connected to the LumiraDx Connect Manager for extended functionality and configuration. LumiraDx EHR Connect can enable the transfer of patient test results to the Electronic Health Record (EHR).

The LumiraDx Platform comprises:

Contained within this packaging	Available separately
• LumiraDx Instrument	• LumiraDx Test Strips • LumiraDx Quality Controls • LumiraDx Barcode Scanner • LumiraDx Printer

LumiraDx Connect diagnostic connectivity solution:

- LumiraDx Connect Manager
    - LumiraDx Connect App (for iOS and Android)
    - LumiraDx Connect Hub
- LumiraDx EHR Connect

The mode of operation and selection of Platform components is dependent on the following requirements of the organization:

- Types of tests to be performed
- Number of testing sites and users
- System administration, integration, and data transfer to the EHR

About this Platform User Manual

Read this LumiraDx Platform User Manual and the LumiraDx Test Strip Product Inserts carefully and completely before testing for the first time.

This Platform User Manual provides the information required to operate and care for the LumiraDx Instrument.

If error messages appear on the Instrument touch-screen, follow the instructions displayed or refer to the "Troubleshooting" chapter. For questions not answered in the LumiraDx Platform User Manual or Product Inserts, please contact Customer Services. Refer to the "Customer Services" chapter of this Platform User Manual for contact information.

Please note: Instructions are combined with example screenshots. Some screens may look different on the Instrument depending on the test or mode of operation. All screens, test names and results displayed in this Platform User Manual are intended only as examples.

This Platform User Manual highlights cautions and important information:

This symbol indicates a caution. Refer to safety-related warnings and precaution notes in the Instructions for Use accompanying this product, e.g. Platform User Manual, Test Strip Product Insert or Quality Control Pack Insert	⚠

1.   Introduction

1.1   Intended use

The LumiraDx Instrument (hereafter referred to as Instrument) is intended for use with the LumiraDx family of Test Strips (hereafter referred to as Test Strips) for the in vitro measurement of various analytes in a range of biological samples by trained healthcare professionals.

1.2   Important information

Read this LumiraDx Platform User Manual and the LumiraDx Test Strip Product Inserts carefully and completely before testing. Pay attention to the "Important safety information" at the start of this Platform User Manual before operating the Instrument. In addition, please watch the LumiraDx Platform Training Video available at kc.lumiradx.com.

1.3   Summary of the test procedure

To perform a patient test, the user is required to insert a Test Strip, apply a small sample volume of one drop, and close the Instrument door. Patient ID can be entered using the touch-screen keyboard or LumiraDx Barcode Scanner.

When the test process is complete, the result is displayed on the touch-screen and the user can optionally add a comment. Upon completion of the test, the Instrument stores the test result.

The Instrument provides visual and audible prompts throughout the test process.

1.4   Principles of operation

The Instrument automatically processes the Test Strip including sample movement, reagent mixing, thermal control and fluorescent reading of the reaction product and provides a calibrated, quantitative or qualitative result. Each Lot of Test Strips requires a LumiraDx Lot Calibration File, which provides the Instrument with the information required to process the test. The Lot Calibration File is installed by placing the RFID tag in the Test Strip Carton against the RFID reader in the Instrument.

1.4.1 Quality assurance

The LumiraDx Instrument ensures the quality of test results obtained through the following features:

- Automated checks of the correct functioning of the Instrument at power on and during operation.
    - This includes electrical component operation, heater operation, battery charge state, mechanical actuators and sensors and optical system performance.
- Monitoring of Test Strip performance and controls during test runtime.
- Onboard Quality Control (OBC) assay.

Ability to perform Quality Control Tests using LumiraDx Quality Controls to meet regulatory compliance requirements.

1.5 Storage and operating conditions

1.5.1 LumiraDx Test Strips

For specific information on Test Strip storage and operating conditions, refer to the relevant LumiraDx Test Strip Product Inserts.

1.5.2 LumiraDx Instrument

The Instrument is portable and can be used across a range of settings, such as care homes, primary care clinics, hospital wards and departments, pharmacy and laboratories. The Instrument is not intended for hand-held operation.

The Instrument can be stored or transported at a temperature between -10°C and 50°C (14°F and 122°F).

To power on and access the Instrument result history, operate the LumiraDx Instrument at a temperature between 15°C and 30°C (59°F and 86°F), and at a relative humidity between 10 % and 90 % (non-condensing). Specific test operating conditions may be more restrictive. Allow time for the Instrument to acclimatize to operating temperatures if it has been stored in a cold environment.

Always place the Instrument on a level, stable surface when powering up or starting a test. Testing should be performed in a location where the air vents located in the back of the Instrument will not be blocked, i.e. on a table top away from soft surfaces. The Instrument will display an error message if these operating conditions are not met.

Avoid placing the Instrument in direct sunlight. This may interfere with proper functioning of the Instrument.

Refer to the "Instrument Specifications" chapter of this Platform User Manual for additional information on operating conditions and complete Instrument specifications.

1.6   Warnings

Inserting Test Strips • **Do NOT** touch Test Strip Sample Application Area. • **Do NOT** bend or fold the Test Strip. • **Do NOT** touch Test Strip contacts. • **Do NOT** apply sample until prompted.	⚠

Performing a patient test • Wear a clean pair of gloves before performing a patient test. • Place the Instrument on a level, stable surface before starting a test. • Apply sample **AFTER** inserting the Test Strip and the Instrument prompt. • **Do NOT** apply more than one drop of sample. • Close the Instrument door after applying the sample and the Instrument prompt. • **Do NOT** touch the Test Strip until the test has finished and the result is displayed. • **Do NOT** open the door or move the Instrument during the test or an error will result and the test result will not be saved. • Dispose of all Test Strips used for patient testing safely in accordance with local regulations and procedures. • Follow the test operating conditions in the LumiraDx Test Strip Product Insert. • Follow the information on correct handling of Test Strips in the LumiraDx Test Strip Product Insert.	⚠

Performing a Quality Control test • Place the Instrument on a level, stable surface before starting a test. • Use only LumiraDx Quality Controls. • Apply Quality Control solution **AFTER** inserting the Test Strip and the Instrument prompt. • **Do NOT** apply more than one drop of Quality Control solution. • Close the Instrument door after applying the Quality Control solution and the Instrument prompt.	⚠

- **Do NOT** touch the Test Strip until the test has finished and the result is displayed.

- **Do NOT** open the door or move the Instrument during the test or an error will result and the test result will not be saved.

- Dispose of all Test Strips used for Quality Control testing safely in accordance with local regulations and procedures.

- Follow the test operating conditions in the LumiraDx Test Strip Product Insert.

- Follow the information on correct handling of Test Strips in the LumiraDx Test Strip Product Insert.

Cleaning and disinfecting

- **Do NOT** attempt to put any objects or cleaning materials inside the Test Strip slot.

- Always wear gloves whilst cleaning and disinfecting the Instrument.

- Only use LumiraDx recommended cleaning and disinfecting materials on the Instrument surfaces.

- Only use a damp and not wet swab or cloth for cleaning. Excess liquid may damage the Instrument.

- Always use LumiraDx approved wipes to disinfect the Instrument. Details of LumiraDx approved wipes can be found at lumiradx.com.

- **Do NOT** spray or pour solution directly onto the Instrument.

- Following cleaning and disinfection, and before performing a patient test, change gloves and wash hands.

Instrument disposal

- **Do NOT** attempt to replace or reinstate the battery**.**

FCC Radiation Exposure

This Instrument Complies with FCC's RF radiation exposure limits set forth for an uncontrolled environment. To maintain compliance follow the instructions below:

- The transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

- Avoid direct contact to the antenna, or keep contact to a minimum while using the Instrument.

1.7   Precautions

Only operate the LumiraDx Instrument for its intended purpose and in accordance with this Platform User Manual and warnings. If the Instrument is used in a manner not specified in the Platform User Manual, protection provided by the equipment will be impaired. The LumiraDx Instrument (including power supply unit) is designed to operate within the manufacturer specifications. Do not exceed the manufacturer specifications when in use.

Avoidance of electrical shock, fire and explosions • Use only the power supply unit that is provided with the Instrument. Use the appropriate power blade for the region. The correct power supply unit and adapter is required to maintain the safety and electromagnetic compatibility of the system. • Always operate this Instrument on a clean, level and stable surface. Do not drop the Instrument. Ensure that air flow to the ventilation openings located on the back of the Instrument are not restricted. • Risk of electrical shock. Do not operate the Instrument or the power supply unit if it has been opened, damaged or exposed to moisture, condensation or rain. • Overheating can cause the battery pack to catch fire or explode.	⚠

Safe disposal • Follow proper infection control guidelines for handling all specimens and related items. Properly dispose of all contaminated waste according to local regulations. • The LumiraDx Instrument and its components must be treated as potentially biohazardous waste. Decontamination (i.e. a combination of processes including cleaning, disinfection and/or sterilization) is required before reuse, recycling, or disposal. • Dispose of the system or its components according to the appropriate local regulations.	⚠

Electromagnetic interference • Do not use the Instrument near strong electromagnetic fields, which could interfere with the proper operation of the Instrument.	⚠

Electromagnetic compatibility	

• The Instrument has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. The Instrument generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this Instrument does cause harmful interference to radio or television reception, which can be determined by turning the Instrument off and on, the user is encouraged to try to correct the interference by one of the following measures:
    a. Reorient or relocate the receiving antenna.
    b. Increase the separation between the Instrument and receiver
    c. Connect the Instrument into an outlet on a circuit different from that to which the receiver is connected.
    d. Consult the dealer or an experienced radio/TV technician for help
	⚠

1.8   Help and support

Information about using the LumiraDx Instrument can be found in this Platform User Manual. Information about the Test Strips and test performance can be found in the LumiraDx Test Strip Product Inserts and Quality Control Pack Inserts. Information about LumiraDx Connect Manager and LumiraDx EHR Connect can be found in the LumiraDx Connect User Manual.

The documents can also be found at kc.lumiradx.com.

If error messages appear on the screen, refer to the "Troubleshooting" chapter in this Platform User Manual. For questions not answered in the LumiraDx User Manuals or Product Inserts, please contact Customer Services. Refer to the "Customer Services" chapter of this Platform User Manual for contact information.

2.   Getting Started

2.1   Unpacking

The LumiraDx Instrument package includes the following contents:

1. LumiraDx Instrument

2. LumiraDx Power Supply Unit

3. Platform User Manual

4. Platform Quick Reference Guide (including passwords for Standalone operation)

5. Connect User Manual

Inspect the Instrument and packaging for damage before use. Report any damage to Customer Services. Refer to the "Customer Services" chapter of this Platform User Manual for contact information.

2.2   Powering the Instrument on and off

The Instrument must be fully charged before first use. It will take approximately 2 hours to fully charge the battery using the power supply unit provided.

