ENGLISH

lumiraDx™ SARS-CoV-2 Ag Test

For Professional Use Only
For Emergency Use Authorization (EUA) Only
***For In Vitro* Diagnostic Use**

REF LD1600010R048

IVD Rx Only

SPEC-32311 R13 ART-00570 R14 Date of Revision 2025-06

LumiraDx SARS-CoV-2 Ag Test

The LumiraDx Severe Acute Respiratory Syndrome (SARS) CoV-2 Antigen (Ag) Test Strips (hereafter referred to as Test Strips) are to be used with the LumiraDx Platform. The LumiraDx Platform is a point of care system for professional use which is used for *in vitro* diagnostic tests. It comprises a portable LumiraDx Instrument and a LumiraDx Test Strip for the required test. This test is for **HEALTHCARE PROFESSIONAL USE ONLY** and allows users to perform tests using small sample volumes and to view results quickly on the Instrument touchscreen.

Intended use

The LumiraDx SARS-CoV-2 Ag Test is a rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2. In direct anterior nasal swab and nasopharyngeal swab specimens collected by a healthcare provider from individuals who are suspected of COVID-19 within the first twelve (12) days of symptom onset when tested at least twice over three days with at least 48 hours between tests and from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet the requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The LumiraDx SARS-CoV-2 Ag Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal swab and nasopharyngeal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease.

All negative results are presumptive and confirmation with a molecular assay, if necessary, for patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of a patient's recent exposures, history and presence of clinical signs and symptoms consistent with COVID-19.

The LumiraDx SARS-CoV-2 Ag Test is intended for use by medical professionals or operators who are proficient in performing tests in point of care settings.

The LumiraDx SARS-CoV-2 Ag Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

Caution: For *in vitro* diagnostic use.

Before you start testing, if you are new to the LumiraDx Instrument and LumiraDx Platform, you must read the LumiraDx Platform User Manual, the LumiraDx SARS-CoV-2 Ag Test Quick Reference Instructions and this entire Product Insert. In addition you can view the LumiraDx Platform Training Video available at **go.roche.com/lumiradx**.

Summary and explanation of the Test

The World Health Organization (WHO) have named the disease caused by SARS-CoV-2 virus as coronavirus 2019 or COVID-19[1]. The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, headache, conjunctivitis, sore throat, diarrhea, loss of taste or smell, or a rash on skin or discoloration of fingers or toes. These symptoms are usually mild and begin gradually. Some people become infected but do not develop any symptoms and do not feel unwell. However, the disease can develop rapidly and have high morbidity in certain populations, especially those with underlying health conditions. The disease can spread from person to person through small droplets from the nose or mouth which are spread when a person with COVID-19 coughs or exhales. Most estimates of the incubation period for COVID-19 range from 2-14 days[2].

The use of a LumiraDx SARS-CoV-2 Ag Test will enable the physician to verify infection quickly, begin proper treatment and to initiate isolation precautions helping prevent further spread of infection.

Principle of the assay

The LumiraDx SAR-CoV-2 Ag Test is a single use fluorescence immunoassay device designed to detect the presence of the nucleocapsid protein antigen directly from SARS-CoV-2 in either anterior nasal swab or nasopharyngeal swab samples, without transport media.

The test procedure involves collecting an anterior nasal swab or nasopharyngeal swab sample using a recommended swab which is eluted into a vial containing Extraction Buffer. A single drop of the sample in Extraction Buffer is added to the Test Strip using the vial dropper cap provided. The LumiraDx Instrument is programmed to perform the test protocol using the dried reagents contained within the Test Strips. The test result is determined from the amount of fluorescence the Instrument detects within the measurement zone of the Test Strip. The concentration of the analyte in the sample is proportional to the fluorescence detected. The results are displayed on the Instrument touchscreen within 12 minutes from the addition of the sample.

Materials provided

- LumiraDx Test Strips packed individually in sealed desiccant foil pouches.
- LumiraDx Test Product Insert
- RFID (Radio frequency ID) Tag held inside the Test Strip carton
- Extraction Buffer Vials
- Dropper Lids
- LumiraDx SARS-CoV-2 Ag Test Quick Reference Instructions

Materials required but not provided with the Test Strip carton

- LumiraDx Instrument
- LumiraDx SARS-CoV-2 Ag Quality Controls (as required to meet local and organisational compliance)
- LumiraDx Connect if connectivity required (refer to LumiraDx Connect User Manual)
- Standard nasal or nasopharyngeal collection equipment
- Please visit go.roche.com/lumiradx for a list of anterior nasal and nasopharyngeal swabs validated for use with the LumiraDx SARS-CoV-2 Ag test

Warnings and precautions

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- For *in vitro* diagnostic use
- For prescription use only.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories; use by laboratories certified under the CLIA that meet the requirements to perform moderate, high or waived complexity tests.This product is authorized for use at the Point of Care (POC), i.e. in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- If the patient has had symptoms longer than 12 days, consider testing at least three times over five days with at least 48 hours between tests.
- Do not open the test strip until ready for immediate use.
- Discard and do not use any damaged or dropped Test Strips or other materials.
- Check the integrity of the individual swab packaging for damage. If damaged discard and do not use.
- Discard and do not use any damaged or dropped Nasal collection swabs.
- Only use the LumiraDx validated swabs listed at go.roche.com/lumiradx for use with the LumiraDx SARS-CoV-2 Ag test when collecting anterior nasal swab or nasopharyngeal swab specimens.
- Ensure the appropriate swab type is used to collect the anterior nasal swab or nasopharyngeal swab specimen.
- To avoid sample contamination avoid touching the swab sampling head before and after sample collection.
- Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results.
- The test cannot be visually interpreted; the LumiraDx Instrument must be used to generate results.
- Do not use the kit components beyond the expiration date
- Test components are single-use. Do not re-use.
- Do not mix components from different kit lots.
- Samples must be processed as indicated in the Sample Extraction and Performing a Test sections of this Product Insert.
- All components of this kit should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.
- Refer to the product safety data sheet for risk and safety phrases and disposal information. The product safety data sheet is available via our website at **go.roche.com/lumiradx**.
- Exercise the normal precautions required for handling all laboratory reagents. Wear protective clothing such as laboratory coats, disposable gloves, safety mask and eye protection when samples are collected and evaluated.
- Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2 patient samples. Patient swabs, used Test Strips and used extraction buffer vials may be potentially infectious. Proper handling and disposal methods for the test result is established by the laboratory in accordance with local, state and federal regulations.
- Reagents encapsulated within the Test Strip are present in extremely small amounts however, should any reagent become exposed it should be treated as potentially infectious.
- Be careful to minimize the risks of cross-contamination when testing patient specimens, which can cause false positive results. Insufficient cleaning of the workspace, insufficient disinfection of the instrument, or inappropriate use of protective equipment (for example, failing to change gloves between patients) can increase the risk of cross-contamination between specimens with subsequent false positive results. Consider the CDC guidance available at **https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html** for changing gloves and cleaning work area between specimen handling and processing.
- Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. Wash hands after use. Do not use solvents, chemicals (see table below), if the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. **If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**

Chemical Name	Concentrations	GHS Code
Hydrochloric acid	< 0.01%	H302, H315, H320
Sodium azide	0.09%	H302, H315, H320

- For more information on EUAs please visit: https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergencyuse-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

Storing the Test Strips

Store the Test Strips in their original carton. You can store the Test Strips at a temperature between 2°C and 30°C, (36°F and 86°F). Avoid freezing or storing in any area that could exceed 30°C. When stored properly the Test Strips can be used until the expiration date printed on the Test Strip foil pouch and the Test Strip carton. Discard the Test Strips if they are beyond the expiration date.

Handling the Test Strips

When you are ready to perform a test, open the Test Strip carton, take out a Test Strip, and remove it from the foil pouch. Hold the Test Strip by gripping the blue label end with the label facing upward. Do not touch Test Strip Sample Application Area. Do not bend or fold the Test Strip. Do not touch Test Strip contacts. After removing the Test Strip from the foil pouch, it should be used immediately. Do not use the Test Strip if there are any visible signs of damage to the foil pouch such as tears or holes.

Sample material

The following samples can be used with the LumiraDx SARS-CoV-2 Ag Test Strip:

- Anterior Nasal Swab Sample (NS)
- Nasopharyngeal Swab Sample (NPS)

The Test device contains

- Rabbit and mouse monoclonal antibodies
- Fluorescent particles
- Magnetic particles
- Buffer and stabilizing agents

Preparing the Instrument to perform a Test

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.

Refer to the section on **Performing a Test** in this Product Insert for information on how to test a Patient sample. The LumiraDx Quick Reference Instructions (QRI) provide an illustrated step-by-step procedure on how to run a Test. Operate the LumiraDx Platform at room temperature between 15°C and 30°C (59°F and 86°F) and 10% - 75% relative humidity

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.

Lot Calibration File installation

Lot Calibration Files are required to provide the Instrument with information needed to perform diagnostic tests. This only needs to be completed once for each Test Strips Lot.The Instrument will prompt to install the Lot Calibration File when inserting a new Test Strip Lot.

RFID chip code reader

Locate ((( ))) symbol on Instrument.

Installation

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



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

When indicated by the touchscreen, open the foil pouch just before use and insert the LumiraDx Test Strip into the LumiraDx Instrument.The Instrument will indicate when it is ready for the sample to be applied.

The LumiraDx SARS-CoV-2 Ag Test results should be evaluated by a Healthcare Professional in the context of all available clinical and laboratory data.

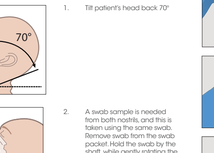
Instructions for sample collection

When collecting any type of sample, follow universal collection precautions and guidelines according to your organization. For collection of anterior nasal swabs and nasopharyngeal swabs, follow the Centers for Disease Control and Prevention (CDC) Swab Collection Guidelines and swab manufacturers' recommendations. Users should be trained in appropriate sample collection and handling procedures.

The steps that follow apply to an anterior nasal swab and nasopharyngeal swab.

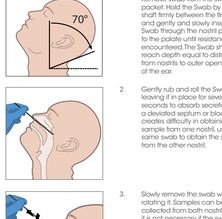
Please visit go.roche.com/lumiradx for a list of anterior nasal and nasopharyngeal swabs validated by LumiraDx for use with the LumiraDx SARS-CoV-2 Ag test.

Sampling from an anterior nasal swab



1. Tilt patient's head back 70°
2. A swab sample is needed from both nostrils, and this is taken using the same swab. Remove swab from the swab packet. Hold the swab by the shaft, while gently rotating the swab, insert swab less than one inch into the first nostril until resistance is met at Turbinates. (Turbinates are the small structures inside the nose).
3. Rotate the swab at least 4 times against the nasal wall for 10-15 seconds. Remove and repeat this process by using the same swab into the second nostril. Then place the Swab into the Extraction Vial. See instructions for Sample Extraction.

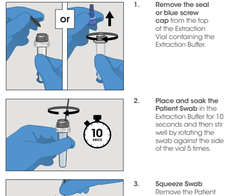
Sampling from a nasopharyngeal swab



1. Tilt patients head back 70°. Remove swab from the swab packet. Hold the Swab by the shaft firmly between the fingers and gently and slowly insert Swab through the nostril parallel to the palate until resistance is encountered.The Swab should reach depth equal to distance from nostrils to outer opening of the ear.
2. Gently rub and roll the Swab, leaving it in place for several seconds to absorb secretions. If a deviated septum or turbinate blockage creates difficulty in obtaining the sample from one nostril, use the same swab to obtain the sample from the other nostril.
3. Slowly remove the swab while rotating it. Samples can be collected from both nostrils, but it is not necessary if the swab is saturated with fluid from the first nostril. Remove and then place the swab in the Extraction vial. See instructions for Sample Extraction.

After patient swabbing, process the Swab in the Extraction Vial as soon as possible, but do not place the swab back into the swab packaging sleeve after sample collection.

Instructions for sample extraction



1. **Remove the seal or blue screw cap** from the top of the Extraction Vial containing the Extraction Buffer.
2. **Place and soak the Patient Swab** in the Extraction Buffer for 10 seconds and then stir well by rotating the swab against the side of the vial 5 times.
3. **Squeeze Swab** Remove the Patient Swab while squeezing the middle of the Extraction Vial to remove the liquid from the swab. Discard the swab in biohazard waste.
4. **Firmly attach the clear or purple Dropper Lid** to the top of the Extraction Vial. The extracted sample must be used within 5 hours of preparation when stored at room temperature. Extracted nasal or nasopharyngeal swab samples may be frozen at -80°C and used up to 5 days after freezing.
5. **Gently invert the Extraction Vial** five times just before applying the sample to the Test Strip.

Performing a Test (refer to the Quick Reference Instructions to make sure that your Instrument has been prepared before starting this step).

If using a frozen sample, the sample must be at room temperature before testing.

1. **Gently invert** the Extraction Vial five times (5x) just before applying the sample to the Test Strip.
2. **Apply the extracted sample from the Extraction Vial** onto the Sample Application Area of the inserted Test Strip.To do this gently press the sides of the extraction vial until **one whole drop** is visible and allow it to touch the Sample Application Area of the Test Strip. The sample will then be drawn by capillary action into the Test Strip. When the sample is applied the Instrument will sound (if sounds are enabled) and a confirmation message will be displayed.The touchscreen of the LumiraDx Instrument will request the user to **immediately close the door (Note: you have 10 seconds only to close the door).**
3. **Do not add more than one drop of sample.** Do not open the door while the test is in progress.The touchscreen will indicate test progress.
4. **The result** will appear on the Instrument touchscreen within 12 minutes of applying the sample and starting the test.The results will be displayed as a **positive or negative result SARS-CoV-2Ag** on the Instrument screen. (see Fig 1. and Fig 2).
5. **Dispose** of the swab, Extraction Vial and Test Strip in the appropriate biohazard waste.
6. **Disinfection** of the Instrument with LumiraDx approved materials is recommended if contamination is suspected and at least once per day when in use. A list of approved disinfecting materials is available at go.roche.com/lumiradx. Use the wipe until the surface of the Instrument is visibly wet. Allow the surface to remain wet for **1 minute** and let air dry.
7. **If you need to retest,** you will use a new Test Strip. Use the same extraction vial and repeat the test.The extracted sample must be used within 5 hours of preparation when stored at room temperature. Extracted nasal and nasopharyngeal swab samples may be frozen at -80°C and used up to 5 days after freezing.

Interpretation of Results

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

COVID-19 Positive (+)

The result will be displayed on the Instrument screen - example of positive result screen display:



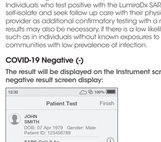
Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self- isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the LumiraDx SARS-CoV-2 Ag test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

COVID-19 Negative (-)

The result will be displayed on the Instrument screen - example of negative result screen display:



To increase the chance that the negative result for COVID-19 is accurate, you should:

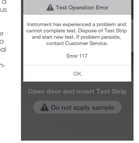
- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19.There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If there is a high suspicion of COVID-19 like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with their physician or healthcare provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Invalid test results

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 ⚠ 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. Refer to the LumiraDx Platform User Manual if an error message is displayed on the LumiraDx Instrument touch-screen and contact Customer Support on telephone number **1-800-800-5973.**



Example of an error screen

If the On Board Control (OBC) fails, an error message will be shown and no test result will be returned. Follow the on screen instructions to dispose of the Test Strip and start a new test with a new Test Strip and a new drop of extracted sample. If the problem persists, contact Customer Support.

