LumiraDx SARS-CoV-2 Ab Test Strip Product Insert

LumiraDx SARS-CoV-2 Ab Test

For Professional Use Only

For use under an Emergency Use Authorization (EUA) Only

For In Vitro Diagnostic Use Only

Rx Use Only

SPEC- 34695 Rev 2; ART- 01514 Rev 2 **Date of Revision 2022/08**

LumiraDx SARS-CoV-2 Ab Test

The LumiraDx SARS-CoV-2 Ab 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 touch-screen.

Intended use:
The LumiraDx SARS-CoV-2 Ab Test is a rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform for the qualitative detection of total antibodies to SARS-CoV-2 in human serum, plasma (dipotassium EDTA), venous whole blood (dipotassium EDTA), and fingerstick whole blood. The LumiraDx SARS-CoV-2 Ab Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. The LumiraDx SARS-CoV-2 Ab Test should not be used to diagnose or exclude acute SARS-CoV-2 infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.

Testing of venous whole blood, plasma, and serum specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet requirements to perform high or moderate complexity tests.

Testing of fingerstick whole blood specimens 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 high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens 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.

Results are for the detection of SARS-CoV-2 total antibodies. Antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The sensitivity of LumiraDx SARS-CoV-2 Ab Test early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary. False positive results for LumiraDx SARS-CoV-2 Ab Test may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a second, different total antibody assay.

Samples should only be tested from individuals that are 15 days or more post-symptom onset.

The LumiraDx SARS-CoV-2 Ab Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

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 Quick Reference Instructions and this entire product insert. Information available here: https://www.lumiradx.com/us-en/what-we-do/diagnostics/test-technology/antibody-test

Summary and explanation of the Test:

The World Health Organisation (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 SARS-CoV-2 Ab Test utilizes a combination of SARS CoV-2 antigen (RBD and S1 spike) coated magnetic particles and fluorescent particles for the detection of total antibody (Ab) raised in the immune response to SARS-CoV-2 infection in human serum, plasma (dipotassium EDTA), venous whole blood (dipotassium EDTA), and fingerstick whole blood.

Principle of the assay: The LumiraDx SARS-CoV-2 Ab Test is a single use fluorescence immunoassay device designed to detect the presence of SARS-CoV-2 total antibody (Ab) in human serum, plasma (dipotassium EDTA), venous whole blood (dipotassium EDTA), and fingerstick whole blood. The test procedure involves the addition of serum, plasma, venous whole blood, or fingerstick whole blood sample to the sample application area of the Test Strip inserted in the Instrument, which is programmed to perform the analysis when the sample has reacted with the reagents within the Test Strip. The analysis is based on the amount of fluorescence the Instrument detects within the measurement area of the Test Strip. The qualitative results are displayed on the Instrument touch-screen in approximately 11 minutes from the addition of sample.

Materials provided:

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

Materials required but not provided with the Test Strip carton:

- LumiraDx Instrument (available for purchase separately; Catalogue# L001000330001)

- Standard blood collection equipment (alcohol swabs, high flow lancets if using fingerstick whole blood sample, Blood collection tube if using venous whole blood sample, Transfer tubes, appropriate biowaste disposal)
- LumiraDx SARS-CoV-2 Ab Quality Controls (available for purchase separately from LumiraDx UK Ltd; Catalogue# L017080109002)
- LumiraDx Connect, if connectivity required (refer to LumiraDx Connect User Manual)
- Sarstedt Minivette POCT 20µl transfer pipette (Catalogue# 17.2111.020), if using the alternative transfer tube method to apply a fingerstick whole blood sample to the Test Strip.

Warnings and precautions

- For *in vitro* diagnostic use only
- Do not use the kit components beyond the expiration date
- For prescription use only
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for detecting the presence of total antibodies to 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 diagnostics 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.
- 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.
- Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results.
- Refrigerated whole blood, serum or plasma specimens must be allowed to reach room temperature before testing. Before use, mix whole blood venous, plasma and serum specimens thoroughly by gently inverting the tube several times.
- The test cannot be visually interpreted; the LumiraDx Instrument must be used to generate results.
- Do not reuse any kit components.
- Specimens must be processed as indicated in the Specimen sample collection and Performing a Test sections of this Product Insert. Failure to follow the instructions for use can result in inaccurate results.
- 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 https://lumiradx.com/us-en/what-we-do/diagnostics/test-technology/antibody-test.
- Exercise the normal precautions required for handling all laboratory reagents. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated.
- Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2 patient samples. Patient specimens, used Test Strips and used Transfer tubes may be potentially infectious. Proper handling and disposal methods should be established by the laboratory in accordance with local, state and federal regulations.
- For additional information on safety, handling, and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at lumiradx.com
- A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
- Not for the screening of donated blood.