Place the Instrument on a level, stable surface. Power on by briefly pressing the power button at the rear of the Instrument. You will hear the Instrument powering on and the display will be blank for several seconds. When prompted enter user ID and/or password to login.

The Instrument touch-screen will dim after 2 minutes of inactivity. Tap the touch-screen to restore the touch-screen brightness.

To power the Instrument off after use, press the power button at the rear of the Instrument for 2 seconds, and tap the screen message to confirm power off. The Instrument should be powered off for transportation and when not in use.

2.3   Instrument self-check

The Instrument will perform a self-check when starting up. Ensure that the Instrument is on a level, stable surface during this process. If the Instrument door is open, the Instrument will prompt to close the door before performing the self-check. If a Test Strip is inserted at this time, the Instrument will prompt to remove the Test Strip and close the door. The self-check will not proceed until the door is closed.

2.4   User ID

There are two types of identification used with the Instrument:

General user

Allows general users to use the Instrument to perform patient and Quality Control tests, view result history, and adjust preferences including screen brightness and sounds.

Administrator

The administrator has additional rights to Instrument settings including language, time and date if the Instrument is being operated in standalone mode. If the Instrument is being managed in a connected mode then these settings will be downloaded from Connect Manager.

2.5   Operating mode and first time setup

The language and current date and time will need to be set by the administrator prior to performing a patient test. Other sound and display preferences can be set by any user.

Settings will automatically be downloaded to the Instrument if connecting to LumiraDx Connect Manager. Refer to the "Instrument operation" chapter of this Platform User Manual for more information on first time setup.

2.6   The LumiraDx Instrument

The Instrument is used in conjunction with the LumiraDx family of Test Strips for the in vitro quantification of various analytes in a range of biological samples (whole blood, plasma, serum, urine).
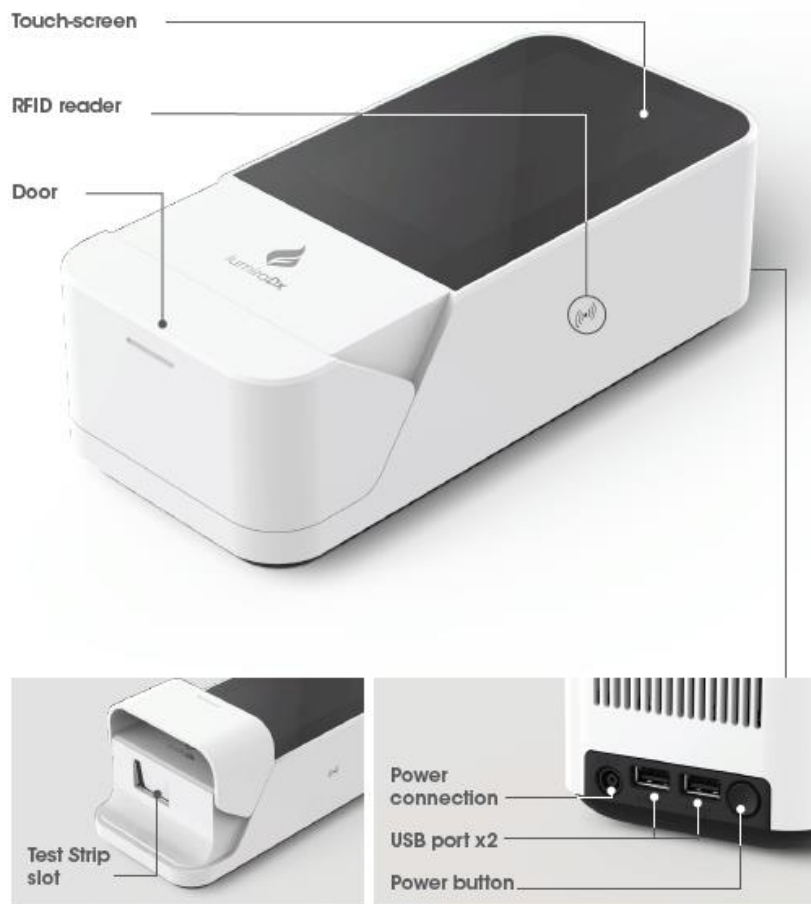
2.7   Power supply

The LumiraDx Instrument contains a rechargeable non-removable battery. If the battery is critically low, the Instrument will prompt to connect the power supply unit. It will take approximately 2 hours to fully charge the battery. The Instrument can be operated while charging the battery.

During operation, the Instrument touch-screen always displays the battery power level and provides an alert when the battery level is low. To save power when battery operated, the Instrument will automatically power off after 55 minutes, unless the touch-screen is tapped. When the Instrument powers off, all result records will remain in the Instrument memory and any Instrument settings will be maintained.

Refer to the "Instrument Specifications" chapter of this Platform User Manual for additional information on operating conditions and complete Instrument specifications.

2.8   LumiraDx Lot Calibration File installation

LumiraDx Lot Calibration Files are required to provide the Instrument with the information needed to perform diagnostic tests. Every manufactured Lot of Test Strips has a unique Lot Calibration File. This contains information about the test method, the Lot number, the calibration data and expiration date.

Lot Calibration File installation is performed manually. Locate the RFID reader by looking for the *RFIDICON* symbol on the side of the Instrument. To install a new Lot Calibration File, touch the back of the Test Strip Carton to the *RFIDICON* symbol to install. When the Lot Calibration File is installed the Instrument will sound and a confirmation message will be displayed.

The Instrument will prompt to install the Lot Calibration File when inserting a new Test Strip Lot. Once installed, the Instrument will have all the information required to process the test, and any future tests from the same Lot of Test Strips.

RFID reader

Locate ((•)) symbol on Instrument.

Installation

Touch back of Test Strip Carton ((•)) symbol to install.

Confirmation

The Instrument will sound and a confirmation message will be displayed.

2.9 Extended functionality and operating modes

The LumiraDx Instrument can be used in Standalone mode, or two Connected modes: "Managed" and "EHR Connected" (meaning connected to the organization's electronic health record). Refer to the LumiraDx Connect User Manual for further information.

Standalone

Run patient tests and quality control tests.

Store test results together with time, date and patient ID.

LumiraDx Instrument

Managed

Configure single or multiple Instruments.

Create workgroups and user login credentials.

Manage compliance and governance functions.

LumiraDx Instrument
& LumiraDx Connect Hub or LumiraDx Connect App

LumiraDx Connect Manager

EHR Connected

Integrate with Electronic Health Record for transfer of patient test results.

View patient results in your LIS or HIS.

LumiraDx Instrument
& LumiraDx Connect Hub or LumiraDx Connect App

LumiraDx Connect Manager

Electronic Health Record

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3. Preparation for Testing

All samples are potentially infectious and are capable of transmitting pathogens between patients and healthcare professionals.

3.1 Handling Test Strips

When you are ready to perform a test, select a Test Strip and check the expiry date. Discard the Test Strips if they are past the expiration date. If within the expiry date open the Test Strip Carton, take out one Test Strip, and remove it from the foil pouch from the end indicated by the tear triangles. Refer to the LumiraDx Test Strip Product Insert for further information on handling and stability.
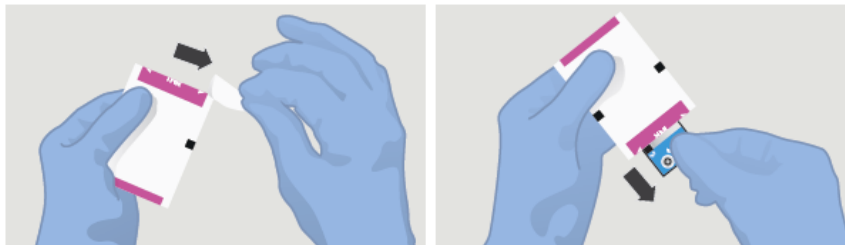
Commented [LS2]: Colour to match COVID-19 strip foils

3.2   Inserting and removing Test Strips

Hold the Test Strip by gripping the blue label end with the label facing upward.

Line up the black alignment rib on the Test Strip with the black line on the Instrument. Insert the Test Strip gently as far as it will go. The Instrument will sound when the Test Strip is detected if sounds are turned on in the Instrument settings (see section 4.5).

To remove a Test Strip from the Instrument, gently pull the blue label and pull straight out.

Do NOT touch Test Strip Sample Application Area. **Do NOT** bend or fold the Test Strip. **Do NOT** touch Test Strip contacts.	⚠️

Test Strip contacts

Alignment rib

Line up black line on Test Strip with black line on Instrument.

Test type

INR

Sample Application Area

Apply sample or Quality Control solution **AFTER** inserting Test Strip.

Note: Test Strip may appear differently.

Commented [LS3]: Replace INR strip with SARS-CoV-2 IgG/IgM strip

3.3   Capillary sample collection and application

When collecting any type of sample, follow universal blood collection precautions and guidelines according to your organization. Refer to Test Strip Product Insert for information on sample types and collection. Samples can be applied directly from a finger stick or a transfer tube can be used.

Details of LumiraDx recommended transfer tubes are available at lumiradx.com and sample application training videos are available at kc.lumiradx.com.

Collecting a capillary blood sample from a finger stick

Use a lancet near the finger tip on the side which faces down.

To increase the blood flow in the finger before lancing, ask the patient to rinse their hands in warm water, hold their arm straight down at their side, or massage the finger from its base to produce a sufficiently large hanging blood drop.

Applying a finger stick sample to the Test Strip

Allow the hanging blood drop to just touch the centre of the sample application area of the Test Strip.

Ensure that the sample is applied centrally and completely fills the sample application area in one clean drop.

Do not allow the finger to touch the test strip to avoid smearing the sample.

When the sample is detected, the Instrument will sound and a confirmation message will be displayed.
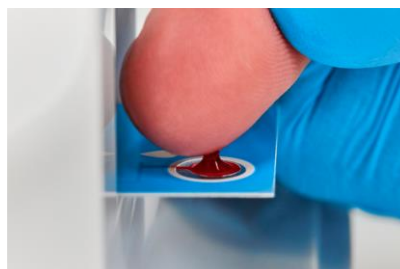
Collecting a capillary blood sample using a transfer tube

To use a transfer tube to collect a blood sample follow the steps described previously to increase the blood flow to the selected finger and use a lancet to produce a blood droplet on the end of the finger.

Holding the transfer tube horizontally, touch the tip to the blood sample. Capillary action will automatically draw the sample into the tube.

- **Do NOT** squeeze the bulb of the transfer tube before or during sample collection.

- **Do NOT** allow the transfer tube to touch the finger.

- Ensure the transfer tube is filled to the black fill line or to the end of the collection tube depending on what type of transfer tube is being used.