Built-in controls

The Instrument reads the 2D bar code on each Test Strip and can identify if the strip has exceeded the expiry date for use, and if the strip Lot Calibration file has not yet been loaded, at which point it will request it.

The LumiraDx Instrument and LumiraDx SARS-CoV-2 Ag Test Strips have several quality control functions integrated to ensure validity of each test run.These checks ensure that a sufficient sample is applied and that the assay sequence of the Test Strip is as expected.The checks also ensure that the Test Strip has not been damaged or used previously. If these checks are not verified, the test run will be rejected and an error message displayed on the Instrument touchscreen.

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.
- Ability to perform iQuality Control Tests using LumiraDx iQuality Control solutions to meet regulatory compliance requirements.

External Quality Controls

External liquid iQuality Controls for SARS-CoV-2 Ag are available from LumiraDx and may be used to demonstrate that the Test is functioning properly by demonstrating the correct Instrument and Test Strip product test performance by the operator.External iQuality Control requirements should be established in accordance with applicable local and federal regulations or accreditations requirements. It is recommended that external control testing be performed with each new operator and before using a new lot or shipment of the LumiraDx SARS-CoV-2 Ag Test.Refer to the LumiraDx SARS-CoV-2 Ag iQuality Controls pack insert available at **go.roche.com/lumiradx** for detailed instructions.

LumiraDx SARS-CoV-2 Ag Quality Controls are purchased separately.

If the LumiraDx SARS-CoV-2 Ag Quality Controls do not perform as expected, do not run any tests, but repeat the control test. If you still do not support patient results and contact Customer Support on telephone number **1-800-800-5973.**

Cleaning and disinfection

Cleaning and disinfection of the Instrument should follow and be performed according to established site protocols and schedules.

To clean the Instrument wipe the external surfaces with a soft, slightly damp cloth when it appears visibly dirty.

It is recommended to disinfect the Instrument if contamination is suspected and at least once per day when in use with LumiraDx approved materials. Details of LumiraDx approved disinfectant materials can be found at go.roche.com/lumiradx. Use the material until the surface of the Instrument is visibly wet. Allow the surface to remain wet for **1 minute** and let air dry. **Avoid USB ports and power inlet. Do not spray or pour solution directly onto the Instrument. Do not put any objects or cleaning materials into the Test Strip slot.**

Limitations

- This test detects both viable (live) and non-viable, SARS-CoV and SARS-CoV-2 Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- Test results should be considered in the context of all available clinical and diagnostic information, including patient history and other test results.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- If the test is positive, then patients from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between June 2020 and March 2021. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- Clinical performance was established on frozen samples and performance may be different with fresh clinical samples.
- Users should test samples as quickly as possible after sample collection.
- Extracted anterior nasal samples or nasopharyngeal samples may be frozen at -80°C and used up to 5 days after freezing.
- Swab samples and Extraction buffer must be at room temperature before testing.
- Positive test results do not rule out co-infection with other pathogens
- A false negative result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected inappropriately, therefore a negative test result does not rule out the possibility of SARS-CoV-2 infection.
- The amount of antigen in a sample may decrease as the duration of illness increases. Samples collected after 12 days are more likely to be negative compared to RTPCR.
- The contents of this kit are for qualitative detection of SARS-CoV-2 antigens from nasal swab and nasopharyngeal samples only.
- For information on swabs that have been validated by LumiraDx for use with the LumiraDx SARS-CoV-2 Ag Test please visit go.roche.com/lumiradx.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests . This means that there is a higher chance this test will give a negative result in an individual with COVID-19 as compared to a molecular test especially in patients with low viral load.

Conditions of Authorization for the Laboratory

The LumiraDx SARS-CoV-2 Ag Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website:

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas.

However, to assist clinical laboratories using the LumiraDx SARS-CoV-2 Ag Test ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

- Authorized laboratories[1] using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.
- Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must collect information on the performance of your product and must report any significant deviations from the established performance characteristics of your product of which they become aware to DMD/CHITT/OPEQ/CDRH (via email: **CDRH-EUA-Reporting@fda.hhs.gov**) and you (if applicable).[2]
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- You, authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1] The letter of authorization refers to "laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet the requirements to perform moderately high or waived complexity tests.This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation," as "authorized laboratories."

Clinical performance – Anterior Nasal Swab

The performance of the LumiraDx SARS-CoV-2 Ag Test was established with 297 direct nasal swabs prospectively collected from individual subjects between June 2020 and July 2020 during the 2020 COVID-19 pandemic. Samples were collected from sequentially enrolled subjects who presented with symptoms of COVID-19 (159) or key workers (98) at increased risk of infection. No positive results were observed from patients without symptoms or beyond 12 days of symptom onset. Dual nasal swabs were simultaneously collected and then randomly allocated to testing with the LumiraDx test or an EUA RTPCR assay. Samples were collected from 6 sites across the United States (5) and United Kingdom (1), including four sites in which minimally trained operators collected and tested fresh samples.

Swabs were collected and extracted into the LumiraDx extraction buffer without transport media. Samples were tested fresh or frozen within 1h of collection and stored until tested.Samples were thawed and sequentially tested according to the Product Insert, with operators blinded to the RTPCR result.The performance of the LumiraDx SARS-CoV-2 Ag Test was compared to the results from anterior nasal swabs collected into 3ml universal transport medium (UTM) and tested with an EUA RTPCR method.

Patient demographics

Patient demographics (age, time elapsed since onset of symptoms) are available for the 257 samples used in the study.The table below shows the positive results broken down by age of the patient:

Age	LumiraDx SARS-CoV-2 Ag (n = 81)		
	Total #	Positive	Prevalence
≤ 5 years	13	0	N/A
6 to 21 years	29	6	20.7%
22 to 59 years	200	70	35.0%
≥ 60 years	15	5	33.3%

Positive results broken down by days since symptom onset

Days since symptom onset	Cumulative RT-PCR Positive(+)	Cumulative LumiraDx Positive(+)	PPA	95% Confidence interval	
0	6	6	100.0%	61.0%	100.0%
1	12	12	100.0%	75.8%	100.0%
2	28	28	100.0%	87.9%	100.0%
3	37	37	100.0%	90.6%	100.0%
4	55	54	98.2%	90.4%	99.7%
5	61	60	98.4%	91.3%	99.7%
6	67	66	98.5%	92.0%	99.7%
7	73	72	98.6%	92.6%	99.8%
8	75	74	98.7%	92.8%	99.8%
9	75	74	98.7%	92.8%	99.8%
10	77	76	98.7%	93.0%	99.8%
11	80	79	98.8%	93.3%	99.8%
12	83	81	97.6%	91.6%	99.3%

Final data analysis is presented below

Reference RT-PCR Assay							95% Wilson Score CI	
							LCI	UCI
LumiraDx SARS-CoV-2 Ag Test		POS	NEG	Total	PPA	97.6%	91.6%	99.3%
	POS	81	6	87	NPA	96.6%	92.7%	98.4%
	NEG	2	168	170	Prevalence	32.3%	26.9%	38.2%
	TOTAL	83	174	257				

PPA - Positive Percent Agreement (Sensitivity)
NPA – Negative Percent Agreement (Specificity)
UCI – Upper Confidence Interval
CI - Confidence Interval
LCI – Lower Confidence Interval

Clinical Performance – Nasopharyngeal Swabs

The performance of the SARS-CoV-2 Ag Test was established with 255 nasopharyngeal swabs prospectively collected from individual subjects between August 2020 and September 2020 during the 2020 COVID pandemic. Subjects were presenting with symptoms of COVID-19 being screened for infection. Samples were collected from 6 sites across the United States. Swabs were collected and extracted into the LumiraDx Extraction Buffer. Samples were tested fresh within 1h of collection and tested according to the Product Insert.The performance of the LumiraDx SARS-CoV-2 Ag Test was compared to the results from nasopharyngeal samples collected into 3ml universal transport medium (UTM) and tested with an EUA authorized PCR method.

Patient demographics

Patient demographics (age, time elapsed since onset of symptoms) are available for the 255 samples used in the study.The table below shows the positive results broken down by age of the patient:

Age	LumiraDx SARS-CoV-2 Ag (n = 39)		
	Total #	Positive	Prevalence
≤ 5 years	22	0	0.0%
6 to 21 years	59	9	15.3%
22 to 59 years	150	28	18.7%
≥ 60 years	24	2	8.3%

Positive and negative results broken down by days since symptom onset

Days since symptom onset	Cumulative PCR Positive (+)	LumiraDx Positive (+)	PPA	LCI	UCI	NPA	LCI	UCI
0	2	2	100.0%	34.2%	100.0%	100.0%	75.8%	100.0%
1	6	6	100.0%	61.0%	100.0%	100.0%	93.4%	100.0%
2	9	9	100.0%	70.1%	100.0%	100.0%	96.2%	100.0%
3	17	17	100.0%	81.6%	100.0%	98.6%	94.9%	99.6%
4	22	22	100.0%	85.1%	100.0%	98.8%	95.7%	99.7%
5	23	23	100.0%	85.7%	100.0%	98.4%	95.3%	99.4%
6	26	26	100.0%	87.1%	100.0%	98.5%	95.6%	99.5%
7	34	34	100.0%	89.8%	100.0%	98.5%	95.7%	99.5%
8	36	36	100.0%	90.4%	100.0%	98.6%	95.8%	99.5%
9	36	36	100.0%	90.4%	100.0%	98.6%	95.9%	99.5%
10	39	38	97.4%	86.8%	99.5%	98.1%	95.2%	99.3%
11	40	39	97.5%	87.1%	99.6%	97.7%	94.6%	99.0%
12	40	39	97.5%	87.1%	99.6%	97.7%	94.7%	99.0%

Final data analysis is presented below

Reference RT-PCR Assay							95% Wilson Score CI	
							LCI	UCI
LumiraDx SARS-CoV-2 Ag Test		POS	NEG	Total	PPA	97.5%	87.1%	99.6%
	POS	39	5	44	NPA	97.7%	94.7%	99.0%
	NEG	1	210	211	Prevalence	15.7%	11.7%	20.7%
	TOTAL	40	215	255				

NIH study on three Lateral Flow OTC rapid Antigen tests (Not including LumiraDx)

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app.Two-day serial antigen testing is defined as performing two antigen tests 36 - 48 hours apart.Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test with serial testing in individuals is described in the table below.

Note: This study was not performed using LumiraDx assay.

Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in the study combined (LumiraDx not included in this study), however, the data is being applied to all antigen tests to support serial testing.

Days after first PCR Positive Test Result	Asymptomatic on first day of testing			Symptomatic on first day of testing		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)	-	4/9 (44.4%)	3/7 (42.9%)	-

1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.

2 Tests = two (2) tests performed an average of 48 hours apart.The first test performed on the indicated day and the second test performed 48 hours later.

3 Tests = three (3) tests performance an average of 48 hours apart.The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

Analytical performance

Limit of Detection - LOD (analytical sensitivity)

Limit of Detection (LoD) studies determined the lowest detectable concentration of SARS-CoV-2 at which 100% of all (true positive) replicates test positive. The LoD for the LumiraDx SARS-CoV-2 Ag test was established using limiting dilutions of gamma-irradiated SARS-CoV-2 (BEIResources NR-52287). The NR-52287 is a preparation of SARS-Related Coronavirus 2 (SARS-CoV-2), isolate USA-WA1/2020, that has been inactivated by gamma-irradiation at 5 x 10^6 RADs. The material was supplied frozen at a concentration of 2.8 x 10^5 $TCID_{50}$/mL.

Limit of Detection (LoD) screening

An initial LoD screening study was performed using a 5-fold serial dilutions (six dilutions in total) of the gamma-irradiated virus made in pooled negative human nasal matrix starting at a test concentration of 2 x 10^5 $TCID_{50}$/mL (as shown in table below) and processed for each study as described above. These dilutions were tested in triplicate.The volume of solution spiked onto each swab was 50µL.The lowest concentration at which all (3 out of 3 replicates) were positive was chosen for LoD Range finding.This was 32 $TCID_{50}$/mL. Based upon the testing procedure for this study the LoD of 32 $TCID_{50}$/mL equates to 1.6 $TCID_{50}$/swab.

SARS-CoV-2 tested ($TCID_{50}$/mL)	Test result
20000	3/3 positive
4000	3/3 positive
800	3/3 positive
160	3/3 positive
32	3/3 positive
6.4	0/3 positive

Limit of Detection range finding

Using the 32 $TCID_{50}$/mL concentration, the LoD was further refined using a 2-fold dilution series (four dilutions in total) of the gamma-irradiated SARS-CoV-2 virus made in pooled negative human nasal matrix.These dilutions were tested in triplicate. The lowest concentration at which all (3 out of 3 replicates) were positive was treated as the tentative LoD for the LumiraDx SARS-CoV-2 Ag Test.This was 32 $TCID_{50}$/mL.

SARS-CoV-2 tested ($TCID_{50}$/mL)	Test result
32	3/3 positive
16	0/3 positive
8	1/3 positive
4	0/3 positive

Limit of Detection (LoD) confirmation

The LoD of the LumiraDx SARS-CoV-2 Ag Test was then confirmed by testing 20 replicates with concentrations at the tentative Limit of Detection. The final LoD of the LumiraDx SARS-CoV-2 Ag Test was determined to be the lowest concentration resulting in positive detection of twenty (20) out of twenty (20) replicates. Based on this testing the LoD for nasal swab samples was confirmed as: 32 $TCID_{50}$/mL. Based upon the testing procedure for this study the LoD of 32 $TCID_{50}$/mL equates to 1.6 $TCID_{50}$/swab.

Starting Material Concentration	Estimated LOD	No. Positive/Total	% Positive
2.8 x 10^5 $TCID_{50}$/mL	32 $TCID_{50}$/mL	20/20	100

Omicron Testing

The performance of this test device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant.This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. Specimen pools were prepared by the RADx® team using clinical pooled samples from currently circulating Omicron strains and tested by RADx® to assess performance with the Omicron variant. Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have different clinical performance compared to other EUA-authorized tests. Compared to an EUA-authorized RT-PCR method, the SARS-CoV-2 Ag test detected 100% of five virus Omicron samples at a Ct-value of 23.6 (n=5). Less than 50% of Omicron dilutions at Ct-values of 24.0 and 24.8 were detected (n=5). Omicron dilutions at lower viral concentrations (Ct-values greater than 25.8 for live virus) were not detected by LumiraDx SARS-CoV-2 Ag test in this study.See summary data table below.

Omicron Pool 2 - Live Dilution		Assay #1	Assay #2	LumiraDx SARS-CoV-2 Ag Test*
	Ct:N2 Ave.	Percent Positive (n=5)	Percent Positive (n=5)	Percent Positive (n=5)
Dilution 1	19.8	100	100	100
Dilution 2	20.8	100	100	100
Dilution 3	21.5	100	100	100
Dilution 4	22.7	100	100	100
Dilution 5	23.6	100	0	100
Dilution 6	24.0	60	0	40
Dilution 7	24.8	0	0	20
Dilution 8	25.8	0	0	0
Dilution 9	27.4	0	0	0
Dilution 10	28.1	0	0	0
Dilution 11	29.1	0	0	0

*Testing was conducted using a multiplexed version of the test, which comprises the same SARS-CoV-2 test design and components.