- If air bubbles are seen discard the transfer tube and start again.
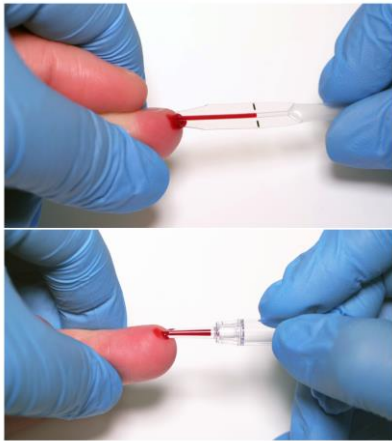
Applying a transfer tube sample to the Test Strip

Hold the filled transfer tube vertically over the Sample Application Area and gently squeeze the bulb or depress the plunger to move the sample to the tip of the transfer tube.

Allow the blood drop to touch the sample application area without releasing the pressure on the bulb to apply the sample.

When the sample is detected, the Instrument will sound, and a confirmation message will be displayed.

Dispose of the lancet in the appropriate clinical waste. Clean the patient's finger with a clean tissue and apply slight pressure.

If you need to retest, use a new Test Strip and lancet, and a different finger.
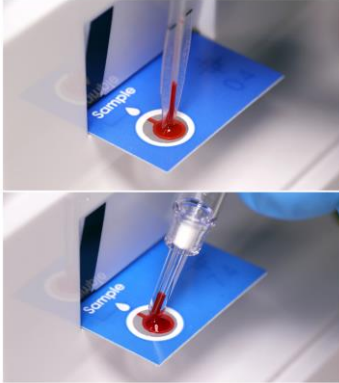
Do NOT apply more than one drop of sample. **Do NOT** touch the Test Strip until the test has finished and the result is displayed.	⚠️

3.4 Sample application using other sample types

Refer to LumiraDx Test Strip Product Inserts for information on available sample types per test, and procedures to transfer other sample types to the Sample Application Area of the Test Strip. Use the recommended transfer procedure to dispense a small sample of one drop onto the circular Sample Application Area on top of the inserted Test Strip.

3.5 Quality Control solution application

Refer to LumiraDx Quality Control Pack Inserts for information on testing with LumiraDx Quality Controls.

4.   Instrument Operation

The LumiraDx Instrument can be used in three modes; Standalone, Managed or EHR Connected.

This chapter describes how to perform first time setup, set preferences, perform patient and Quality Control tests, and view result history. Extended functionality for Connected Instruments is also described.

Please note:

- Instructions are combined with example screenshots. Some screens may appear differently depending on the test or mode of operation. All screens, test names and results displayed in this Platform User Manual are intended only as examples.

- You can only hear the sounds on the LumiraDx Instrument when they are turned on. This Platform User Manual presumes that the sounds are turned on.

4.1   Home Screen
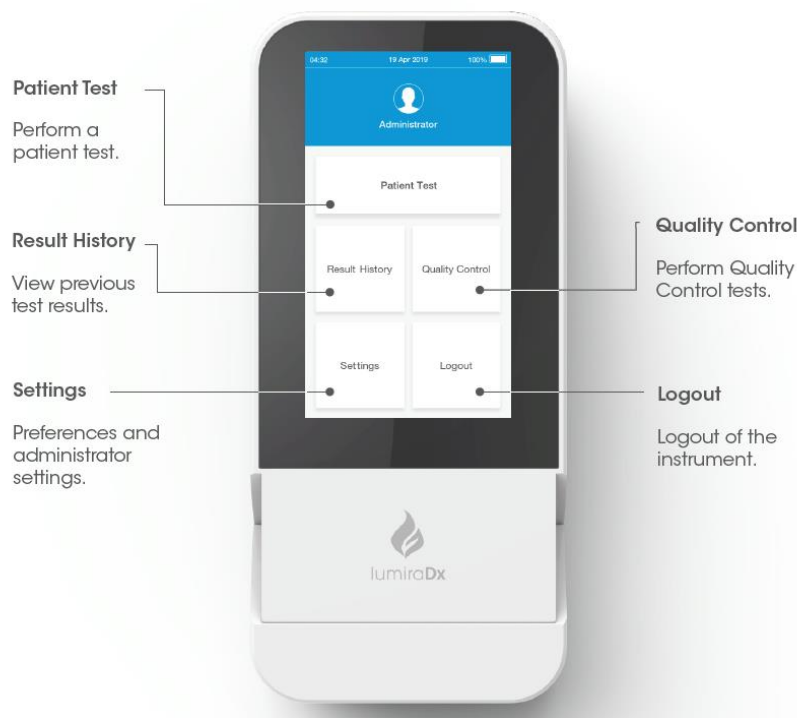
4.2   Settings Menu
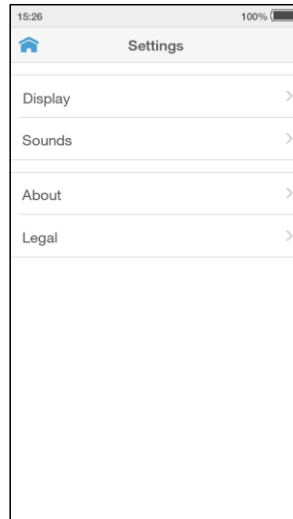

General user settings menu

All users can set display and sound preferences in the Settings menu. Refer to the "Instrument Operation" chapter in this Platform User Manual for instructions.

Administrator settings menu

The administrator can set date and time. Refer to the "Instrument Operation" chapter in this Platform User Manual for instructions.

The About screen provides information on Instrument software and hardware versions, and serial number. For Connected Instruments the screen will also display the Organization, Instrument and WorkGroup names.

Factory Reset can be used to delete all data currently stored on the Instrument, including result history and settings.
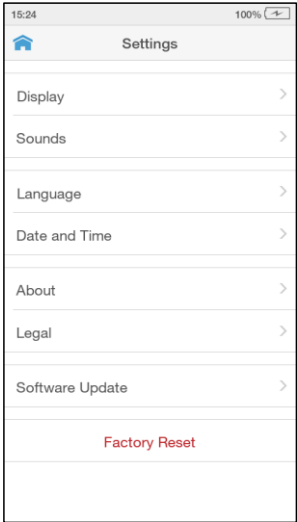

4.3　Standalone Instrument First Time Setup

For Standalone mode Instruments the language and current date and time will need to be set by the administrator prior to performing a patient test. Other sound and display preferences can be set by any user.

Administrator and general user passwords for Standalone operation are provided on a tear out sheet in the Platform Quick Reference Guide.

1. Power on

Power on the Instrument by pressing the power button at the rear of the Instrument. You will hear the Instrument powering on, and the display will be a blank black screen for several seconds before starting up. If the screen is just dimmed tap the touch-screen to wake up the Instrument.
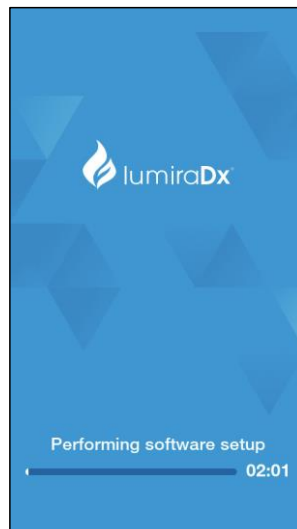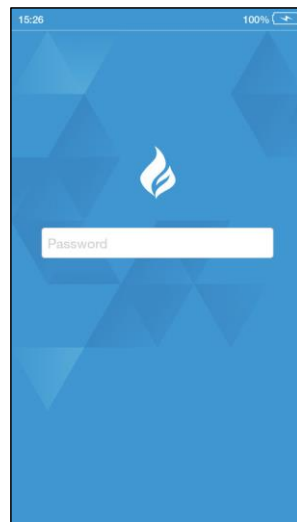

2. Enter Password

Tap the password field to display the keyboard.

Enter password (using administrator password supplied) and tap 'Login' to complete the login.

Note: Administrator password is provided on a tear out sheet in the Platform Quick Reference Guide.

3. Set language

The language is set to English by default. To set a different language go to 'Settings' and tap 'Language'.

Choose a language from the list for the text appearing on the display. The currently set language is ticked.

Tap 'Done' to save and return to the Settings menu.
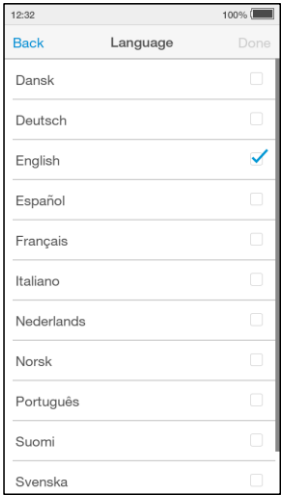
4. Set date and time

Go to 'Settings' and tap 'Date and Time'.

Tap the date field and use the selection wheel to set the current date. Tap 'Enter'.

Tap the time field and use the selection wheel to set the current time. Tap 'Enter'.

Tap 'Done', then check the date and time are correct and tap 'Confirm' to save.

Return to the home screen and tap 'Logout'.

4.4　Connected Instrument First Time Setup

Connected system setup should be completed by the administrator on Connect Manager. Refer to the LumiraDx Connect User Manual for further information.

Power on by pressing the power button at the rear of the Instrument. You will hear the Instrument powering on and the display will be blank for several seconds before starting up. Follow the steps for Standalone first-time setup to set the language.
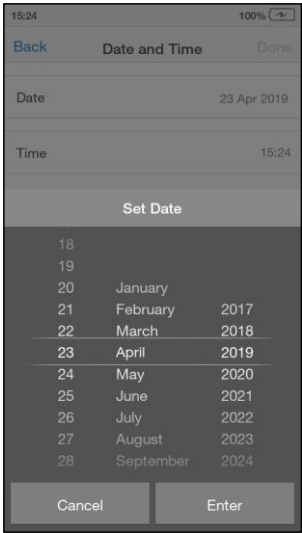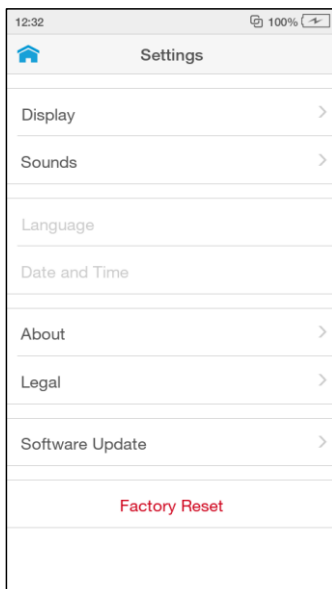
To download other Instrument settings, ensure the Instrument is within range of a LumiraDx Connect Hub or a device running the LumiraDx Connect App (within approximately 10 metres). If *LINKICON* appears at the top of the screen, the Instrument is connected to Connect Manager and the Instrument settings will download and install automatically. Time, date, and language settings will be set automatically if the Instrument is in range of a LumiraDx Connect Hub and these settings will be greyed out in the settings menu.

12:32	100%
🏠	**Settings**
Display	>
Sounds	>
Language	
Date and Time	
About	>
Legal	>
Software Update	>
Factory Reset	

Downloading settings for first time setup will take up to 4 minutes.

A *CLOUD ICON* will appear at the top of the screen for EHR Connected Instruments. This integrates the LumiraDx Instrument with the existing Electronic Health Record for transfer of patient test results. Patient test results can then be viewed within the LIS or HIS.

The Instrument status bar
displays a ⊡ when the
Instrument is connected
to Connect Manager

| 15:24 | 23 Apr 2019 | ☁ ⊡ 100% ⬆ |

The Instrument status bar
displays a ☁ when the
Instrument is connected
to the Electronic Health
Record
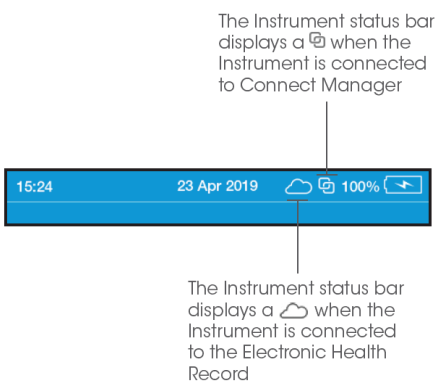
4.5   Display and Sound Preferences

All users can set display and sound preferences in the Settings menu.

Display

In the Display menu the brightness of the display can be set.

Go to 'Settings' and tap 'Display'. Use the slider to adjust the brightness.

Tap 'Done' to save and return to the Settings menu.
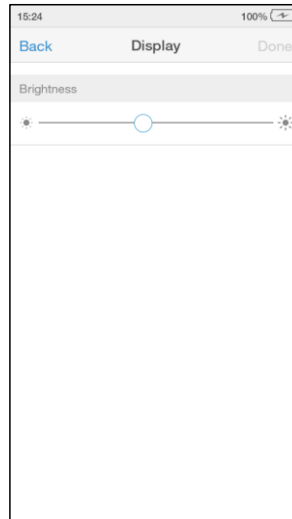
Sounds

In the Sounds menu the key clicks and audible alerts can be turned on or off.

Go to 'Settings' and tap 'Sounds'. Set sounds on or off, or to set the volume using the slider.

Tap 'Done' to save and return to the Settings menu.

4.6   Performing a Patient Test

This Platform User Manual describes the basic patient test method for the LumiraDx Instrument. If there are differences in the test method for a particular diagnostic test, the Instrument will prompt at each step of the process. Please refer to the LumiraDx Test Strip Product Insert before performing a new test for specific test information.
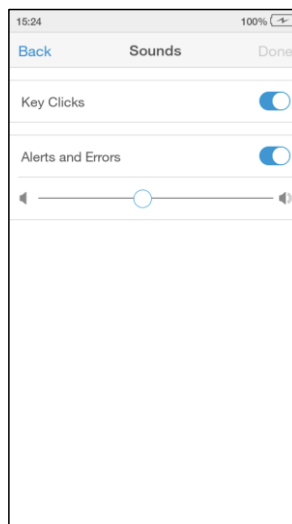
Important Notes

ALWAYS • Place the Instrument on a level, stable surface before starting a test. • Apply sample **AFTER** inserting the Test Strip and the Instrument prompt. • Follow the test operating conditions in the LumiraDx Test Strip Product Insert. • Follow the information on correct handling of Test Strips in the LumiraDx Test Strip Product Insert.	⚠

To view test information during a patient test, or on the test result screen, tap the *INFOICON* at the top of the touch-screen.

15:26		100% 🔋
Cancel	Patient Test	ⓘ
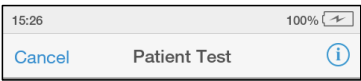
To cancel a patient test tap 'Cancel' at the top of the touch-screen and follow the Instrument prompts.

1. Power on and login

Power on the Instrument by pressing the power button at the rear of the Instrument. You will hear the instrument powering on and the display will be a blank black screen for several seconds before starting up. If the display is dimmed tap the touch-screen to wake up the instrument.

If using a Standalone Instrument with just a password field, tap the password field to display the keyboard.

Enter password and tap 'Login' to complete the login.
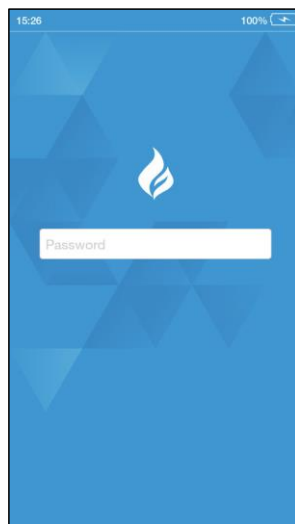
If using a Connected Instrument, tap the User ID field to use the keyboard to enter User ID. Alternatively, scan User ID using the Barcode Scanner. Refer to the "Ancillary devices" chapter in this Platform User Manual for scanning instructions.

Tap the password field to display the keyboard.

Enter password and tap 'Login' to complete the login.

2. Check date and time

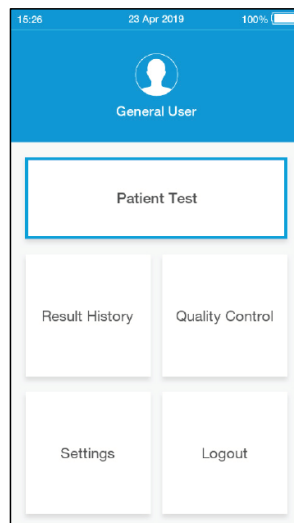Check that the date and time are correct. If not correct, the current date and time will need to be set by the administrator. Refer to "First time setup" in this chapter for more information.

3. Tap Patient Test

Tap the 'Patient Test' button on the home screen.

4. Enter patient details

Tap any field to use the keyboard to enter patient details, or scan the patient ID using the Barcode Scanner. Refer to the "Ancillary devices" chapter in this Platform User Manual for scanning instructions.

Use the 'Enter' button on the keyboard to move from field to field, or tap a field to enter additional details.

Complete all available patient details, then tap 'Next' to continue.

Note: Tap 'Next' if no patient details are available.

5. Using the Instrument in EHR Connected mode

If the Instrument has an active connection to the EHR, scan the Patient ID using the Barcode Scanner or search for the patient in the HIS or LIS by entering patient details, then tap 'Search'.

Note: If no patient details are available, tap 'Search' without adding any details. To search for a patient either the full Patient ID or Last Name must be entered.

EHR Connect patient search

If only one patient matches the details entered, the Instrument will show the 'Confirm Patient Details' screen. If between 2 and 5 patients match the search details entered, the list of matches will be shown. Select the correct patient from the search list.

Note: Tap 'Skip' to proceed without selecting one of the patients available in the search list.
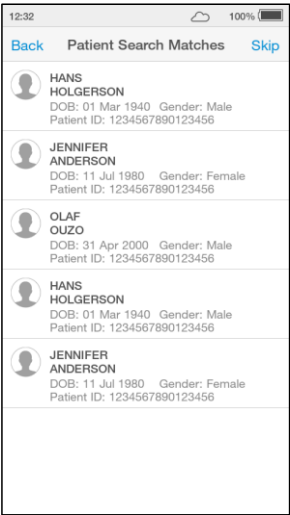
No patient match

If the search times out, no patient matches are found, or more than 5 patients matches are found a message will display. Tap 'proceed' to proceed with the test without verifying the patient details or tap 'cancel' to go back and try a new search.
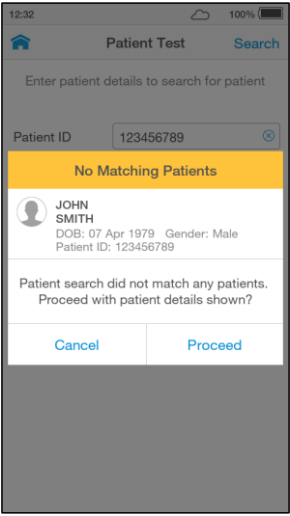
6. Confirm patient details

Check patient details are correct and tap 'Confirm' to proceed.
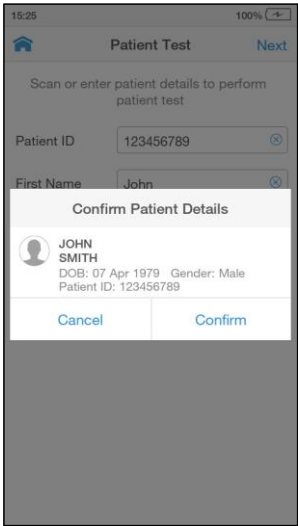
7. Open door and Insert Test Strip

The Instrument display will prompt to open the door and insert a Test Strip.

Remove a Test Strip from its packaging and hold with the blue label side facing upward.

Line up the black alignment rib on the Test Strip with the black line on the Instrument. Insert the Test Strip gently as far as it will go.

The Instrument will sound when the Test Strip is detected.

Do NOT touch Test Strip Sample Application Area. **Do NOT** touch Test Strip contacts. **Do NOT** apply sample until prompted.	⚠️
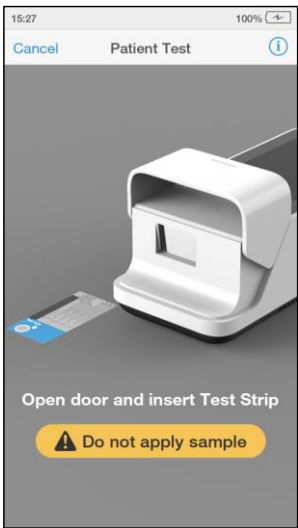
8. Select sample type

Select the intended sample type from the list displayed.

Sample type is test type dependent (refer to the LumiraDx Test Strip Product Insert for more information).

Note: The Instrument will prompt to install the Lot Calibration File when inserting a new Test Strip Lot.

Note: Capillary Blood refers to both finger stick and transfer tube applications.
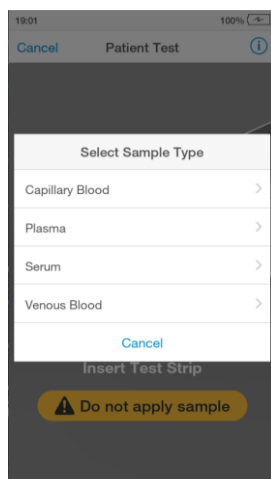
9. Confirm test and sample type

Check the test and sample type is correct and tap 'Confirm' to proceed.