Cross-reactivity (analytical specificity) and microbial interference studies

Cross-reactivity and interference of the LumiraDx SARS-CoV-2 Ag Test was evaluated by testing a panel of related pathogens, high prevalence disease agents and normal or pathogenic flora including various microorganisms and viruses and negative matrix that are reasonably likely to be encountered in the clinical sample and could potentially cross-react or interfere with the LumiraDx SARS CoV-2 Ag Test.Each organism and virus were tested in the absence or presence of heat inactivated SARS-CoV-2 at 3 x LoD.

Microorganism	Source	Concentration	Cross-Reactivity (Yes/No)	Interference (Yes/No)
Human coronavirus 229E	Zeptometrix	1 x 10^5 PFU/mL	No (3/3 negative)	No (3/3 positive)
Human coronavirus OC43	Zeptometrix	1 x 10^5 PFU/mL	No (3/3 negative)	No (19/20 positive)
Human coronavirus NL63	Zeptometrix	9.87 x 10^3 PFU/mL	No (3/3 negative)	No (3/3 positive)
MERS coronavirus	Zeptometrix	7930 PFU/mL	No (2/2 negative)	No (3/3 positive)
Adenovirus (e.g. C1 Ad. 71)	Zeptometrix	1 x 10^5 PFU/mL	No (3/3 negative)	No (3/3 positive)
Human Metapneumovirus (HMPV)	Zeptometrix	1 x 10^5 PFU/mL	No (3/3 negative)	No (3/3 positive)
Parainfluenza virus Type 1	Zeptometrix	1 x 10^5 PFU/mL	No (3/3 negative)	No (3/3 positive)
Parainfluenza virus Type 2	Zeptometrix	1 x 10^5 PFU/mL	No (3/3 negative)	No (3/3 positive)
Parainfluenza virus Type 3	Zeptometrix	1 x 10^5 PFU/mL	No (3/3 negative)	No (3/3 positive)
Parainfluenza virus Type 4a	Zeptometrix	1 x 10^5 PFU/mL	No (3/3 negative)	No (3/3 positive)
Influenza A H3N2 (Wisconsin/67/05)	Zeptometrix	8.82 x 10^3 PFU/mL	No (3/3 negative)	No (3/3 positive)
Influenza A H1N1	Zeptometrix	1 x 10^5 PFU/mL	No (3/3 negative)	No (3/3 positive)
Influenza B (Malaysia/2506/04)	Zeptometrix	2.92 x 10^3 PFU/mL	No (3/3 negative)	No (19/20 positive)
Enterovirus	Zeptometrix	1 x 10^5 PFU/mL	No (3/3 negative)	No (3/3 positive)
Respiratory syncytial virus	Zeptometrix	1 x 10^5 PFU/mL	No (3/3 negative)	No (3/3 positive)
Rhinovirus	Zeptometrix	4.17 x 10^3 PFU/mL	No (3/3 negative)	No (3/3 positive)
Haemophilus influenzae	Zeptometrix	1 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 positive)
Streptococcus pneumoniae	Zeptometrix	1 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 positive)
Streptococcus pyogenes	Zeptometrix	1 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 positive)
Candida albicans	Zeptometrix	1 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 positive)
Pooled human nasal wash	LumiraDx	14% v/v	No (3/3 negative)	No (3/3 positive)
Bordetella pertussis	Zeptometrix	1 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 positive)
Mycoplasma pneumoniae	ATCC	1 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 positive)
Chlamydia pneumoniae	ATCC	1 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 positive)
Legionella pneumophila	Zeptometrix	1 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 positive)
Mycobacterium tuberculosis	Zeptometrix	1 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 positive)
Pneumocystis jirovecii	Zeptometrix	1 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 positive)
Pseudomonas aeruginosa	Zeptometrix	1 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 positive)
Staphylococcus Epidermidis	Zeptometrix	1 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 positive)
Streptococcus Salivarius	Zeptometrix	1 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 positive)
Staphylococcus aureus	ATCC	1 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 positive)

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for wet testing, *in silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology.

- For Human Coronavirus HKU1, homology exists between the SARS-CoV-2 nucleocapsid protein and Human Coronavirus HKU1. BLAST results showed 30 sequence IDs, all nucleocapsid protein, showing homology. Sequence ID AGW27840.1 had the highest alignment score and was found to be 39.1% homologous across 76% of the sequences, this is relatively low but cross-reactivity cannot be fully ruled out.
- For SARS-Coronavirus, high homology exists between the SARS-CoV-2 nucleocapsid protein and SARS-Coronavirus. BLAST results showed 68 sequence IDs, mostly nucleocapsid protein, showing homology. Sequence ID AAR87518.1, had the highest alignment score isolated from a human patient and was found to be 90.76% homologous across 100% of the sequence. This is high and cross-reactivity is likely.
- For MERS-Coronavirus, high homology exists between the SARS-CoV-2 nucleocapsid protein and MERS-Coronavirus. BLAST results showed at least 114 sequence IDs, mostly nucleocapsid protein, showing homology. Sequence IDs AHY61344.1 and AWH69950.1, had the highest alignment scores isolated from a human patient and were found to be 49.4% and 50.3% homologous across 88% of the sequence. Whilst this potentially represents moderate cross-reactivity testing of the MERS virus at 7930 PFU/mL showed no reactivity (see table above).

Endogenous interference studies

A study was performed to demonstrate that potentially interfering substances that may be found in the upper respiratory tract in symptomatic subjects (including over the counter medications) do not cross-react or interfere with the detection of SARS-CoV-2 in the LumiraDx SARS-CoV-2 Ag Test. Each substance was tested in triplicate in the absence or presence of SARS-CoV-2 at 3 x LoD. Substances for testing were selected based on the respiratory samples guidance in **http://www.accessdata.fda.gov/cdrh_docs/reviews/K112177.pdf**. The final concentration of the substances tested are documented in the Table below.

Interfering substance	Concentration	Interference (Yes/No)
Benzocaine	150 mg/dL	No (3/3 Negative, 3/3 Positive)
Blood (human)	5%	No (3/3 Negative, 3/3 Positive)
Mucin	5 mg/mL	No (3/3 Negative, 3/3 Positive)
Naso GEL (NeilMed)	5% v/v	No (3/3 Negative, 3/3 Positive)
CVS Nasal Drops (phenylephrine)	15% v/v	No (3/3 Negative, 3/3 Positive)
Afrin (Oxymetazoline)	15% v/v	No (3/3 Negative, 3/3 Positive)
CVS Nasal Spray (Cromolyn)	15% v/v	No (3/3 Negative, 3/3 Positive)
Zicam Cold Remedy	5% v/v	No (3/3 Negative, 3/3 Positive)
Homeopathic (Alkalol)	10 % v/v	No (3/3 Negative, 3/3 Positive)
Sore Throat Phenol Spray	15% v/v	No (3/3 Negative, 3/3 Positive)
Tobramycin	3.3 mg/dL	No (3/3 Negative, 3/3 Positive)
Mupirocin	0.15 mg/dL	No (3/3 Negative, 3/3 Positive)
Fluticasone	0.000126 mg/dL	No (5/5 Negative, 4/4 Positive)
Tamiflu (Oseltamivir phosphate)	500 mg/dL	No (3/3 Negative, 3/3 Positive)
Budesonide	0.00063 mg/dL	No (3/3 Negative, 3/3 Positive)
Biotin	0.35 mg/dL	No (3/3 Negative, 3/3 Positive)

High dose hook effect

High Dose Hook Effect studies determine the level at which false negative results can be seen when very high levels of target are present in a tested sample. To determine if the LumiraDx SARS-CoV-2 Ag Test suffers from any high dose hook effect, increasing concentrations of gamma-irradiated SARS CoV-2 virus (BEI Resources NR-52287) were tested up to a concentration of 1.4 x 10^5 $TCID_{50}$/mL. In this study, the starting material was spiked into a volume of pooled human nasal matrix obtained from healthy donors and confirmed negative for SARS-CoV-2. At each dilution, 50 µL samples were added to swabs and the swabs processed for testing on the LumiraDx SARS-CoV-2 Ag Test as per the Product Insert using the procedure appropriate for patient nasal swab samples.

No impact on test performance or high dose hook effect was observed up to 1.4 x 10^3 $TCID_{50}$/mL of gamma-irradiated SARS-CoV-2 with the LumiraDx SARS-CoV-2 Ag Test.

Test dilution	Concentration (TCID₅₀/mL)	Mean signal (ADC Units)
1	0	495
2	62.5	26100.6
3	250	63013.8
4	1000	83451.8
5	1.4 x 10^5	86220

Point of care use

The LumiraDx SARS-CoV-2 Ag Test was used by 8 untrained users in 4 sites across the United States. Untrained users tested 132 patients and ran 148 tests.

References

1. World Health Organization www.who.int
2. Centers for Disease Control and Prevention www.cdc.gov

Symbols glossary

	Temperature limitation
	Manufacturer
IVD	*In Vitro* Diagnostic Medical Device
REF	Catalogue Number
LOT	Batch code/Lot Number
STERILE EO	Indicates a medical device that has been sterilized using ethylene oxide
	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	Use by
	Consult Instructions for Use
2	Do Not Re-use
Rx Only	Prescription Use Only
	Do not re-sterilize
	Indicates the presence of the Radio Frequency Identification (?RFID) reader/tag.
	Date of manufacture

Technical Support

For product inquiries and technical support, please contact Roche Customer Support Center at **1-800-800-5973**.

Limited warranty

LumiraDx SARS-CoV-2 Ag Test Strips – As per shelf life.

Unused strips must be stored according to the required storage conditions as printed in this product insert and they can be used only up to the expiry date printed on the Test Strip pouch and Test Strip box. For the applicable warranty period, LumiraDx warrants 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, 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 Test Strips. 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 the 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 SARS-CoV-2 Ag Test 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.

Intellectual property

The LumiraDx Instrument, Test Strips and all provided LumiraDx documentation ("Products") are protected by law.The Intellectual Property of the LumiraDx Products remains at LumiraDx. Details of relevant Intellectual Property regarding our products can be found at **go.roche.com/lumiradx**.

Legal notices

Copyright © 2025 LumiraDx UK and affiliates. All rights reserved. LumiraDx and Flame logo are protected trademarks of LumiraDx International LTD. Full details of these and other registrations of LumiraDx can be found at **go.roche.com/lumiradx**. All other trademarks are the property of their respective owners.

Manufacturer information

Test Strips

LumiraDx UK Ltd
Dumyat Business Park, Alloa, FK10 2PB, UK
Company number: 09206123

Distribution in USA: Roche Diagnostics, 9115 Hague Road, Indianapolis, IN 46256, USA.

LumiraDx™ SARS-CoV-2 Ag Test

Quick Reference Instructions For

Emergency Use Authorization (EUA) Only. For *in vitro* Diagnostic Use. Rx Only.

SPEC-32757 R11 S-COM-ART-00406 R13 Date of Rev 2025-06

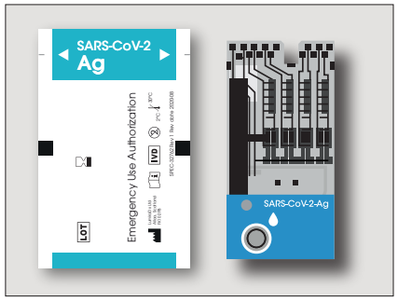
Warning and Precautions:

Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results. All kit components can be discarded as biohazard waste according to local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information. The product safety data sheet is available at **go.roche.com/lumiradx**. Exercise the normal precautions required for handling all laboratory reagents. Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2 patient samples. Patient swabs, used Test Strips and used extraction **buffer** vials may be potentially infectious. Proper handling and disposal methods should be established by the laboratory in accordance with local, state and federal regulations. Reagents encapsulated within the Test Strip are present in extremely small amounts however, should any reagent become exposed it should be treated as potentially infectious. **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. If the patient has had symptoms longer than 12 days, consider testing at least three times over five days with at least 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.**

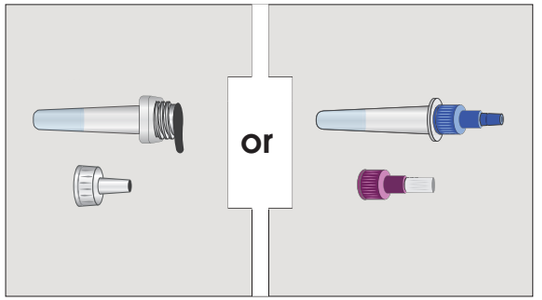
In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories; use by laboratories **certified** under the CLIA that meet the requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA **Certificate** of Waiver, **Certificate** of Compliance, or **Certificate** of Accreditation. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

LumiraDx SARS-CoV-2 Ag Test Kit Components

Test Strip



Extraction Vial and Dropper Lids



The LumiraDx SARS-CoV-2 Ag Test is a rapid **microfluidic** immunofluorescence assay for use with the LumiraDx Platform intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal swab and nasopharyngeal swab specimens collected by a healthcare provider from individuals who are suspected of COVID-19 within the **first** twelve (12) days of symptom onset when tested at least twice over three days with at least 48 hours between tests and from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests. Study the **LumiraDx Platform User Manual** and **LumiraDx SARS-CoV-2 Ag Test Strip Product Insert** thoroughly before using these **Quick Reference Instructions** or performing a test. This is not a complete product insert.

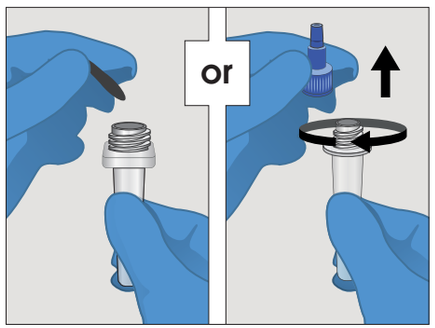
Operate the LumiraDx Platform at room temperature between 15°C and 30°C (59°F and 86°F) and 10% - 75% relative humidity. The extracted sample must be used within 5 hours of preparation when stored at room temperature. Extracted nasal or nasopharyngeal samples may be frozen at -80°C and used up to 5 days after freezing. Samples and extraction buffer must be at room temperature before testing. Check expiration date on outer test kit carton and each individual test package before using. **Do not use any test components beyond its expiration date.** Refer to the LumiraDx SARS-CoV-2 Ag Test Strip Product Insert for Sample Collection, Warning and Precautions, and Limitations.

Preparing the sample

Collect a patient swab sample before following steps 1 – 4 of **Running the Test.**

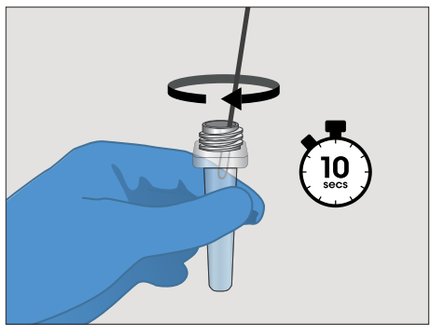
Sample Collection and Handling: Proper sample collection and handling of anterior nasal and nasopharyngeal swabs is required to ensure accurate results (refer to product insert). Additional training or guidance is recommended if operators are not experienced with sample collection and handling procedures.

Storage and Stability: Store the Test Strips at room temperature – between 2˚C and 30˚C (36˚F and 86˚F). When stored correctly, the Test Strips can be used until the expiration date printed on the Test Strip foil pouch and the Test Strip carton. The dates printed on the Test foil pouch and the Test Strip carton will always be the same.