Note: A progress bar will indicate if the Instrument is heating the Test Strip.
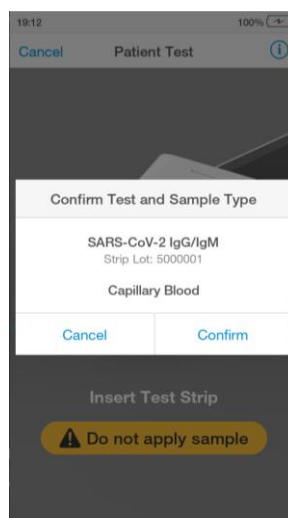
10. Apply sample

The Instrument display will prompt when to apply the sample.

Apply the sample directly to the circular Sample Application Area on top of the Test Strip. The sample must cover the entire Sample Application Area. Refer to the "Handling Test Strips" chapter in this Platform User Manual for sample application instructions.

The Test Strip draws up the sample by capillary action.

Note: Pay attention to the countdown for sample application to avoid test errors. This will be displayed as a countdown bar, and the Instrument will sound with 10 seconds remaining. If the sample is not applied by the end of the countdown the Instrument will display an error message.

When the sample is detected the Instrument will sound and a confirmation message will be displayed.

Do NOT apply more than one drop of sample. **Do NOT** touch the Test Strip until the test has finished and the result is displayed.	⚠
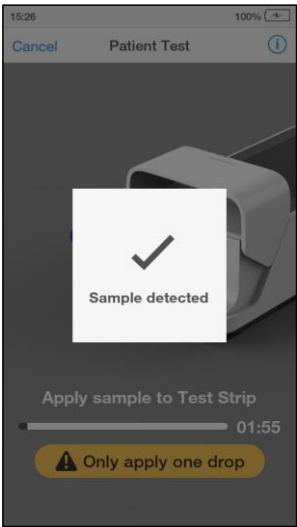
11. Immediately close door to continue

The Instrument display will prompt to close the door.

Note: The countdown bar is only displayed for a few seconds. It is important to close the door quickly when prompted to avoid test errors. If the door is not closed by the end of the countdown the Instrument will sound and display an error message.
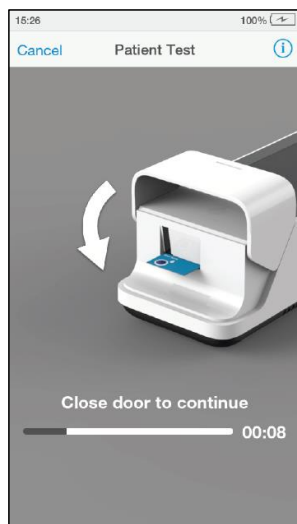
12. Test processing

The test will start and a progress bar will be displayed whilst the test is processing.

Note: Each test type has a different processing time.

Do NOT open the door or move the Instrument during the test or an error will result and the test result will not be saved.	⚠
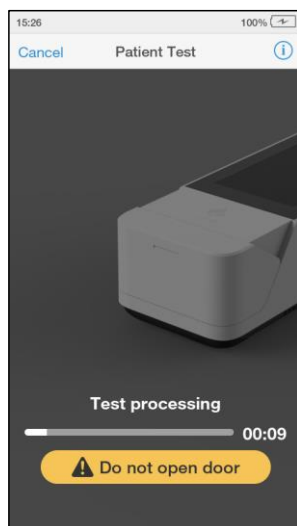
13. Review result

When the test is complete the result will be displayed on the screen (an example result is shown here).

If a LumiraDx Printer is connected to the Instrument, a 'Print' option will be available. Tap 'Print' to print the test result.

Review the result then tap 'Finish' or tap 'Comment' to add a comment, if required. A comment may be up to 50 characters in length.

To reject a test result, go to 'Comment' and tap 'Reject result'. A comment must be added if a test result is rejected.

Once the desired comment(s) are entered tap 'Done' to return the result screen.

Tap 'Finish' to save the test result to Result History and complete the test.

Note: If operating the Instrument in a connected mode, you must tap 'Finish' for the result and any comments to be sent to the EHR.

Commented [LS4]: Extra screenshot added.

13. Remove and dispose of Test Strip

The Instrument will prompt to remove the Test Strip.

Gently pull the blue label end of the Test Strip to remove and dispose.

Disinfect the Instrument between patient tests. Refer to the "Cleaning and Disinfecting" chapter in this Platform User Manual for further information.

Close the Instrument door.

Dispose of all Test Strips used for patient testing safely in accordance with local regulations and procedures.	⚠
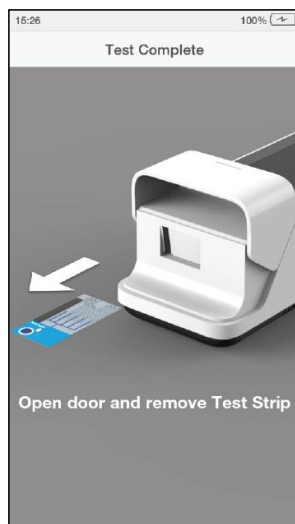
4.7   Quality Control

The LumiraDx Instrument has a number of built-in QC functions. In addition to these, LumiraDx Quality Controls can be used to meet compliance requirements as required.

To perform QC testing with LumiraDx Quality Controls, you will need:

- LumiraDx Instrument

- LumiraDx Test Strips

- LumiraDx Quality Controls

Preparing for a QC test requires the same steps as preparing to perform a patient test. The only difference in the test method is the use of Quality Controls instead of patient samples.

Instruments being managed in a Connected mode may have the Quality Control policy set to 'Mandatory' by in the Connect Manager settings. This means that users and administrators are not able to perform a patient test when a Quality Control test for that particular test is due. The timing and frequency of mandatory Quality Control tests are configurable in Connect Manager.

For information on LumiraDx Quality Controls refer to the LumiraDx Quality Control Pack Inserts.	📖ℹ

4.8 Performing a Quality Control test

This Platform User Manual describes the basic Quality Control test method for the LumiraDx platform. If there are differences in the test method for a particular QC test, the Instrument will prompt at each step of the process. Please refer to the LumiraDx Test Strip Product Insert before performing a new QC test for specific information.

Important Notes

ALWAYS	
- Wear a clean pair of gloves before performing a QC test. - Place the Instrument on a level, stable surface before starting a test. - Use only LumiraDx Quality Controls. - Apply Quality Control **AFTER** inserting the Test Strip and the Instrument prompt. - Follow the test operating conditions in the LumiraDx Test Strip Product Insert. - Follow the information on correct handling of Test Strips in the LumiraDx Test Strip Product Insert.	⚠

To view test information during a QC test, or on the test result screen, tap the *INFOICON* at the top of the touch-screen.

15:27	100% 🔋
Cancel	Quality Control Test	ⓘ
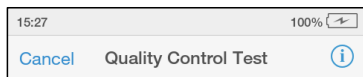
To cancel a QC test tap 'Cancel' at the top of the touch-screen and follow the Instrument prompts.

1. Power on and login

2. Check date and time

Check that the date and time are correct. If not correct, the current date and time will need to be set by the administrator. (Refer to "First time setup" in this chapter for more information).

3. Prepare Quality Control solution

Prepare the Quality Control according to the LumiraDx Quality Control Pack Insert.

4. Tap Quality Control

Tap the 'Quality Control' button on the home screen.
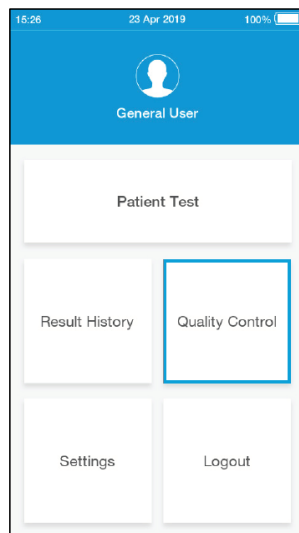
5. Select Quality Control Test

Tap 'Quality Control Test' from the Quality Control menu.
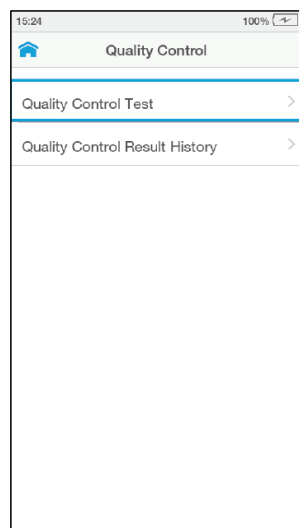
6. Open door and Insert Test Strip

The Instrument display will prompt to open the door and insert a Test Strip.

Remove a Test Strip from its packaging and hold with the blue label side facing upward.

Line up the black alignment rib on the Test Strip with the black line on the Instrument. Insert the Test Strip gently as far as it will go.

The Instrument will sound when the Test Strip is detected.

Do NOT touch Test Strip Sample Application Area. **Do NOT** touch Test Strip contacts. **Do NOT** apply Quality Control until prompted.	⚠
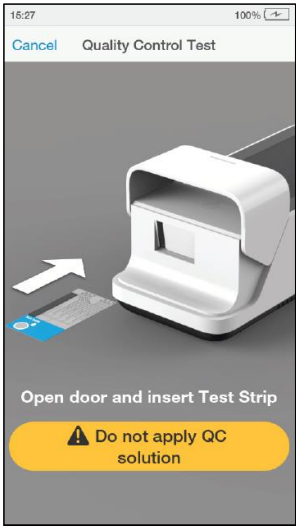
7. Confirm test type

Check the test type is correct and tap 'Confirm' to proceed.

Note: The Instrument will prompt to install the Lot Calibration File when inserting a new Test Strip Lot.
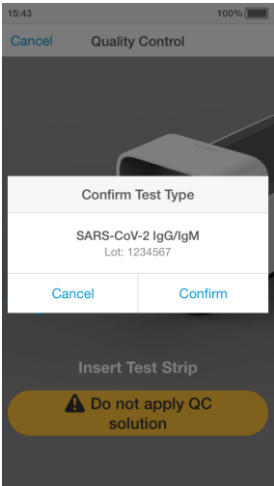
8. Select Quality Control level

Select the intended Quality Control from the list displayed.

Please refer to the LumiraDx Quality Control Pack Insert for more information.

Note: The Instrument will prompt when to apply the Quality Control solution to the Test Strip.
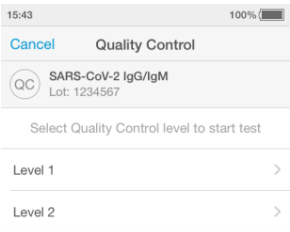
9. Enter Quality Control Lot number

Tap the input field to use the keyboard to enter the 16 digit Quality Control Lot number, and tap 'Next' to continue.

Alternatively scan the Quality Control barcode using the Barcode Scanner. Refer to the "Ancillary devices" chapter in this Platform User Manual for scanning instructions.