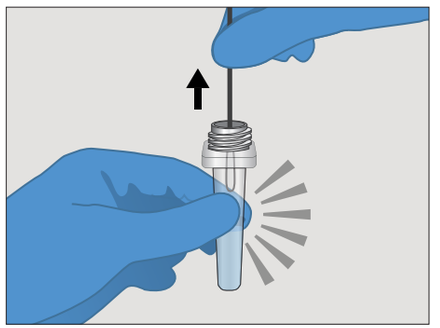
Remove seal

Remove the seal or blue screw cap from the top of the **Extraction Vial** containing the **Extraction Buffer.**



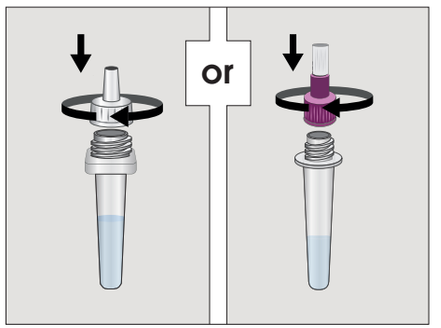
Soak Swab

Place and soak the **Patient Swab** in the **Extraction Buffer** for 10 seconds then stir well by rotating the swab against the side of the vial 5 times.



Squeeze Swab

Remove the **Patient Swab** while squeezing the **Extraction Vial** to remove the liquid from the swab. Discard the swab in biohazard waste.



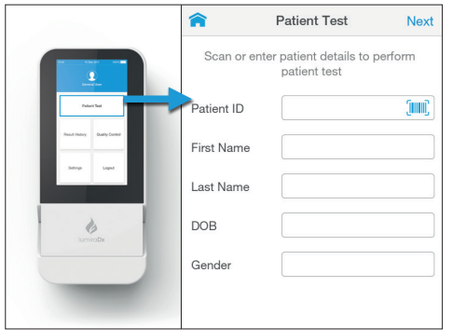
Attach Dropper Lid

Firmly attach the clear or purple **Dropper Lid** to the top of the **Extraction Vial. The extracted sample must be used (see Step 5 and 6 below) within 5h of preparation when stored at room temperature.**

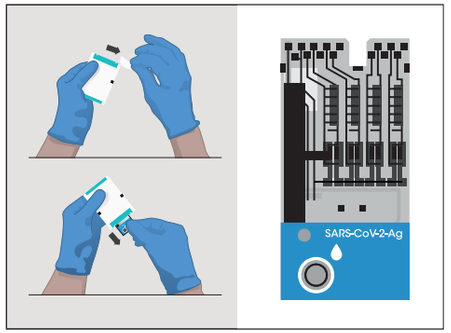
Cleaning and Disinfecting

Wipe the external surfaces of the LumiraDx Instrument with a **soft**, slightly damp cloth when it appears visibly dirty. Disinfect the Instrument **after** each patient test or if contamination is suspected and at least once per day when in use using LumiraDx approved materials. Details of LumiraDx approved disinfectant materials can be found at go.roche.com/lumiradx. Use the material until the surface of the Instrument is visibly wet. Allow the surface to remain wet for **1 minute** and let air dry. **Avoid USB ports and power inlet. Do not spray or pour solution directly onto the Instrument. Do not put any objects or cleaning materials into the Test Strip slot.**

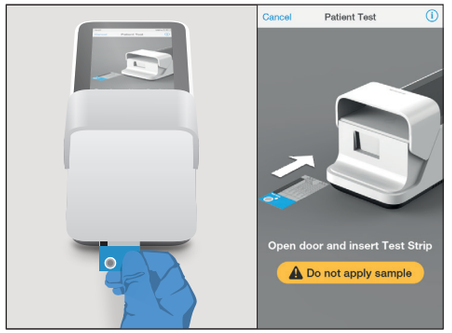
Running the Test



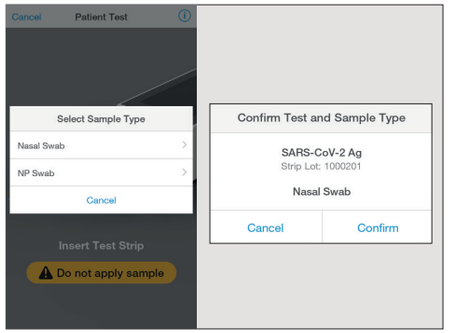
1. Select *Patient Test* from the **Instrument** *Home Screen* and enter patient details using the **Keyboard** or **Barcode Scanner**. See section 10 of the **Platform User Manual** for instructions on using the **Barcode Scanner.**



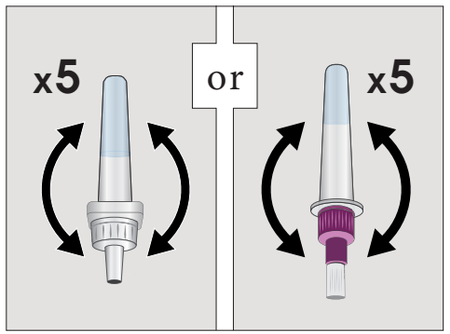
2. Remove the **Test Strip** from its pouch and hold by gripping only the blue portion. **Do not bend the Test Strip or touch any part other than the blue portion.**



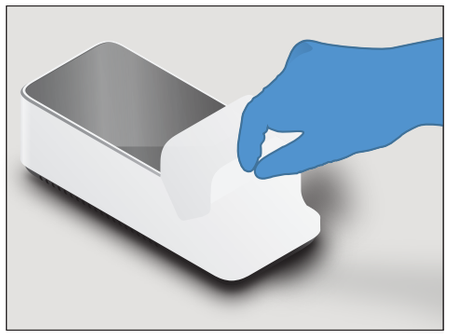
3. When prompted, open the **Instrument** door and gently insert the **Test Strip** as far as it will go. The thick black alignment rib on the **Test Strip** should be on the **left** and line up with the black line on the **Instrument. Do not apply the sample until prompted.** Install the Lot Calibration file if using a new **Test Strip Lot** for the first time. See section 2.8 of the **Platform User Manual.**



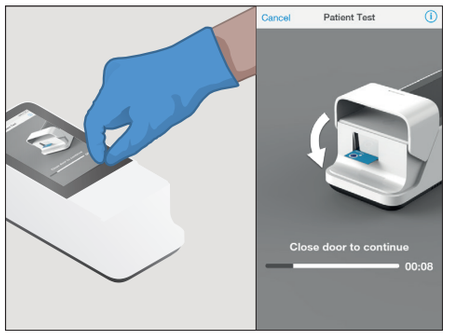
4. Select the appropriate sample type and **confirm** the test type.



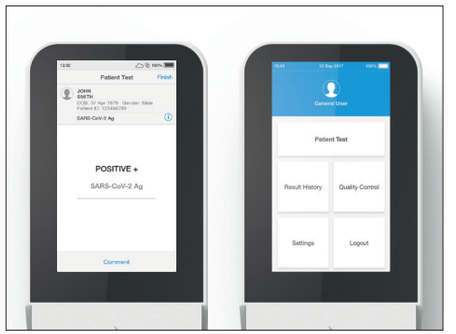
5. Gently invert the **Extraction Vial five** times just before applying the sample to the **Test Strip**.



6. Apply **one whole drop** of the sample onto the **Test Strip Sample Application Area** when prompted by the **Instrument.**



7. Close the door when prompted to continue the test.



8. Results are displayed within 12 minutes of applying the sample. The left-hand image here shows a positive result for SARS-CoV-2 Ag and the right-hand image shows a negative result for SARS-CoV-2 Ag. Tap *Finish* to complete testing or tap *Comment* to leave a comment or to reject the Test, then follow prompts to return to the *Home Screen*. All test results must be read using the LumiraDx Instrument.

INTERPRETATION OF RESULTS

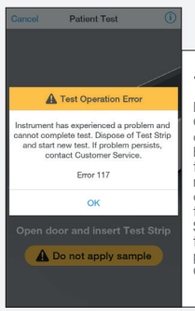
COVID-19 Positive (+)
Repeat testing does not need to be performed if patients have a positive result at any time.
A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self- isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive). Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the **definite** cause of disease. Individuals who test positive with the LumiraDx SARS-CoV-2 Ag test should self-isolate and seek follow up care with their physician or healthcare provider as additional **confirmatory** testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

COVID-19 Negative (-)
To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider. All negative results should be treated as presumptive and **confirmation** with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Invalid Results:
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 ⚠ 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.



⚠ **Example of an error screen:**
If the On Board Control (OBC) fails, an error message will be shown 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 Support.

Quality Controls
To complete Quality Control assessment of the LumiraDx Instrument and SARS-CoV-2 Ag Test Strips, you must use the LumiraDx SARS-CoV-2 Ag Quality Control Pack which are available separately. If the LumiraDx Antigen Quality Controls do not perform as expected, do not report patient results. Retest using a new Test Strip – if problems persist contact Customer Support on telephone number **1-800-800-5973**.

Customer Service
If the **LumiraDx SARS-CoV-2 Ag Test** or the **LumiraDx Instrument** do not perform as expected, please contact Roche Customer Support Center at **1-800-800-5973**

Manufacturer Information
LumiraDx UK Ltd, Dumyat Business Park, Alloa, FK10 2PB, UK.
Company Number: 09206123

Copyright © 2025 LumiraDx UK and **affiliates**. All rights reserved. LumiraDx and Flame logo are protected trademarks of LumiraDx International LTD.
Full details of these and other registrations of LumiraDx can be found at go.roche.com/lumiradx. All other trademarks are the property of their respective owners.



For Emergency Use Authorization Only

In the USA, the LumiraDx SARS-CoV-2 Ag Test and the LumiraDx SARS-CoV-2 Ab Test have not been FDA cleared or approved, but have been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. These products are authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. These products have been authorized only for the detection of proteins from SARS-CoV-2 and the presence of total antibodies to SARS-CoV-2, not for any other viruses or pathogens. In the USA, the emergency use of these products are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

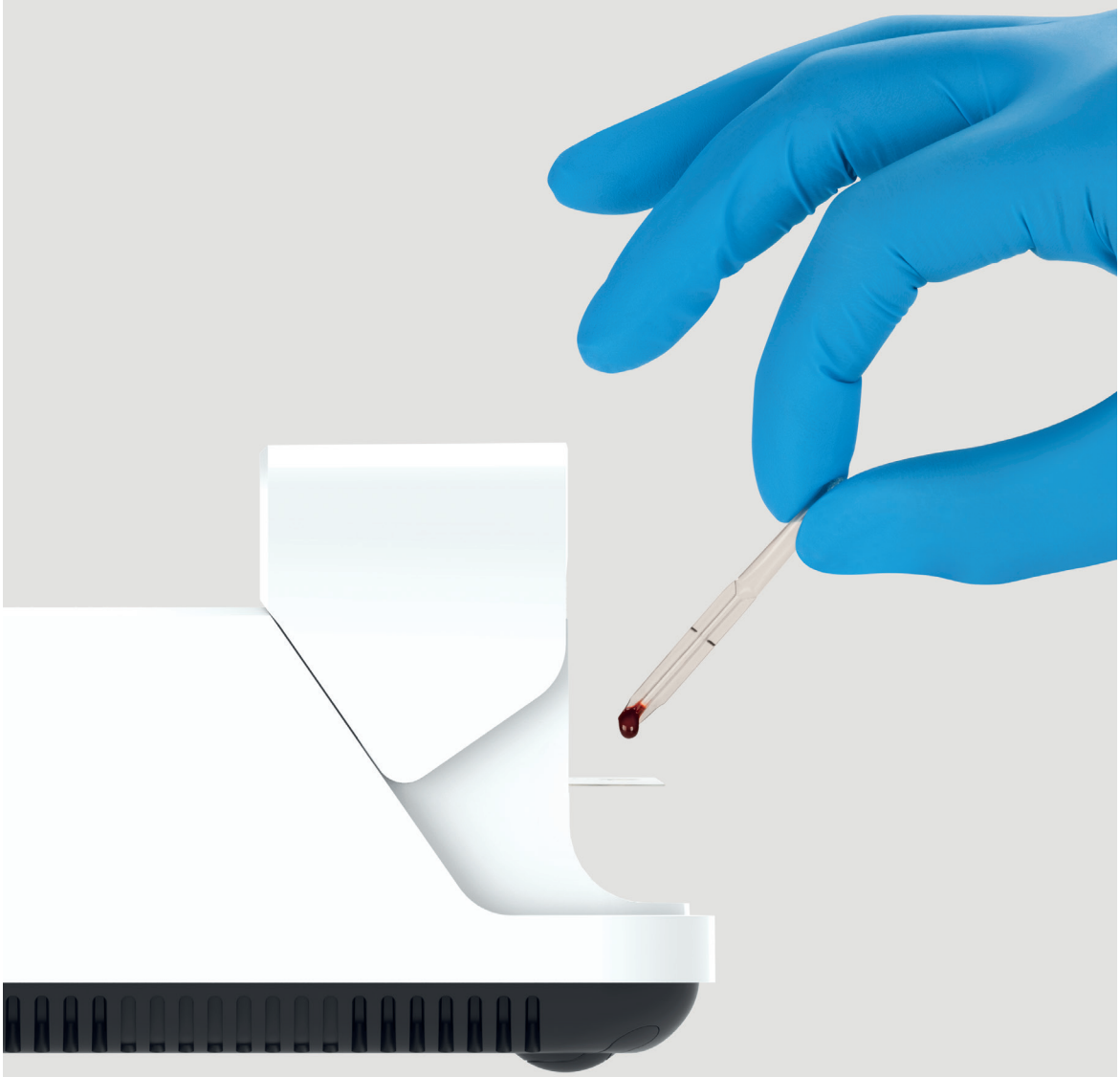
LumiraDx Group Limited, 2025 - © All rights reserved, worldwide.

LumiraDx UK Ltd
Dumyat Business Park
Alloa FK10 2PB, UK

SPEC-32180 Rev 7
ART-00410 Rev 9
Rev Date 2025/06

For product inquiries and technical support, please contact Roche Customer Support Center at 1-800-800-5973.

IumiraDx™ Platform User Manual



Platform User Manual

- In the USA, this product has not been FDA cleared or approved but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has been authorized only for the detection of proteins from SARS-CoV-2 and total antibodies to SARS-CoV-2, not for any other viruses or pathogens. In the USA, - the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- 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.
- For *in vitro* Diagnostic Use
- Rx only

Contents

	Symbols	4
	Instrument icons and buttons	6
	Abbreviations	8
	Important safety information	9
	Overview of the LumiraDx Platform	10
	About this Platform User Manual	14
1	Introduction	11
	1.1 Intended use	11
	1.2 Important information	11
	1.3 Summary of the test procedure	11
	1.4 Principles of operation	12
	1.5 Storage and operating conditions	13
	1.6 Warnings	14
	1.7 Precautions	17
	1.8 Help and support	19
2	Getting Started	20
	2.1 Unpacking	20
	2.2 Powering the Instrument on and off	20
	2.3 Instrument self-check	20
	2.4 User ID	21
	2.5 Operating mode and first-time setup	21
	2.6 The LumiraDx Instrument	22
	2.7 Power supply	23
	2.8 LumiraDx Lot Calibration File installation	24
	2.9 Extended functionality and operating modes	25
3	Preparation for Testing	26
	3.1 Handling Test Strips	26
	3.2 Inserting and removing Test Strips	26
	3.3 Capillary sample collection and application	28
	3.4 Quality Control solution application	28
4	Instrument Operation	29
	4.1 Home Screen	29
	4.2 Settings Menu	30
	4.3 Standalone Instrument First Time Setup	31
	4.4 Connected Instrument First Time Setup	33
	4.5 Display and Sound Preferences	35
	4.6 Performing a Patient Test	36

4.7 Quality Control 46
4.8 Performing a Quality Control test 47
4.9 Result History 57
4.10 Onboard Quality Control 60

5 Cleaning and Disinfecting 62

5.1 Cleaning procedure 64
5.2 Disinfection procedure 64

6 Software Updates 66

6.1 Check software version 66
6.2 Performing a software update 67

7 Troubleshooting 68

8 Maintenance and Disposal 72

9 Instrument Specifications 73

10 Ancillary Devices 74

10.1 LumiraDx Barcode Scanner 74
10.2 LumiraDx Printer 77
10.3 LumiraDx USB Memory Stick 79
10.4 LumiraDx Connect Hub 80
10.5 LumiraDx Connect App 80

11 Customer Services 81

11.1 Warranty 81

12 References 82

13 Compliance 83

13.1 Environmental Practices 83
13.2 Compliance 83

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.
	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.
	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.
	Indicates that the Instrument has an active connection to an Electronic Health Record (EHR).
	Indicates that the Instrument connection to an Electronic Health Record (EHR) is not active.
	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 at least once per day when in use or if contamination is suspected, unless recommended otherwise for specific tests[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.