Note: If the barcode from a different QC level or test from the one selected on the previous screen is entered an error message will display.
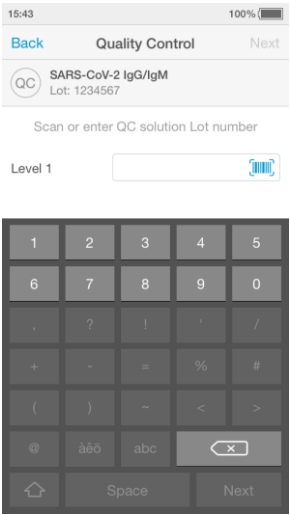
10. Apply Quality Control solution

The Instrument display will prompt to apply the Quality Control sample.

Apply the Quality Control sample directly to the circular Sample Application Area on top of the Test Strip. The solution must cover the entire application area. Refer to LumiraDx Quality Control Pack Inserts for additional information on testing with LumiraDx Quality Controls.

Note: Pay attention to the countdown for sample application to avoid test errors. This will be displayed as a countdown bar. If the sample is not applied by the end of the countdown the Instrument will sound and display an error message.

When the Quality Control sample is detected the Instrument will sound and a confirmation message will be displayed.

Do NOT apply more than one drop of Quality Control sample. **Do NOT** touch the Test Strip until the test has finished and the result is displayed.	⚠️
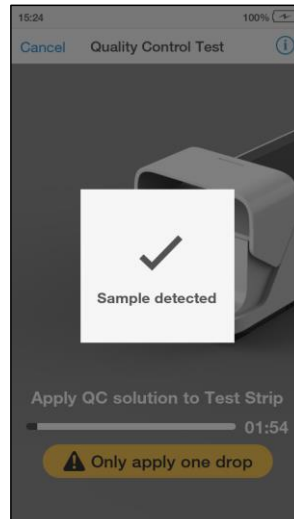
11. Immediately close door to continue

The Instrument display will display a prompt to close the door.

The test will start and a progress bar will be displayed whilst the test is processing.

Note: Pay attention to the countdown for closing the door to avoid test errors. This will be displayed as a countdown bar for only a few seconds. If the door is not closed by the end of the countdown the Instrument will sound and display an error message.

12. QC test processing

The QC test will start and a progress bar will be displayed whilst the test is processing.

Note: Each test type has a different processing time.

Do NOT open the door or move the Instrument during the test or an error will result and the test result will not be saved.	⚠

13. Review QC result

When the QC test is complete the result will be displayed on the screen. An example result is shown here, which shows that the correct result has been obtained for all assays for this QC level.

Review the result then tap 'Finish' or tap 'Comment' to add a comment, if required. A comment may be up to 50 characters in length.

Once the desired comment(s) are entered tap 'Done' to return the result screen.

Tap 'Finish' to save the test result to Result History and complete the test.
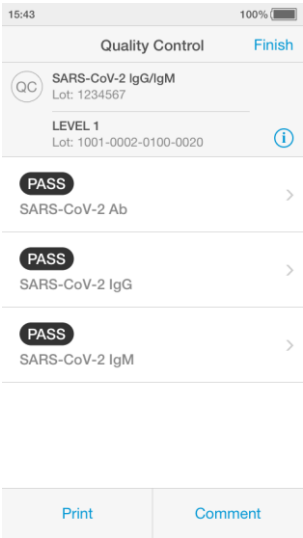
14. Remove and dispose of Test Strip

The Instrument will prompt to remove the Test Strip.

Gently pull the blue label end of the Test Strip to remove and dispose.

Close the instrument door.

Dispose of all Test Strips used for Quality Control testing safely in accordance with local regulations and procedures.	⚠
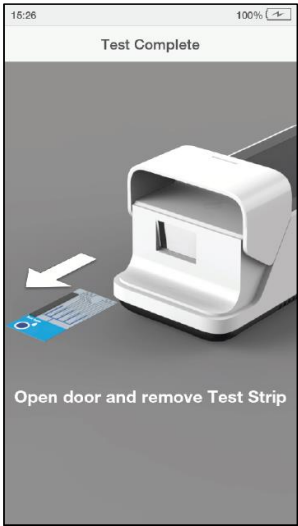
15. Complete remaining QC levels

Multiple QC levels may be required depending on test type.

Refer to the LumiraDx Quality Control Pack Insert for more information on QC levels.

Repeat steps in "Performing a Quality Control test" to test any additional QC levels.
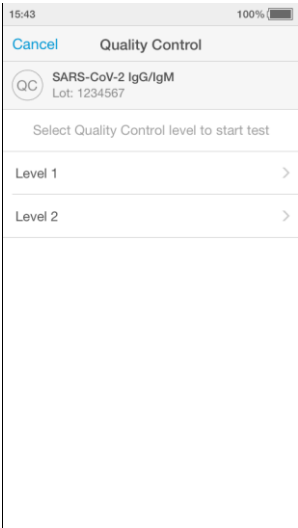
16. Mandatory Quality Control Policy

Connected Instruments with the Quality Control policy set to 'mandatory' will have an additional menu item of 'Quality Control Status'.
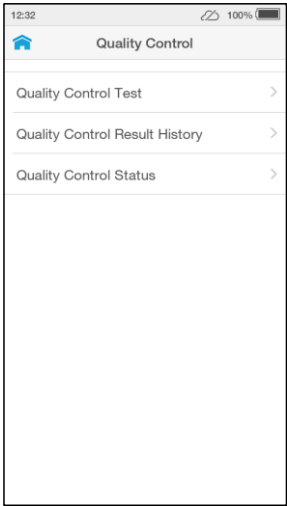
Quality Control test statuses are sorted by 'Recent Tests' meaning test lots for which patient tests or Quality Control tests have been performed recently. 'Other Tests' are test lots which have not had a patient test or QC test performed for more than 90 days.

Note: QC statuses can also be filtered by test type.
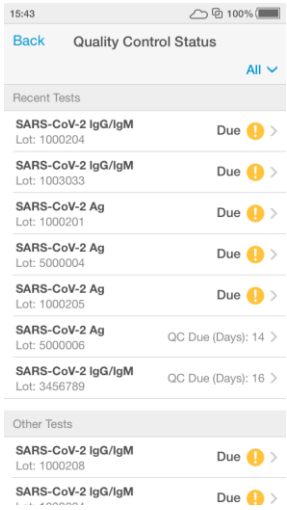
The Quality Control level selection screen will also show the status of each QC level as well as the date of any recently performed QC tests.

After completing a QC test level, the Instrument will return to the QC level selection page until all QC levels have been completed.
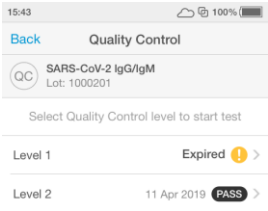
If a user attempts to perform a patient test using a lot for which a mandatory Quality Control test is due, the Instrument will display an alert message and prompt the user to perform a Quality Control test.
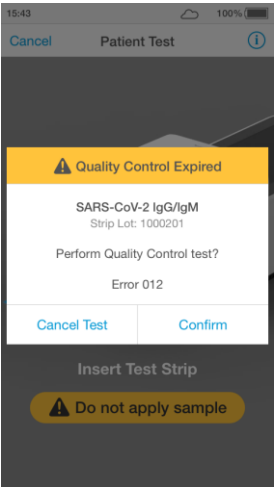
4.9   Result History

The LumiraDx Instrument can save 1000 patient or QC test results, together with respective time, date and comments. If the Instrument memory is full, the oldest result is automatically deleted.

1. Power on and login

2. Tap Result History

To view Patient or QC test results, tap 'Result History'.
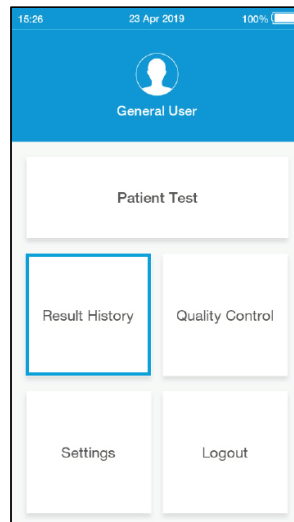
3. Review test results

All entries are shown in date order, with the newest at the top. Test results can be filtered by selecting Patient Tests, QC Tests, Rejected Tests or Invalid Tests.

Test results are marked as Invalid if a system error occurs during test processing. Refer to the "Troubleshooting" chapter of this Platform User Manual for information on errors.

Scroll through the list and tap any entry to view the test result in full.

Search for a patient test result by entering the Patient ID, First Name or Last Name in the search bar from either the Patient Tests, Rejected Tests or Invalid Tests screen.

Note: A search for a partial Patient ID, First Name or Last Name will only work for the start of the search term.
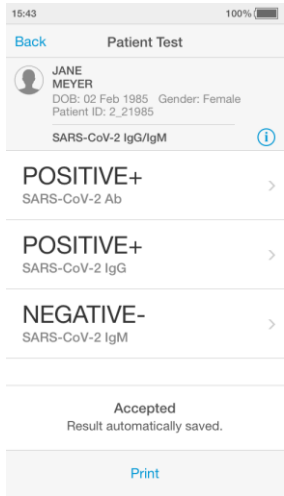
Any patient or QC test result can be printed from the test result details screen by tapping 'Print' when a LumiraDx Printer is connected to an Instrument USB port.

EHR Connected Instruments will indicate whether a test result has been sent to the electronic health record.

A <exclamation> symbol on the home screen indicates that one or more test results have not yet been sent to the EHR.
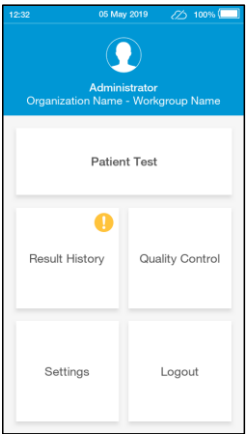
The Result History list will indicate whether test results have been sent to the EHR or not with 'sent' and 'not sent'.

4.10   Onboard Quality Control

In addition to the system checks performed by the Instrument during start up and within the test procedure, LumiraDx Tests also run an onboard quality control assay alongside the patient test.

When a Test has completed and the OBC test has passed, the test result will be displayed as normal. Tapping on the *INFOICON* on the result screen at the end of the test or from the Result History view shows additional details about the test, including '**Control: Valid**' which confirms that the OBC has passed.