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

The LumiraDx Instrument contains 2 USB ports that are for use with approved & supported LumiraDx USB devices only. DO NOT connect any unsupported devices into the USB ports.

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.

This User Manual and its content is copyright of LumiraDx Group Limited, 2025. © All rights reserved, worldwide. Content should be used for use of the LumiraDx Products only and in line with instructions provided. You may not, except with our express written permission, distribute or commercially exploit the content. Nor may you transmit it or store it in any other form of electronic retrieval system other than for the purpose of use of the LumiraDx Instrument or LumiraDx Test Strips.

LumiraDx and Flame logo are protected trademarks of LumiraDx International LTD. Full details of these and other registrations of LumiraDx can be found at go.roche.com/lumiradx. All other trademarks are the property of their respective owners.



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. 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 Carry Case • Disinfectant Material — please refer to LumiraDx website for validated disinfectant materials

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 go.roche.com/lumiradx.

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 performing 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 performing 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

- Always wear gloves whilst cleaning and disinfecting the Instrument.
- Always use LumiraDx recommended materials to disinfect the Instrument. Details of LumiraDx recommended materials can be found at go.roche.com/lumiradx.
- **CAUTION: Excessive liquid may damage the Instrument.** It is important for the protection of the Instrument that exposure to excess moisture is prevented. All disinfection cloths and/or wipes should only be slightly damp, with any excess liquid being manually removed from the cloth or wipe before use.
- **CAUTION:** Liquid should not be placed in or near the vents on the bottom or back of the instrument.
- **CAUTION:** Alcohol wipes alone are not sufficient to disinfect the Instrument for blood-based samples, due to the potential presence of bloodborne pathogens.
- **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 go.roche.com/lumiradx.

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

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.

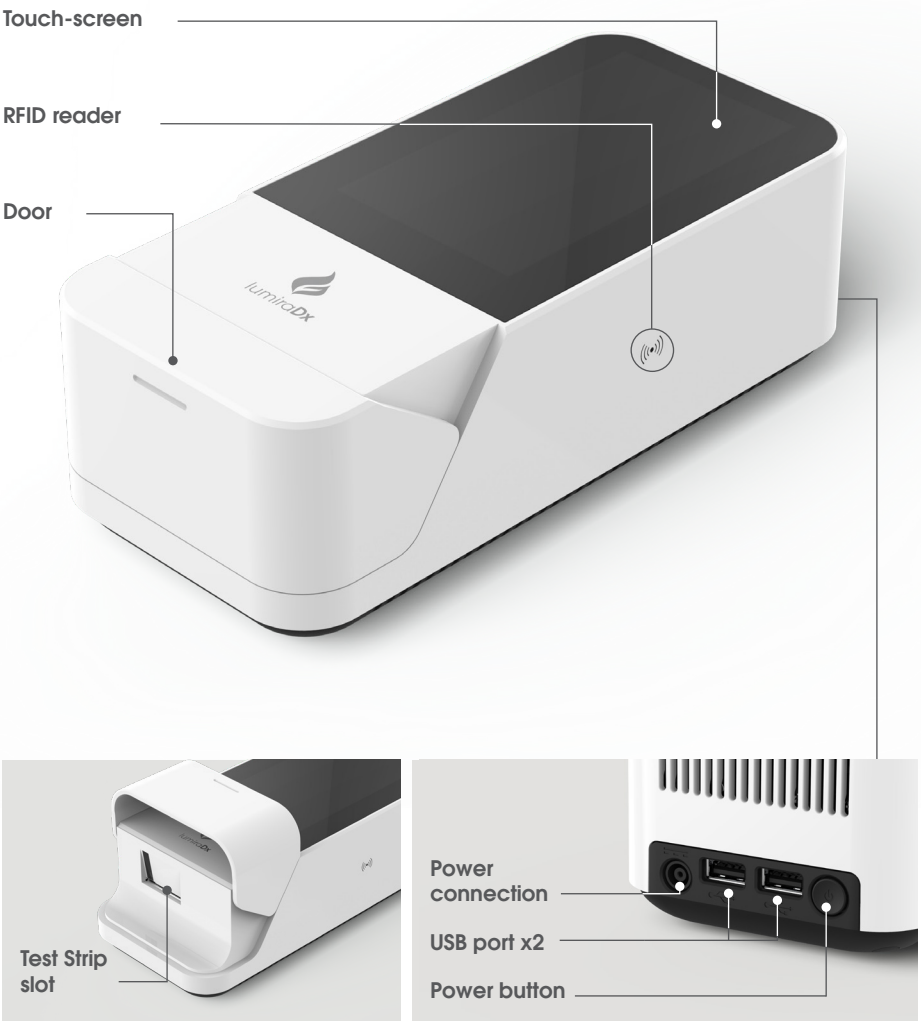
2.5 Operating mode and first time setup

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.



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 ((•)) symbol on the side of the Instrument. To install a new Lot Calibration File, hold the back of the Test Strip Carton to the ((•)) symbol for 3 seconds to install. When the Lot Calibration File is installed the Instrument will sound (if sounds are turned on in the instrument settings) 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.

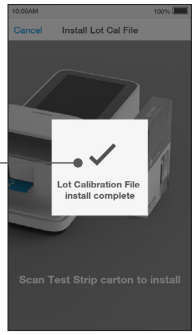


Installation

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

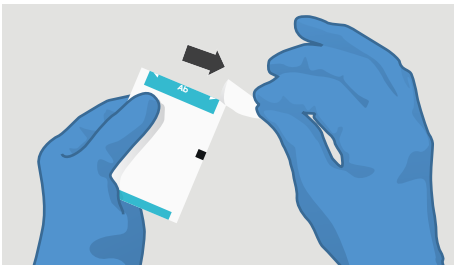
Electronic Health Record

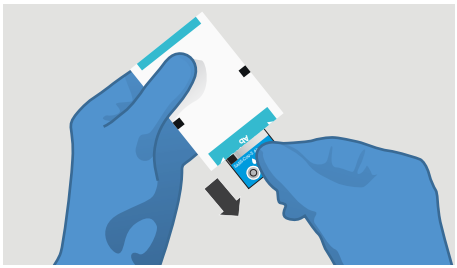
3. Preparation for Testing

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.





3.2 Inserting and removing Test Strips

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

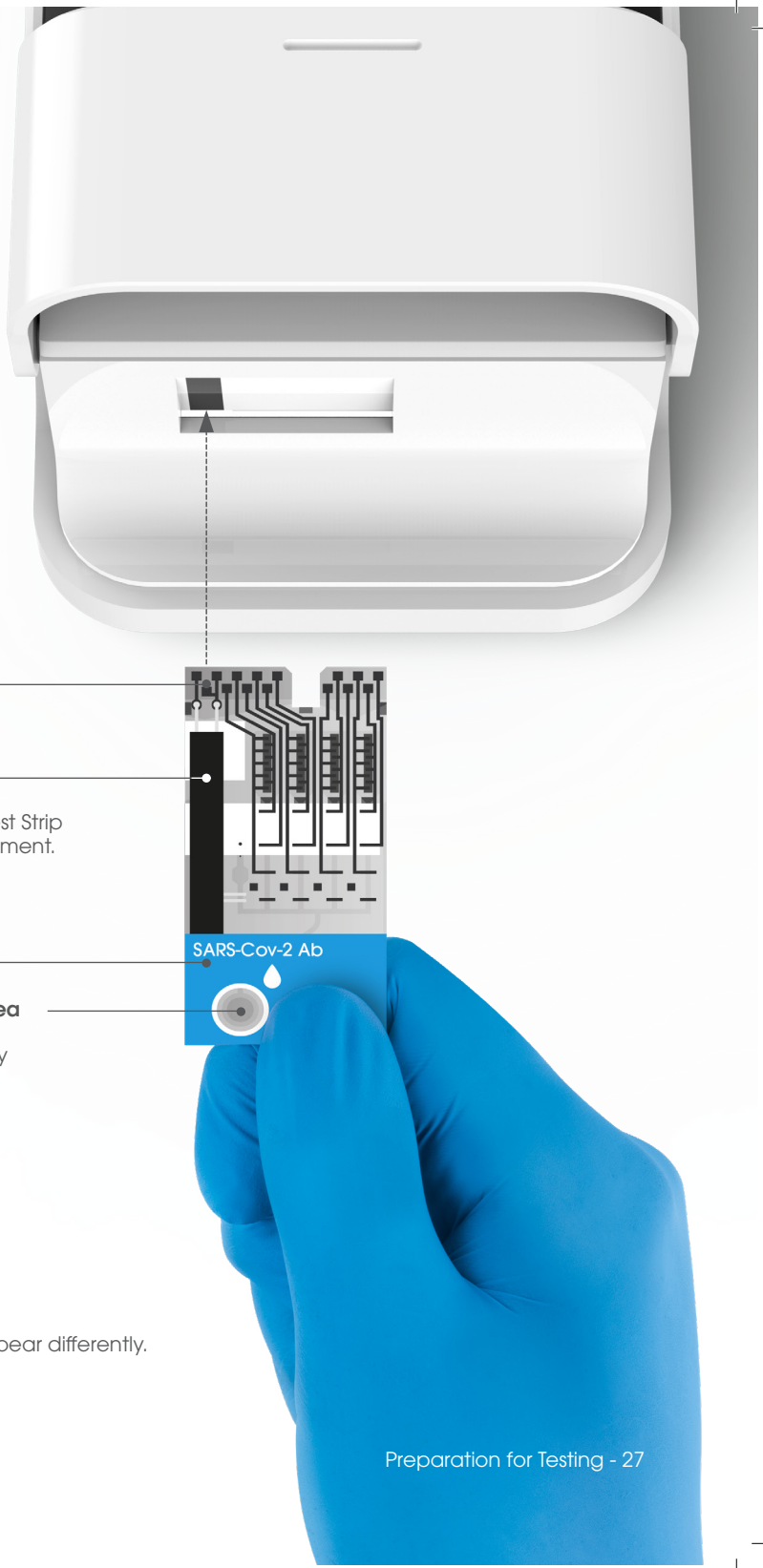
Line up the black alignment rib on the Test Strip with the black line on the Instrument. Insert the Test Strip gently as far as it will go. The Instrument will sound when the Test Strip is detected if sounds are turned on in the Instrument settings (see section 4.5).

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.



Note: Test Strip may appear differently.

3.3 Sample collection and application

When collecting any type of sample, follow universal collection precautions and guidelines according to your organization. Refer to Test Strip Product Insert for information on sample collection and processing. For collection of capillary fingerstick samples: Before lancing ask the patient to rinse their hands in warm water and dry them. This is good practice to remove any residue and to increase the blood flow in the finger.

Details of LumiraDx recommended transfer tubes and swabs are available at go.roche.com/lumiradx and sample application training videos are available at go.roche.com/lumiradx.

Applying a sample to the Test Strip

Apply one drop of the sample to the test strip. Ensure that the sample is applied centrally and completely fills the sample application area in one clean drop.

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

The touchscreen of the LumiraDx Instrument will request the user to **immediately close the door (Note: you have 10 seconds only to close the door)**.

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 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.

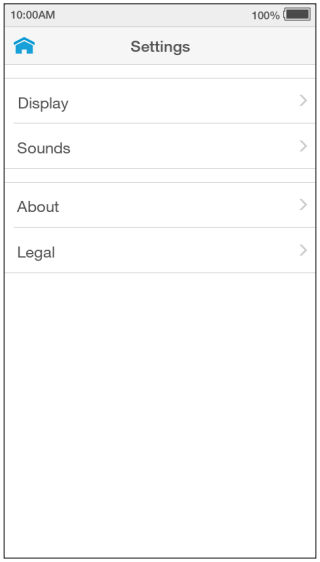
4.1 Home Screen



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.

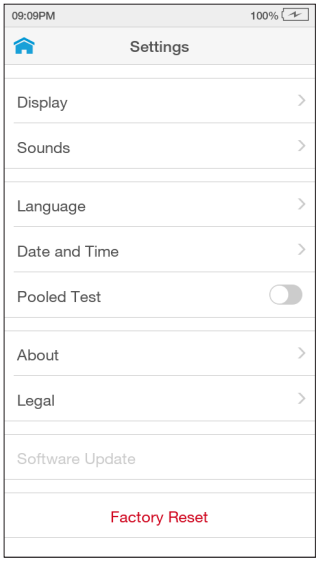


Administrator settings menu

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.

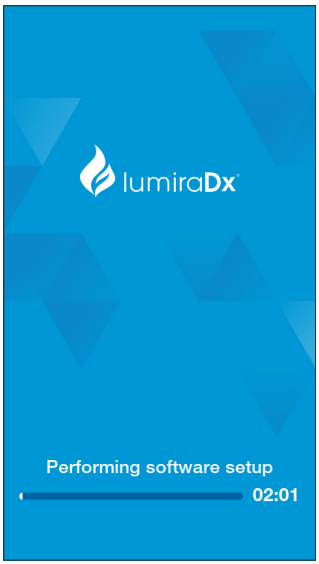
Factory Reset deletes all data currently stored on the Instrument, including result history, settings and Lot Calibration Files.



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 supplied with your LumiraDx Instrument.



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.

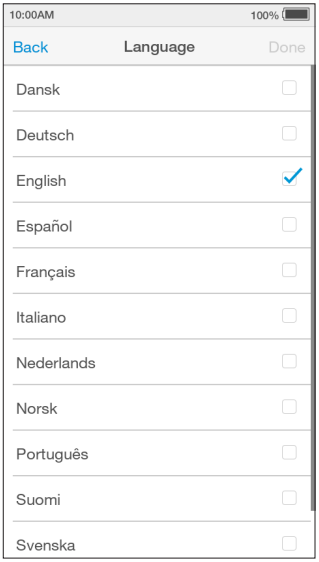


3. Set language

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

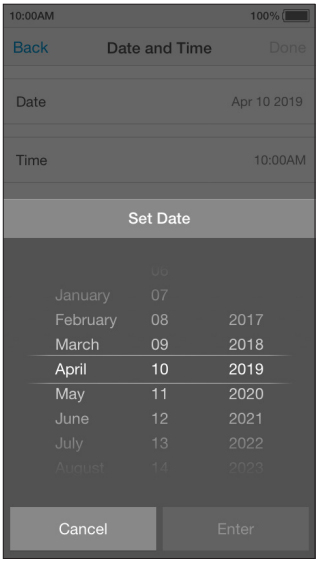
Go to 'Settings' and tap 'Date and Time'.

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'.



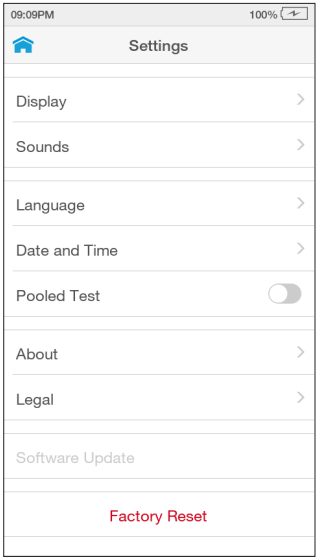
4.4 Connected Instrument First Time Setup

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.

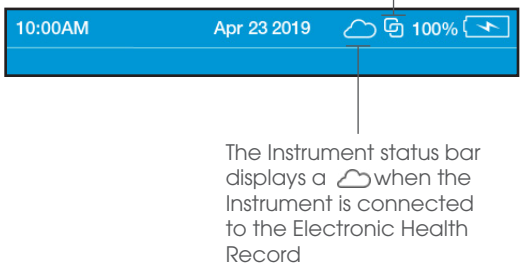
To download other Instrument settings, ensure the Instrument is within range of a LumiraDx Connect Hub or a device running the LumiraDx Connect App (within approximately 10 metres). If appears at the top of the screen, the Instrument is connected to Connect Manager and the Instrument settings will download 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.



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

A ☁ 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.



4.5 Display and Sound Preferences

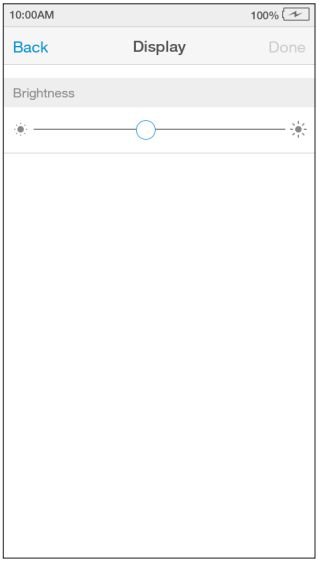
All users can set display and sound preferences in the Settings menu.

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.

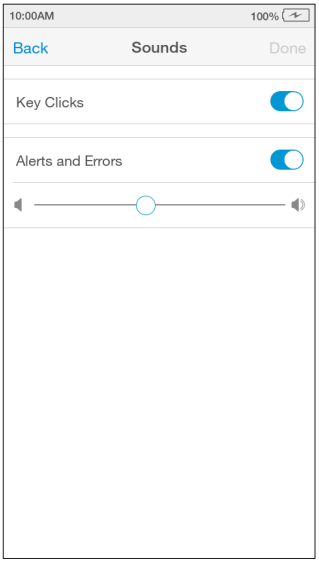


Sounds

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 ⓘ at the top of the touch-screen.



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.

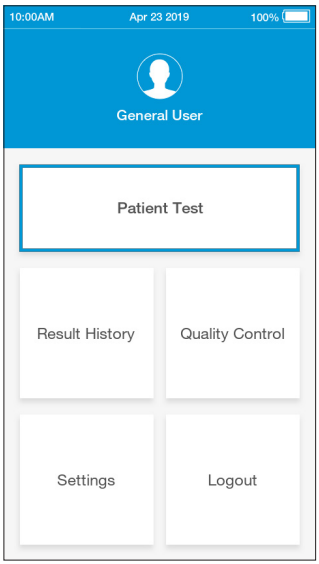
Tap the password field to display the keyboard.

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.

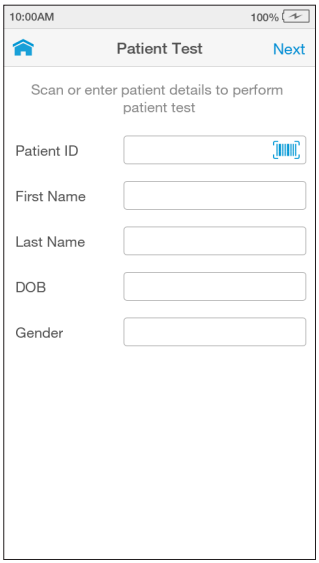
4. Enter patient details

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.

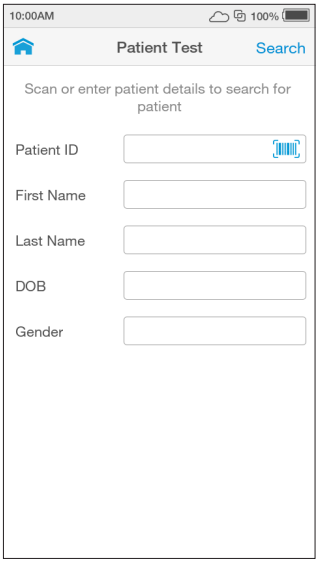
Note: Tap 'Next' if no patient details are available.



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'

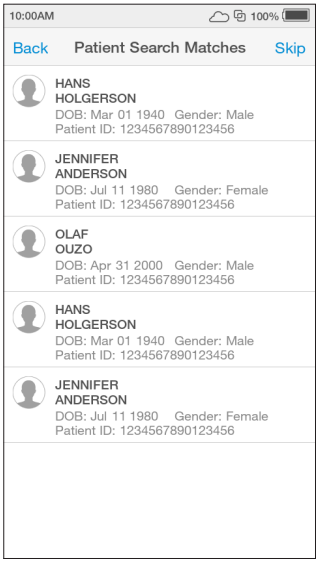
Note: If no patient details are available, tap 'Search' without adding any details. To search for a patient either the full Patient ID or Last Name must be entered.



EHR Connect patient search

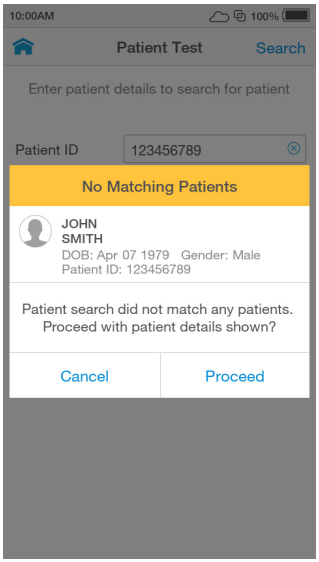
If only one patient matches the details entered, the Instrument will show the 'Confirm Patient Details' screen. If between 2 and 5 patients match the search details entered, the list of matches will be shown. Select the correct patient from the search list.

Note: Tap 'Skip' to proceed without selecting one of the patients available in the search list.



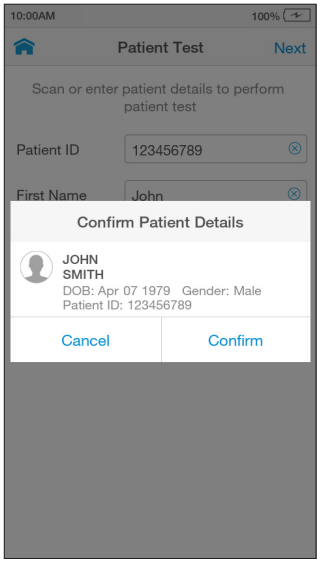
No patient match

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



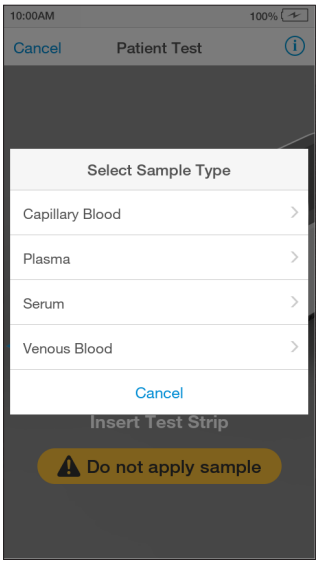
8. Select sample type

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.

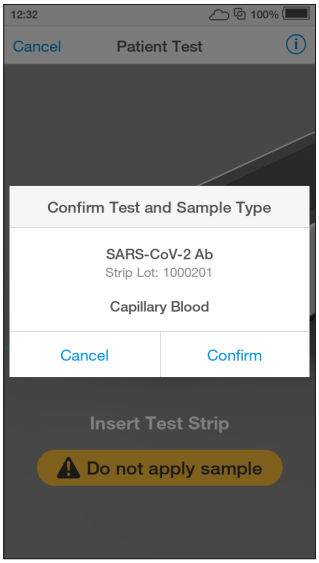
Note: Capillary Blood refers to both finger stick and transfer tube applications.



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.



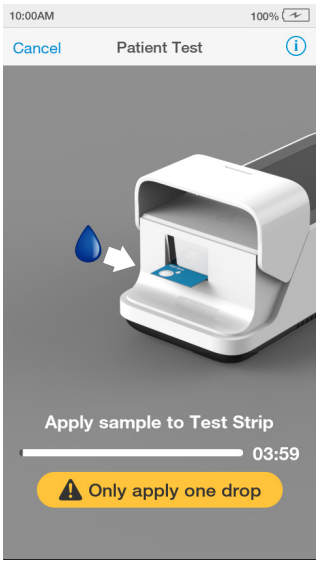
10. Apply sample

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.

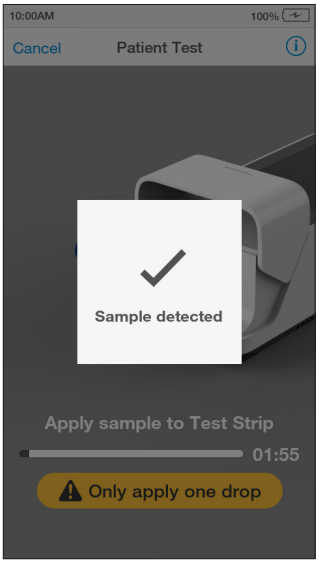
Note: Pay attention to the countdown for sample application to avoid test errors. This will be displayed as a countdown bar, and the Instrument will sound with 10 seconds remaining. If the sample is not applied by the end of the countdown the Instrument will display an error message.



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 occur 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.



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.

Disinfect the Instrument at least once per day when in use or if contamination is suspected, unless recommended otherwise for specific 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 in the Connect Manager system to:

- **Off**
- **Mandatory** – If the Quality Control policy has expired users are unable to perform a patient test, until a Quality Control Test has been performed with a status of PASS.
- **Advisory** – If the Quality Control policy has expired a warning is displayed on the Instrument. Users can acknowledge the warning and proceed with testing.
- **Mandatory with Override** – If the Quality Control policy has expired, users are required to either run a Quality Control Test or override the expired Quality Control policy and run a patient test by entering a comment to explain the reason for the override.

The timing and frequency of mandatory Quality Control tests are configurable in Connect Manager by Policy:

- **Lot** – Users are required to perform a Quality Control test when using a new Test Lot on an Instrument for the first time.
- **Type** – Users are required to perform a Quality Control test when using a new Test Type on an Instrument for the first time.

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

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 performing 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 ⓘ at the top of the touch-screen.



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

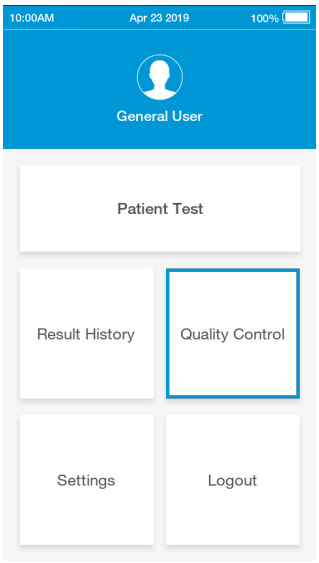
Check that the date and time are correct. If not correct, the current date and time will need to be set by the administrator. (Refer to "First time setup" in this chapter for more information).

3. Prepare Quality Control

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

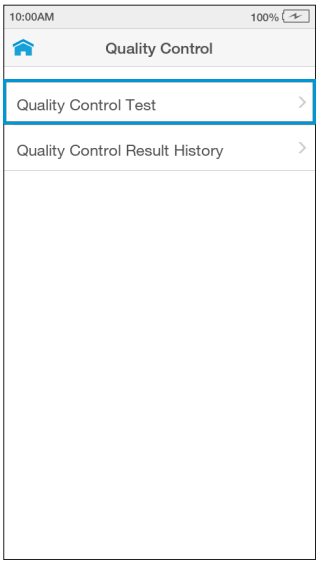
4. Tap Quality Control

Tap the 'Quality Control' button on the home screen.



5. Select Quality Control Test

Tap 'Quality Control Test' from the Quality Control menu.



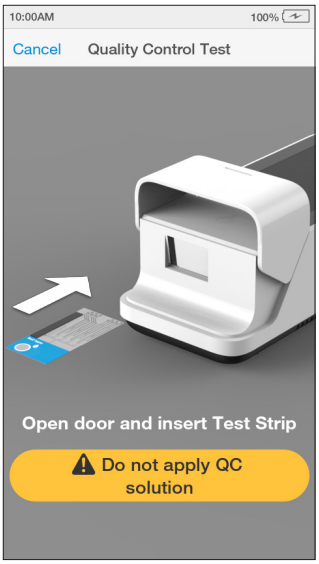
6. Open door and Insert Test Strip

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.

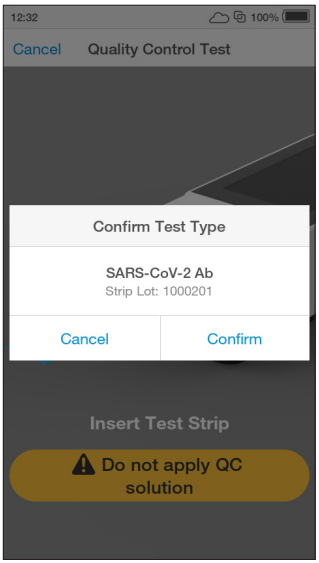
Do NOT touch Test Strip contacts.

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.

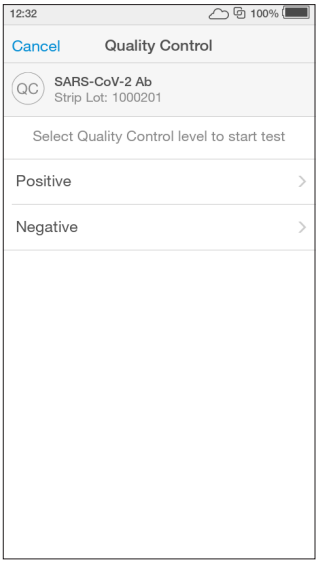


8. Select Quality Control level

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.

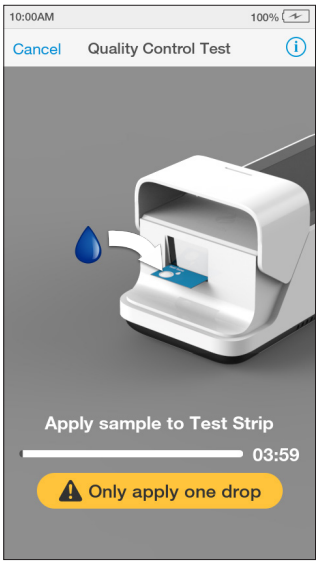


10. Apply Quality Control solution

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.