15:43	100%
Patient Test	Finish

JANE
MEYER
DOB: 02 Feb 1985 Gender: Female
Patient ID: 2_21985

SARS-CoV-2 IgG/IgM   ⓘ

Tested by: Dr. Ramoray
Tested on: 29 Nov 2019 22:33
Strip Lot: 5000001
Test Strip: 512
Expiry: 2021-10-24
Control: Valid
Sample type: Capillary Blood

NEGATIVE-
SARS-CoV-2 IgM   ›

Print	Comment
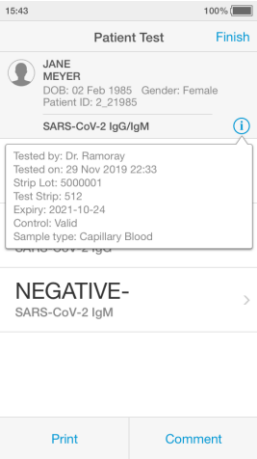
If the OBC fails, then an error message will be displayed and no test result will be returned. Follow the on screen instructions to dispose of the Test Strip and start a new test. If the problem persists, contact Customer Services.
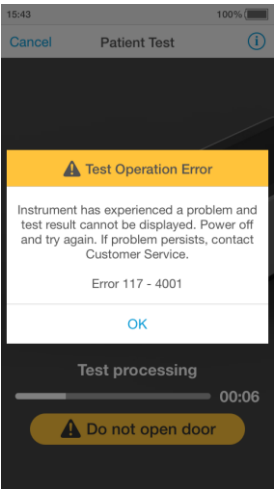
A test which fails the OBC will appear in the 'Invalid' filter of the Results History.
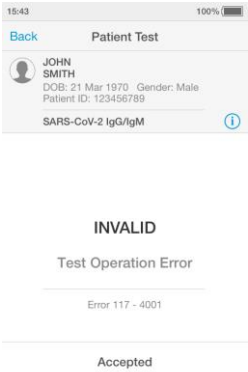
5.   Cleaning and Disinfecting

It is important to observe the disinfection guidelines of your organization. Below are procedures for cleaning and disinfecting the Instrument. Failure to follow these procedures may cause Instrument malfunction.

The difference between cleaning and disinfecting:

Cleaning is the physical removal of dirt or other foreign material from the Instrument surface.

Disinfecting is the chemical removal of harmful microorganisms (pathogens) from the Instrument.

When should the Instrument be cleaned and disinfected?

The Instrument should be cleaned whenever it is visibly dirty. The Instrument should be disinfected after each patient use and anytime you believe the Instrument may be contaminated with a patient sample or Quality Control solution.

What should be cleaned and disinfected?

The following parts of the Instrument can be cleaned and/or disinfected:

- The area around the Test Strip slot
- The entire Instrument housing
- The Instrument touch-screen
- All surfaces of the Instrument door

Do NOT attempt to put any objects or cleaning materials inside the Test Strip slot. Always use LumiraDx approved wipes to disinfect the Instrument. Details of LumiraDx approved wipes can be found at lumiradx.com. Avoid USB ports and power inlet.	⚠️

Cleaning Instrument touch-screen

Cleaning the area around the Test Strip slot

Cleaning procedure

Always wear gloves to clean the Instrument.

Wipe the external surfaces of the Instrument with a soft cloth slightly dampened, not wet. Excess liquid may damage the Instrument.

Disinfection procedure

This procedure should be followed to prevent the risk of blood-borne pathogen transmission after use on each patient and is recommended by the CDC [3].

Always wear gloves to disinfect the Instrument.

Always use LumiraDx approved wipes to disinfect the Instrument. Alcohol wipes alone are not sufficient to disinfect the Instrument.

Use the wipe until the surface of the Instrument is visibly wet. Allow surface to remain wet for **5 minutes**. Let air dry.

Dispose of the wipes in accordance with local procedures.

The Instrument is now ready to perform another test.

For technical assistance or questions and information about LumiraDx approved wipes go to lumiradx.com.

Only use LumiraDx recommended cleaning and disinfecting materials on the Instrument surfaces. Details of LumiraDx approved wipes can be found at lumiradx.com.

Always wear gloves whilst cleaning and disinfecting the Instrument.

Only use a damp and not wet swab or cloth for cleaning. Excess liquid may damage the Instrument.

Do NOT spray or pour solution directly onto the Instrument.

Do NOT attempt to put any objects or cleaning materials inside the Test Strip slot.

Following cleaning and disinfection, and before performing a patient test, change gloves and wash hands.

⚠

6.   Software Updates

LumiraDx will contact administrators when software updates are available. Software updates will be provided on USB memory sticks and should be installed on each Instrument by the administrator. Installing the latest updates will help ensure that the LumiraDx Instrument operates with optimum performance and that the latest features are available. This section describes the steps required to complete the software update.

Note: Ensure that the Instrument is connected to a power supply before whilst performing a software update.

1. Insert USB Memory Stick whilst the Instrument is switched off

Remove the USB Memory Stick from its packaging. Looking at the rear of the Instrument, insert into the right side USB port, nearest the power button.

2. Power on

Power on the Instrument by pressing the power button at the rear of the Instrument.

A progress bar on the Instrument display will indicate installation.

Once installation is completed the Instrument will power on as usual.

Remove the USB memory stick from the Instrument once completed.
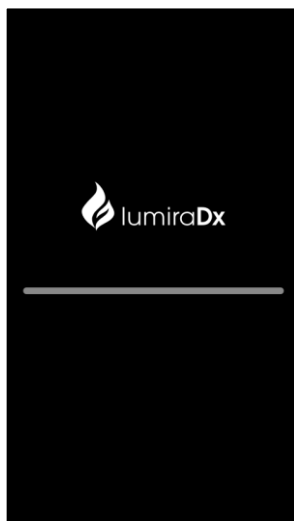
7.   Troubleshooting

The LumiraDx Instrument regularly performs internal checks for unexpected and unwanted conditions. These may arise for technical reasons or due to handling errors.

If an issue occurs, a message will be displayed on the Instrument touch-screen. Alert messages include useful information and are highlighted by an orange banner. Error messages also include a *HAZARD* symbol. All messages will contain a description of the Instrument status or error and an instruction. Error messages contain an identifying code that may be used for further troubleshooting purposes.

Follow the instruction to resolve the issue. If the issue is resolved, continue using the Instrument as required.

If errors occur frequently or the error persists, please note the error code and contact Customer Services. If the Instrument has been dropped, do not proceed with use. In this case, also contact Customer Services for advice. Refer to the "Customer Services" chapter of this Platform User Manual for contact information.

Example alert message:

Low Battery
6% of battery remaining.
OK
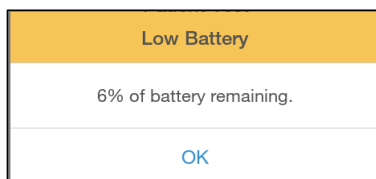
Description and Instruction

Tap 'OK' to proceed. Connect the power supply unit before the battery runs out.

Example error messages:

Error 002

⚠ Door Open
Door opened during test. Test cannot be completed. Dispose of Test Strip and start new test.
Error 002 - 3501
OK
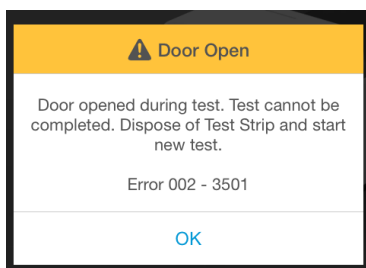
Description and instruction

The Instrument door has been opened while running a test so the test cannot be completed.

Dispose of Test Strip, start a new test and follow the instructions on the display.

Error 004

⚠ **Sample Detected**

Sample applied too early. Test cannot be completed. Dispose of Test Strip and start new test.

Error 004 - 3503

OK
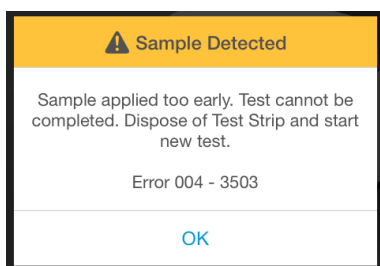
Description and instruction

Sample has been applied too early so the test cannot be completed.

Dispose of Test Strip, start a new test and follow the instructions on the display.

Error 006

⚠ **Instrument Not Level**

Instrument must be level and stationary to perform test. Place Instrument on level, stable surface and start new test.

Error 006 - XXXX

OK
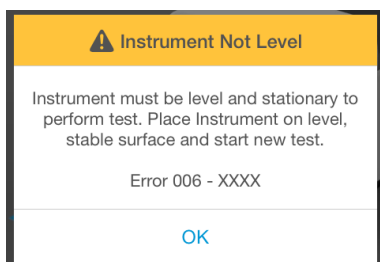
Description and instruction

When a test is performed the Instrument must be level and stationary.

Place the Instrument on a level, stable surface and start a new test.

Error 016

> **⚠ Test Timeout**
>
> Time exceeded to perform action. Test has timed out. Dispose of Test Strip and start again.
>
> Error 016 - XXXX
>
> **OK**
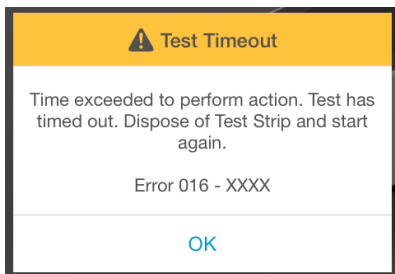
Description and instruction

An action (for example closing the Insrument door) has not been completed within a set time period so the test cannot be completed.

Dispose of Test Strip, start a new test and follow the instructions on the display.

Error 019

> **⚠ Hct Out of Range**
>
> Hematocrit out of range. Sample not suitable for test.
>
> Error 019 - 2105
>
> **OK**
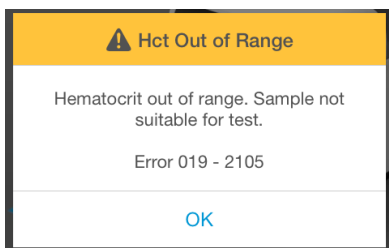
Description and instruction

The Hct value of the sample was detected to be out of range.

Check the allowed Hct range for the test type in the Test Strip Product Insert.

Error 038

> **⚠ Sample Error**
>
> Insufficient sample volume or Instrument has experienced a problem and cannot complete test. Dispose of Test Strip and start new test. If problem persists, contact Customer Service.
>
> Error 038 - 3605
>
> **OK**
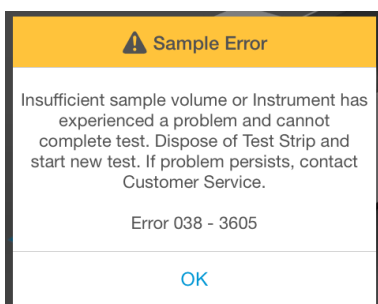
Description and instruction

Insufficient sample volume or Instrument has experienced a problem and cannot complete a test.

Dispose of the Test Strip, start a new test and follow the instructions on the application of samples in this User Manual. If the problem persists, contact Customer Services.

Error 117
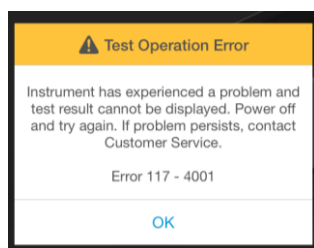
Description and instruction

Onboard Control has failed so the Instrument will not display a result. Power the Instrument off and try again. Contact Customer Services if the problem persists.

Errors and unusual behavior without error alerts

Some conditions may occur that do not result in an error or alert message. If the troubleshooting steps below do not resolve the issue or the problem reoccurs contact Customer Services.

Instrument does not power on	
If pressing the power button does not power on the Instrument:	1. Connect the power supply unit. Wait 15 minutes and press the power button.

Cannot login	
Do not have or know where to find the correct password:	1. Check tear out sheet in the Platform Quick Reference Guide for the login password, or contact the administrator. 2. Tap the password field to bring up the keyboard and enter the password. Tap 'Login' to proceed.

Cannot connect Instrument	
The Instrument is not displaying *LINKICON* symbol:	1. Check that the Instrument is within range of the LumiraDx Connect Hub or the device running the LumiraDx Connect App. 2. Ensure the LumiraDx Connect Hub is powered on and the green Connect light is on.

Lot Calibration File is not installed	
Lot Calibration File is not installed:	1. Refer to the "Getting Started" chapter of this Platform User Manual for instructions on how to install the Lot Calibration File. 2. Ensure that the back of the Test Strip Carton is touching the *RFIDICON* symbol on the side of the Instrument continually until the Instrument sounds and a confirmation message is displayed.

Instrument does not detect the Test Strip	
If the Test Strip is not detected and no message is displayed on the touch-screen:	1. Check that the Test Strip is fully inserted. 2. Check for damage to the Test Strip. If damaged discard and insert a new Test Strip.

The Instrument will not start the test	

If the Instrument will not start the test after applying the sample or Quality Control solution:	Check the Instrument door is fully closed.

Incorrect date or time	
If the date and time is incorrect:	Contact the administrator for "Connected" Instruments, or refer to the "First time setup" section of this Platform User Manual for instructions on setting date and time.

Patient test result is red	
If the patient test result is displayed in red:	Test results that are above or below the analytic range are displayed in red and indicated by the symbols > (above) or < (below).

QC test failure	
If the Quality Control test fails unexpectedly:	1. Check the Quality Control solution type and level matches the test type and QC range information.
	2. Check the expiry date of the Quality Control solution.
	3. Refer to the Quality Control Pack Insert to ensure correct procedure is followed.
	Retest using a new Test Strip. Ensure the Test Strip and Quality Control solution are handled carefully to prevent any contamination.

8.   Maintenance and Disposal

The LumiraDx Instrument does not require user maintenance and has no serviceable parts. No attempt should be made to open the Instrument.

Changes or modifications not expressly approved by LumiraDx UK Ltd could void the user's authority to operate the Instrument.

In case of Instrument failure or damage, or to arrange collection/disposal contact LumiraDx Customer Services.

9. Instrument Specifications

Operating temperature	15 °C to 30 °C (59 °F to 86 °F)
Storage temperature	-10 °C to 50 °C (14 °F to 122 °F)
Relative humidity	10 % to 90 % rh (non-condensing)
Maximum altitude	3,000 m (9,840 feet) operating
Data storage	1000 test results with date, time and comments Lot calibration files
Communications	2 x USB ports RFID Reader 13.56MHz, 0 dBi (EIRP) Bluetooth Low Energy 2.4GHz ISM band, 2400MHz to 2483.5 MHz, 0.5dBm (ERP)
Power supply unit	Input 100-240V / 50-60 Hz / 1.0 – 0.5A Output: 12 V / 3 A
Battery	Lithium Ion Polymer 7.4V 5000 mAh Approx. 20 tests per charge cycle
Dimensions	210 x 97 x 73 mm
Weight	1,100 g

10. Ancillary Devices

10.1 LumiraDx Barcode Scanner

In order to configure the LumiraDx Barcode Scanner please contact LumiraDx Customer Services.

The LumiraDx Barcode Scanner can be used to scan patient ID details when performing a patient test. It can also be used to scan Quality Control Lot numbers. If using a Connected Instrument, the Barcode Scanner can be used to scan User ID for login. Note: The same User ID must be assigned to the user in Connect Manager.

Barcode symbol on screen indicates that you can scan for data entry. Tap symbol for Barcode Scanner instructions.

Scanning distance

Hold scanner approximately 15 cm from barcode.

Scanner lights

Scan button

Press button to scan. A successful scan will be indicated by a beep sound and green light.

Insert USB connector into one of the USB ports at the rear of the Instrument.

LumiraDx Barcode Scanner Cradle

Attaching LumiraDx Barcode Scanner cradle to Instrument

Detaching LumiraDx Barcode Scanner cradle from Instrument

Note: Correct orientation of Barcode Scanner cradle

LumiraDx Desktop Stand

10.2   LumiraDx Printer

The LumiraDx Printer can be used to print a patient or Quality Control test result onto an adhesive label.

Patient and QC tests result can be printed from the Instrument result page following a test, or from the test details page in the Instrument Result History.

The Printer comes with a roll of adhesive paper already installed. Open the paper cup lid and then close ensuring that the paper passes through the paper exit slot. Replacement label rolls can be purchased from LumiraDx.

Insert the rechargeable batteries into the Printer followed by the USB cable and power cable. Fully charge the batteries for 16 hours before first use by connecting the Printer to a power source.

To use the Printer insert the USB connector into one of the USB ports at the rear of the Instrument and press the Printer power button.

Printer status light:

LED Indication	Condition	Solution
On	Printer On	-
Off	Printer Off	-
* * *	Paper Out	Fit new paper
** ** **	Thermal head too hot	Allow head to cool
*** *** ***	Battery cut-out (no charge remaining)	Recharge batteries
**** **** ****	Battery low (approx. 20% charge remaining)	Recharge batteries

10.3   LumiraDx USB Memory Stick

LumiraDx USB Memory Stick used for Instrument
software updates.

Note: Right side USB port nearest the power button
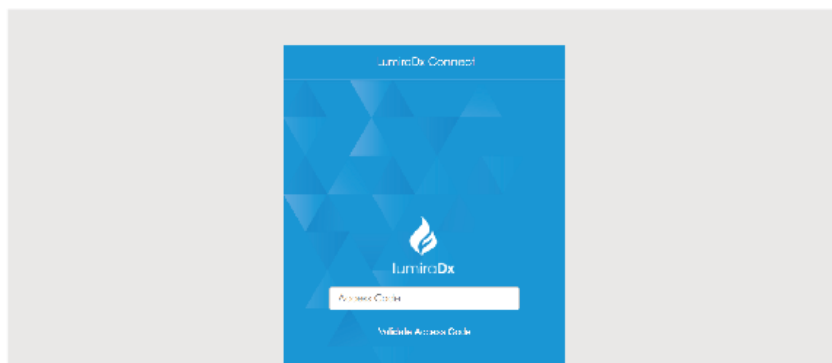at the rear of the Instrument must be used.

10.4   LumiraDx Connect Hub

10.3 LumiraDx Connect Hub

Refer to LumiraDx Connect User Manual and Connect Hub
Pack Insert for information and setup instructions

10.5   LumiraDx Connect App

Refer to LumiraDx Connect User Manual for
information and setup instructions.

11.   Customer Services

For product enquires please contact LumiraDx Customer Services at
customerservices@lumiradx.com.

For your local customer services phone number please visit the Customer Services page at
lumiradx.com

11.1   Warranty

Warranty – Limited Warranty.

LumiraDx Instrument – 2 Year Warranty from date of purchase.

LumiraDx Test Strips – As per shelf life.

For the applicable warranty period, LumiraDx warrants, to the original purchaser only, that each
product shall be (i) of good quality and free of material defects, (ii) function in accordance with
the material specifications referenced in the Product Insert or Platform User Manual, and (iii)
approved by the proper governmental agencies required for the sale of products for their
intended use (the "limited warranty"). If the product fails to meet the requirements of the
limited warranty, then as customer's sole remedy, LumiraDx shall either repair or replace, at
LumiraDx's discretion, the Instrument or Test Strips, as applicable. Except for the limited
warranty stated in this section, LumiraDx disclaims any and all warranties, express or implied,
including but not limited to, any warranty of merchantability, fitness for a particular purpose and
non-infringement regarding the product. LumiraDx's maximum liability with any customer claim
shall not exceed the net product price paid by customer. Neither party shall be liable to the other
party for special, incidental or consequential damages, including, without limitation, loss of

business, profits, data or revenue, even if a party receives notice in advance that these kinds of damages might result.

The limited warranty above shall not apply if the customer has subjected the LumiraDx Instrument or Test Strips to physical abuse, misuse, abnormal use, use inconsistent with the LumiraDx Platform User Manual or Product Insert, fraud, tampering, unusual physical stress, negligence or accidents. Any warranty claim by customer pursuant to the limited warranty shall be made in writing within the applicable limited warranty period.

Details of relevant Intellectual Property regarding this product can be found at lumiradx.com/IP.

Please contact Customer Services for further information about the LumiraDx Instrument third party copyright, privacy notice and general legal statements.

12. References

1.   World Health Organization (2009) Guidelines on hand hygiene in healthcare.
        http://www.who.int/gpsc/5may/tools/9789241597906/en/

2.   World Health Organization (2016) Guidelines on core components of infection
        prevention programs at the national and acute healthcare facility level.
        http://www.who.int/gpsc/ipc-components-guidelines/en/

3.   CDC Guideline for Isolation Precautions: Preventing Transmission of infectious Agents
        in Healthcare Settings 2007.
        https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html

4.   CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses
        Risk for Transmitting Bloodborne Pathogens:
        https://www.cdc.gov/injectionsafety/fingerstick-devicesbgm.html

13. Compliance

13.1 Environmental Practices

LumiraDx complies with all environmental legislation in each country where the product is sold. Please refer to lumiradx.com for further information.

13.2 Compliance

The LumiraDx Platform is for use with SARS-Cov-2 IgG IgM Test Strips and SARS-Cov-2 Ag Test Strips, under the Food and Drug Administration's Emergency Use Authorization only.

The LumiraDx Instrument has been tested and is compliant with:

CAN/CSA-C22.2 No. 61010-1-12 - Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements.

CAN/CSA-C22.2 No. 61010-2-101:15 - Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.

UL 61010-1 (Third Edition) - Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements.

UL 61010-2-101 (Second Edition) - Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.

Back Cover:

LumiraDx UK Ltd

Dumyat Business Park

Alloa FK10 2PB, UK

Commented [LS5]: Remove barcode, REF and L number

SPEC-32180 **Rev1**

ART-00410 **Rev1**

Rev date xxxx/xx

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For product and connectivity support please contact LumiraDx Customer Services at customerservices@lumiradx.com