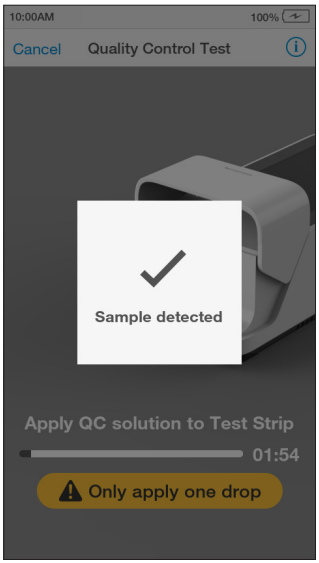
Note: Pay attention to the countdown for sample application to avoid test errors. This will be displayed as a countdown bar. If the sample is not applied by the end of the countdown the Instrument will sound and display an error message.



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.

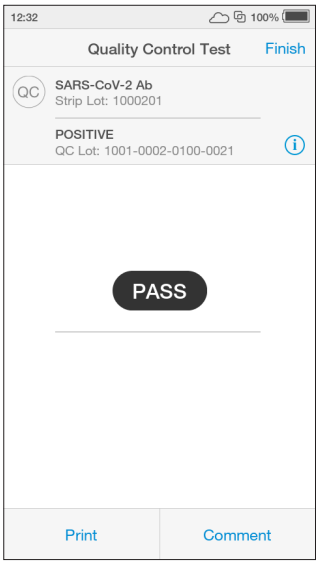
Note: Each test type has a different processing time.

Do NOT open the door or move the Instrument during the test or an error will occur 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.

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

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

The range of results acceptable for each QC level is also detailed in the LumiraDx Quality Control Ranges Product Insert in the Test Strip Carton.

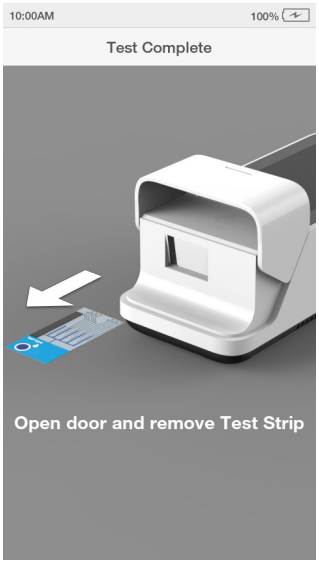
14. Remove and dispose of Test Strip

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.

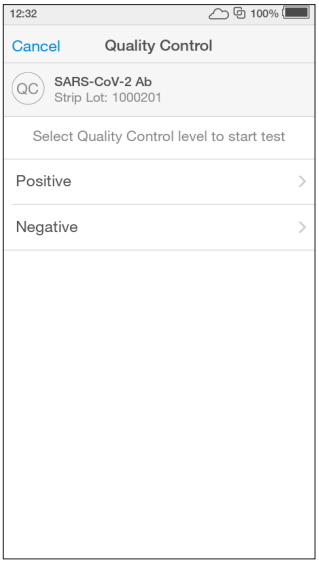


15. Complete remaining QC levels

Multiple QC levels may be required depending on test type.

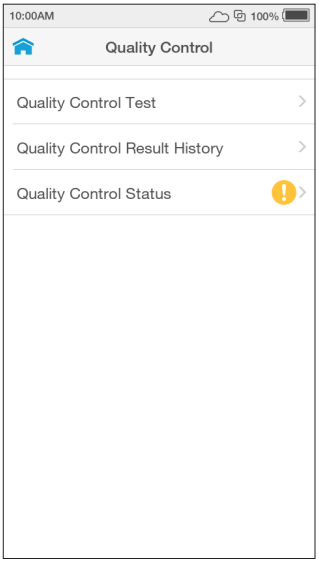
Refer to the LumiraDx Quality Control Pack Insert for more information on QC levels.

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



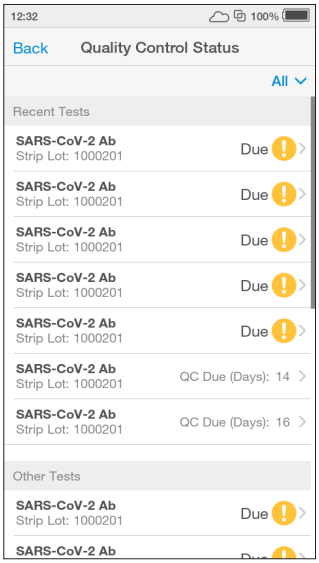
16. Mandatory Quality Control Policy

Connected Instruments with a Quality Control policy enabled will have an additional menu item of 'Quality Control Status'.



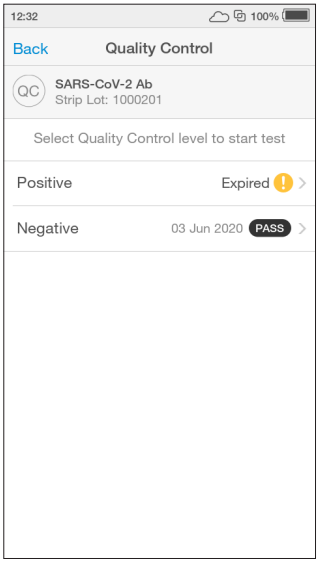
Quality Control test statuses are sorted by 'Recent Tests' meaning test lots for which patient tests or Quality Control tests have been performed recently. 'Other Tests' are test lots which have not had a patient test or QC test performed for more than 90 days.

Note: QC statuses can also be filtered by test type.

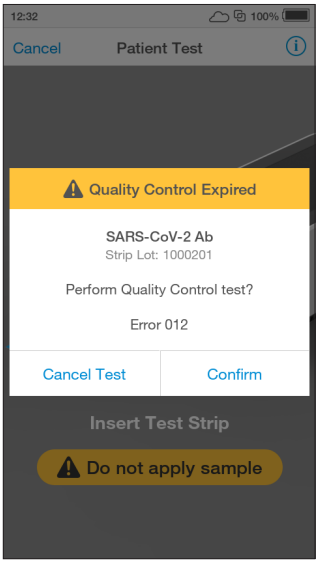


The Quality Control level selection screen will also show the status of each QC level as well as the date of any recently performed QC tests.

After completing a QC test level, the Instrument will return to the QC level selection page until all QC levels have been completed.

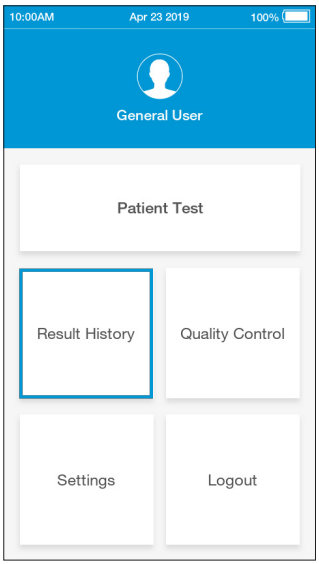


If a user attempts to perform a patient test using a lot for which a mandatory Quality Control test is due, the Instrument will display an alert message and prompt the user to perform a Quality Control test.



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

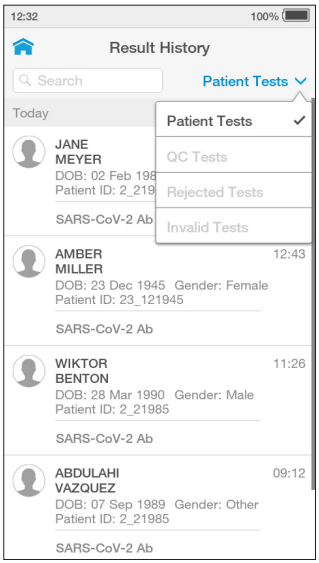
All entries are shown in date order, with the newest at the top. Test results can be filtered by selecting Patient Tests, QC Tests, Rejected Tests or Invalid Tests.

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.

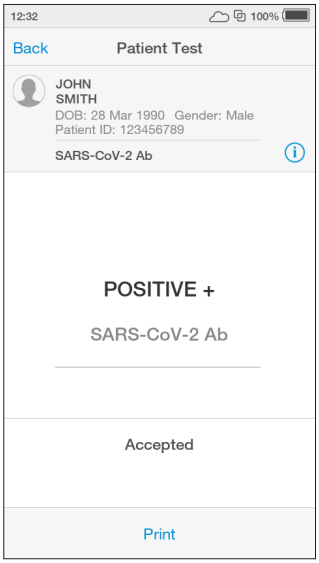
Scroll through the list and tap any entry to view the test result in full.

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.

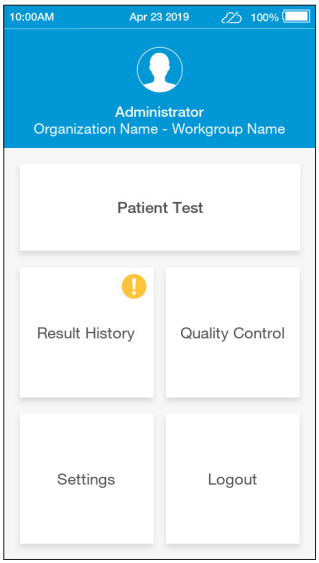


Any patient or QC test result can be printed from the test result details screen by tapping 'Print' when a LumiraDx Printer is connected to an Instrument USB port.

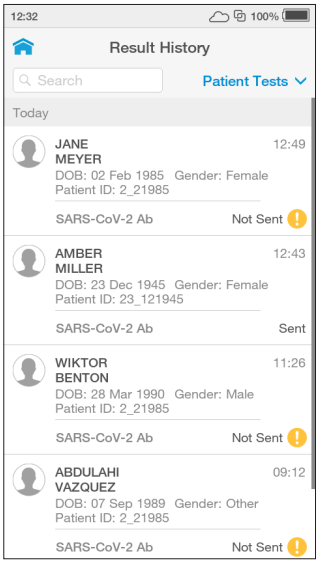


EHR Connected Instruments will indicate whether a test result has been sent to the electronic health record.

A ! symbol on the home screen indicates that one or more test results have not yet been sent to the EHR.



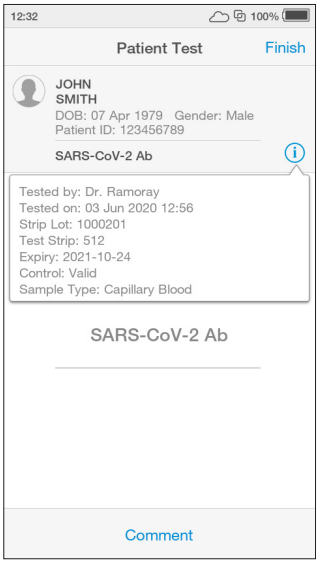
The Result History list will indicate whether test results have been sent to the EHR or not with 'sent' and 'not sent'.



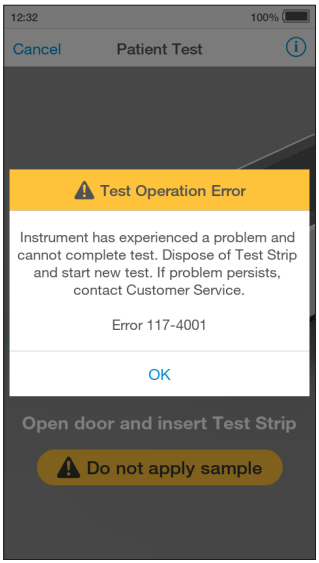
4.10 Onboard Quality Control

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

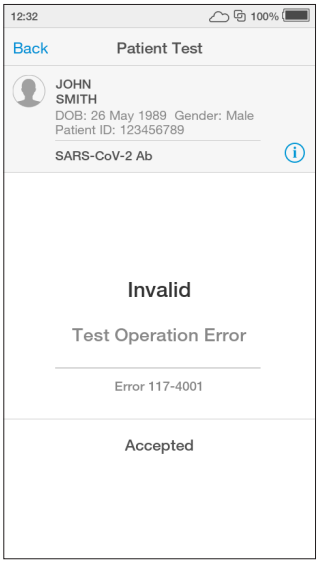
When a test has completed and the OBC test has passed, the test result will be displayed as normal. Tapping on the ⓘ on the result screen at the end of the test or from the Result History view shows additional details about the test, including 'Control: Valid' which confirms that the OBC has passed.



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 destruction 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. It is recommended to disinfect the Instrument with LumiraDx recommended disinfecting material at least once per day when in use or if contamination is suspected, unless recommended otherwise for specific tests. For more information, please refer to the Product Insert for the Test you are performing.

What should be cleaned and disinfected?

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

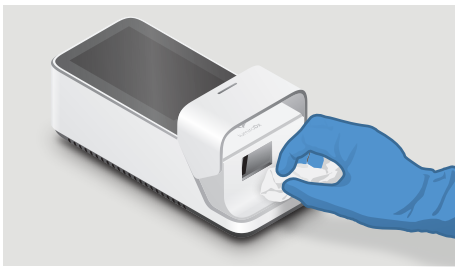
- The area around the Test Strip slot
- The entire Instrument housing
- The Instrument touch-screen
- All surfaces of the Instrument door

Cleaning and disinfecting

- Always wear gloves whilst cleaning and disinfecting the Instrument.
- Always use LumiraDx recommended materials to disinfect the Instrument. Details of LumiraDx recommended materials can be found at go.roche.com/lumiradx.
- **CAUTION: Excessive liquid may damage the Instrument**. It is important for the protection of the Instrument that exposure to excess moisture is prevented. All disinfection cloths and/or wipes should only be slightly damp, with any excess liquid being manually removed from the cloth or wipe before use.
- **CAUTION:** Liquid should not be placed in or near the vents on the bottom or back of the instrument.
- **CAUTION:** Alcohol wipes alone are not sufficient to disinfect the Instrument for blood-based samples, due to the potential presence of bloodborne pathogens.
- **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.



Cleaning Instrument touch-screen



Cleaning the area around the Test Strip slot

5.1 Cleaning procedure

Always wear gloves to clean the Instrument.

Wipe the external surfaces of the Instrument with a soft cloth that is slightly water dampened, but not wet.

CAUTION: Excessive liquid may damage the Instrument.

Dispose of cleaning materials in accordance with local biohazardous waste disposal procedures.

5.2 Disinfection procedure

5.2.1 General guidance on disinfecting the Instrument

Always wear gloves to disinfect the Instrument.

Before disinfecting the Instrument for the first time, it is necessary to remove the protective screen cover by peeling it off.

CAUTION: Excessive liquid may damage the Instrument. Prior to disinfecting, it is necessary to manually squeeze any excess liquid from disinfecting wipes or cloth. The wipe or cloth should be slightly damp, but not dripping or wet prior to disinfecting.

CAUTION: Liquid should not be placed in or near the vents on the bottom or back of the instrument.

It is recommended to disinfect the Instrument with LumiraDx recommended disinfecting material at least once per day when in use or if contamination is suspected, unless recommended otherwise for specific tests. For more information, please refer to the Product Insert for the Test you are performing.

5.2.2 Disinfection guidance – if only testing blood-based samples

It is recommended to disinfect the Instrument after each patient sample, or if contamination is suspected.

CAUTION: Excessive liquid may damage the Instrument. It is important for the protection of the Instrument that exposure to excess moisture is prevented. All disinfection cloths and/or wipes should only be slightly damp, with any excess liquid being manually removed from the cloth before use.

CAUTION: Alcohol wipes alone are not sufficient to disinfect the Instrument for blood-based samples, due to the potential presence of bloodborne pathogens.

Procedure:

1) Using a LumiraDx recommended disinfecting material, wipe the external surfaces of the Instrument while taking care to avoid the door hinges, Test Strip inlet, back and bottom vents, power cord, and USB port.

2) Allow the disinfectant at least 5 minutes contact time before testing the next sample

3) Dispose of disinfectant materials in accordance with local biohazardous waste disposal procedures

The Instrument is now ready to perform another test.

5.2.3 Disinfection guidance – if only testing swab-based samples

It is recommended to disinfect the Instrument at least once per day, or if contamination is suspected.

CAUTION: Excessive liquid may damage the Instrument. It is important for the protection of the Instrument that exposure to excess moisture is prevented. All disinfection cloths and/or wipes should only be slightly damp, with any excess liquid being manually removed from the cloth before use.

Procedure:

1) Using a LumiraDx recommended disinfecting material, wipe the external surfaces of the Instrument while taking care to avoid the door hinges, Test Strip inlet, back and bottom vents, power cord, and USB port.

2) Allow the disinfectant at least 1 minute contact time before testing the next sample.

3) Dispose of disinfectant materials in accordance with local biohazardous waste disposal procedures.

The Instrument is now ready to perform another test.

For technical assistance or questions and information about LumiraDx approved materials go to go.roche.com/lumiradx.

6. Software Updates

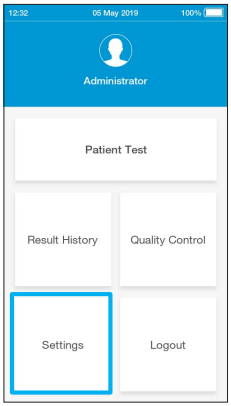
LumiraDx will contact administrators when software updates are available. Software updates will be provided on USB memory sticks and should be installed on each Instrument by the administrator. Installing the latest updates will help ensure that the LumiraDx Instrument operates with optimum performance 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 performing a software update.

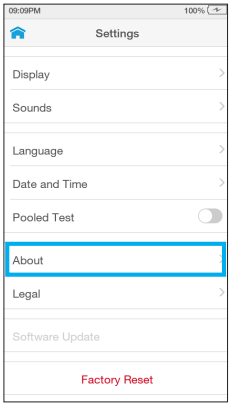
6.1 Check software version

1. Check the software version currently installed on the Instrument

Login to the Instrument from the home-screen tap the settings button



2. Tap the About button





6.2 Performing a software update

1. Power OFF the Instrument.

2. While the instrument is powered OFF, Remove the USB Memory Stick from its packaging and insert it into the USB port nearest to the power button as shown in the image at right.



3. Leave the USB Memory Stick inserted until after step 6.

4. Power ON the Instrument.

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.



5. Allow the Instrument to start up and complete the self-test.

6. Once you reach the login screen, remove the USB stick.

IMPORTANT: Do not remove the USB Memory Stick before the login screen is shown.

IMPORTANT: Please save your USB Memory Stick in the event a re-instalment of software update is required.



7. Troubleshooting

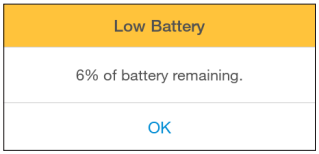
The LumiraDx Instrument regularly performs internal checks for unexpected and unwanted conditions. These may arise for technical reasons or due to handling errors.

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 ⚠ 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.

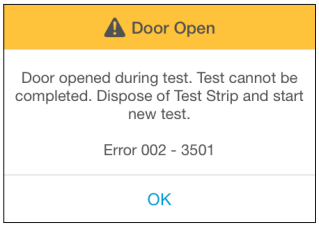
Example alert message:



Description and instruction

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

Example error message: Error 002

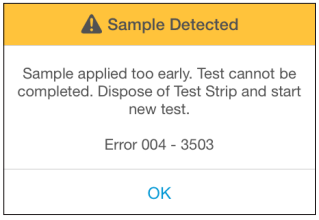


Description and instruction

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.

Example error message: Error 004

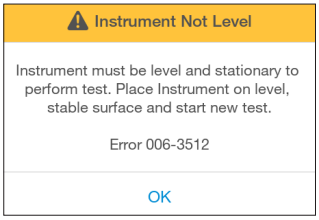


Description and instruction

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.

Example error message: Error 006



Description and instruction

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

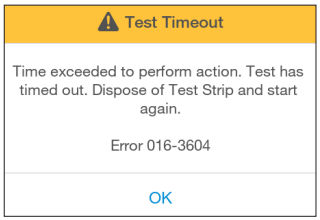
Place the Instrument on a level, stable surface and start a new test.

Example error message: Error 016

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.

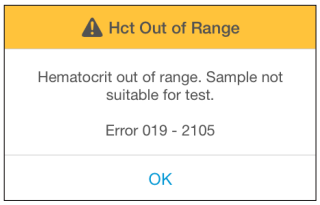


Example error message: Error 019

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.

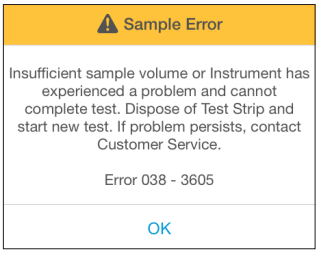


Example error message: Error 038

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.

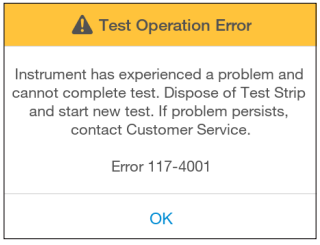


Example error message: Error 117

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 is 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 information sheet supplied with your LumiraDx Instrument 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 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 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). Specific Relative Humidity conditions may be more restrictive please refer to the individual Product Insert for the specific test you are performing.
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 12V / 3A
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 connecter 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.

LumiraDx Printer





Replacing the batteries





Connecting the printer



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.

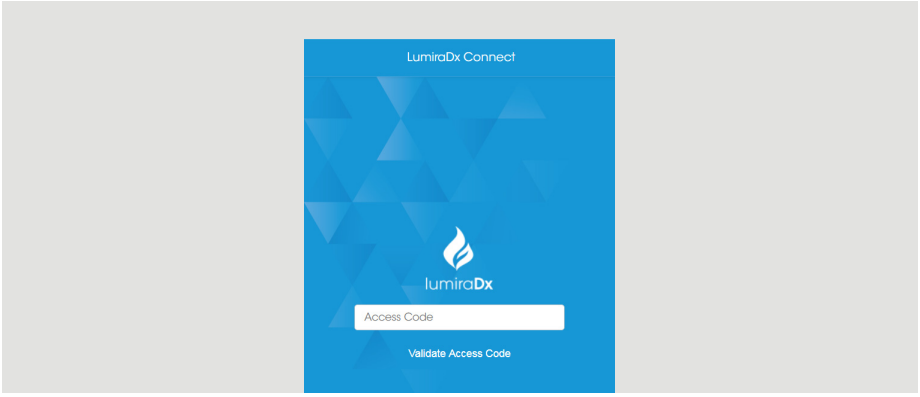
Note: Right side USB port nearest the power button at the rear of the Instrument must be used.

10.4 LumiraDx Connect Hub



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 inquiries and technical support, please contact Roche Customer Support Center at 1-800-800-5973.

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 go.roche.com/lumiradx.

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://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://who.int/gpsc/ipc-components-guidelines/en/
3. CDC Guideline for Isolation Precautions: Preventing Transmission of infectious Agents in Healthcare Settings 2007. https://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://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 go.roche.com/lumiradx for further information.

13.2 Compliance

The LumiraDx Platform is for use 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.

ENGLISH

lumiraDx™ SARS-CoV-2 Ag Quality Controls

For Professional Use Only
For Emergency Use Authorization (EUA) only
For *In Vitro* Diagnostic Use
Rx Use only

SPEC-32441 Rev4
ART-00620 Rev4 Rev Date 2025-06

The LumiraDx SARS-CoV-2 Ag Quality Controls (hereafter referred to as Quality Controls) are liquid quality controls to be used with the LumiraDx Instrument (hereafter referred to as the Instrument) and the LumiraDx SARS-CoV-2 Ag Test (hereafter referred to as SARS-CoV-2 Ag Test).

Read these instructions thoroughly before using the Quality Controls.

Inspect the Quality Controls packaging and contents for damage before use. Report any damage to LumiraDx Customer Services and do not use the kit if any damage is observed to the contents.

To ensure that you are using the Instrument, the SARS-CoV-2 Ag Test and the Quality Controls correctly, read the appropriate Platform User Manual, SARS-CoV-2 Ag Test Product Insert and this entire pack insert. In addition, please watch the LumiraDx Platform Training video available at go.roche.com/lumiradx. The Quality Controls are intended for healthcare professional use only.

Intended use

The LumiraDx SARS-CoV-2 Quality Controls are intended for liquid quality control testing performed on the LumiraDx Instrument when used with the LumiraDx SARS-CoV-2 Ag Test Strip. The Quality Controls provide users with assurance that the device is performing within specification.

Summary and explanation of the test

The LumiraDx SARS-CoV-2 Ag Quality Controls are liquid quality controls. The controls are specifically formulated and manufactured to ensure performance of the test and are used to verify the user's ability to properly perform the test and interpret the results.

It is the responsibility of each laboratory or healthcare setting using the LumiraDx SARS-CoV-2 Ag Test to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use. Quality control requirements should be followed in conformance with local, state, and federal regulations or accreditation requirements and the user laboratory's standard quality control procedures.

Warnings and Precautions

- For *in vitro* diagnostic use.
- This control contains human source material and as with all human based specimens, should be treated as potentially infectious and handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.
- All components of this kit can be discarded as biohazard waste according to the local guidelines.
- Refer to the product safety data sheet for risk and safety phrases and disposal information. The product safety data sheet is available for users upon request.
- Requirements of the appropriate licensing or accrediting body should be incorporated into your quality control program.
- Exercise the normal precautions required for handling all laboratory reagents.

Storage and stability

- Store controls between 2°C and 8°C (36 - 46°F).
- Unopened controls that are stored between 2°C and 8°C (36 and 46°F) can be used until the expiration date. Do not use kits or components beyond the expiration date given on the label.
- Once opened, the vial has a 30 day expiry.
- Open the Control Vials only when you are performing tests.
- Recap and store the Control Vials in their original container at 2°C and 8°C (36 and 46°F) after use.

Carton contents

- 2 x 0.5ml vial SARS-CoV-2 Ag Positive Control
- 2 x 0.5ml vial SARS-CoV-2 Ag Negative Control
- 40 Transfer pipettes (20µl)
- LumiraDx SARS-CoV-2 Ag Quality Control Pack Insert

Materials required but not provided with the Control Carton:

- LumiraDx Instrument
- LumiraDx SARS-CoV-2 Ag Test Strips
- LumiraDx Connect– if connectivity required (refer to LumiraDx Connect User Manual)

Getting ready to test

You will need the LumiraDx Instrument and the following supplies:

- LumiraDx SARS-CoV-2 Ag Test strip(s)
- LumiraDx SARS-CoV-2 Ag Positive or Negative Quality Controls
- Transfer pipette

Preparing the Quality Controls

The liquid controls are supplied ready to use.

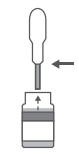
Handling the LumiraDx SARS-CoV-2 Ag Test Strips:

To ensure that you are using the SARS-CoV-2 Ag Test and the Instrument correctly, read the appropriate SARS-CoV-2 Ag Test Strip Product Insert and Platform User Manual.

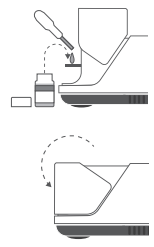
Procedure/performing a test

Consult the LumiraDx Platform User Manual for instructions on how to analyse a Quality Control sample. Open the foil pouch of the SARS-CoV-2 Ag Test Strip just before use and insert the Test Strip into the LumiraDx Instrument. The Instrument will indicate when ready for the sample to be applied.

1. **Draw up the Quality Control solution into the Transfer pipette.** For single bulb pipettes squeeze the bulb, drawing up QC material to where the tip of the pipette tapers as indicated by the arrow on the diagram. Take care to fill only the tip of the pipette to collect approximately 20µL of QC material.



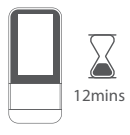
2. **Apply the Quality Control solution to the already inserted SARS-CoV-2 Ag Test Strip.** Hold the pipette over the Sample Application Area of the Test Strip and dispense the Quality Control solution. The LumiraDx Instrument will indicate sample is detected with an audible alert (if the Instrument sounds are enabled). The screen of the LumiraDx Instrument will request the user to close the door. Dispose of pipette.



3. **Do not open the door while the test is in progress**. The touch-screen will indicate test progress.



4. **The Result** will appear on the touch-screen within 12 minutes of applying the Quality Control solution and starting the test. The results will be displayed as a **PASS** or **FAIL** QC result for SARS-CoV-2 Ag on the instrument screen.



5. **NOTE**: If you need to repeat a test, use a new Test Strip.

Expected results

The Instrument displays the result as Pass or Fail. The result is automatically saved in the memory of the Instrument. The system is working properly and all handling has been done correctly when the test results obtained are displayed as PASS.

Symbols glossary:

	Temperature limitation
	Manufacturer
IVD	For *In Vitro* Diagnostic Use Only
REF	Catalogue number
LOT	Lot number
	Use-by date – indicates the date after which the unopened IVD/Quality Control material can not be used.
	Indicates that potential biological risks are associated with the Quality Control material.
	Refer to instructions for use.
CONTROL –	Indicates a negative control
CONTROL +	Indicates a positive control
EUA	Emergency Use Authorization
Rx Only	Prescription Use Only

Technical Support:

For product inquiries and technical support, please contact Roche Customer Support Center at **1-800-800-5973**.

Any adverse results experienced with the use of this product, and/or quality problems should also be reported to Customer Support by telephone at **1-800-800-5973**.

Limited warranty

LumiraDx SARS-CoV-2 Ag Quality Controls Pack – As per shelf life.

For the applicable warranty period, LumiraDx warrants 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 pack insert, 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 the customer's sole remedy, LumiraDx shall either repair or replace, at LumiraDx's discretion, the LumiraDx SARS-CoV-2 Ag Quality Controls Pack. 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 the 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 SARS-CoV-2 Ag Test Strips and Controls Pack to physical abuse, misuse, abnormal use, use inconsistent with the LumiraDx Platform User Manual, SARS-CoV-2 Ag Test Product Insert or SARS-CoV-2 Ag Quality Controls Pack 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.

Intellectual property:

The LumiraDx Instrument, Test Strips and all provided LumiraDx documentation ('Products') are protected by law. The Intellectual Property of the LumiraDx Products remains at LumiraDx. Details of relevant Intellectual Property regarding our products can be found at go.roche.com/lumiradx.

Legal notices:

Copyright © 2025 LumiraDx UK and affiliates. All rights reserved. LumiraDx and Flame logo are protected trademarks of LumiraDx International LTD. Full details of these and other registrations of LumiraDx can be found at go.roche.com/lumiradx. All other trademarks are the property of their respective owners.

Manufacturer information

LumiraDx UK Ltd, Dumyat Business Park, Alloa, FK10 2PB, UK.
Registration Number: 09206123

Distribution in USA:

Roche Diagnostics, 9115 Hague Road, Indianapolis, IN 46256, USA.

In the USA, this test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.