- It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to infection.
- This test should not be used to diagnose or exclude acute SARS-CoV-2 infection.
- The performance of this test has not been established in individuals that have received a COVID-19 vaccine. The clinical significance of a positive or negative antibody result following COVID-19 vaccination has not been established, and the result from this test should not be interpreted as an indication or degree of protection from infection after vaccination.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. The samples for the negative agreement study were collected in the United States and United Kindom either prior to November 2019 or between May 2020 and August 2020. The samples for the positive percent agreement study were collected in the United States and United Kindom between April 2020 and May 2020. 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.

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 passed 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. 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 Ab Test Strip:

- Non-anticoagulated Fingerstick whole blood
- Anticoagulated venous whole blood (K_2-EDTA)
- Plasma (K_2-EDTA)
- Serum

Sample Storage:

- Non-anticoagulated Fingerstick whole blood should be used immediately.
- Anticoagulated venous whole blood (K_2-EDTA) should be used within 1 hour of blood draw otherwise it should be processed to plasma.
- Plasma (K_2-EDTA) is stable for up to 8 hours at room temperature
- Serum is stable for up to 8 hours at room temperature
- Samples that require long term storage prior to testing may be stored at ≤ –20°C. Samples may be frozen and thawed once.

The test device contains:
- SARS-CoV-2 Antigen
- Fluorescent particles
- Magnetic particles
- Buffer and stabilising Agents

Specimen sample collection and preparation for analysis: When collecting any type of sample,

follow universal blood collection precautions and guidelines according to your organization. For specimen collection of venous whole blood, plasma and serum, follow the sample tube manufacturer´s recommended procedure.

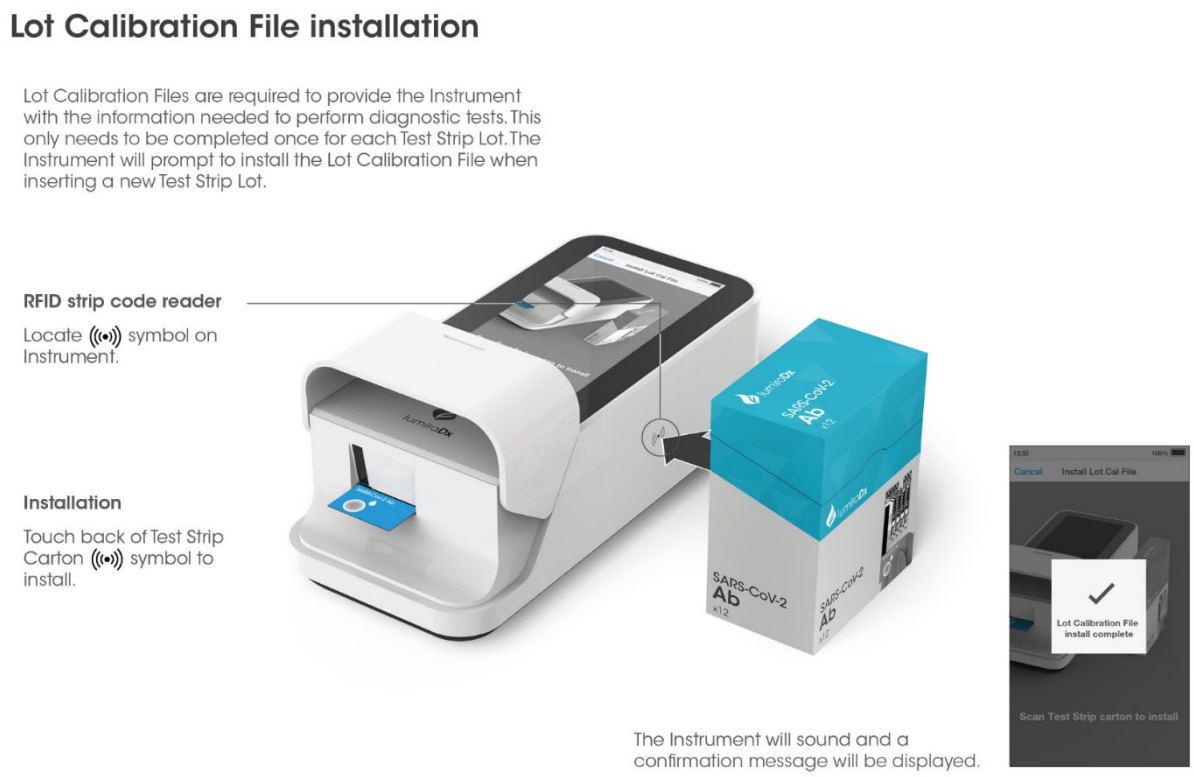
The steps that follow apply to collecting a a fingerstick whole blood sample. Optionally, you may use the Sarstedt Minivette POCT 20µl transfer pipette (cat. No. 17.2111.020, not included with the Test Strips) to transfer the fingerstick blood sample onto the test strip. Only auto-disabling, single use, high flow lancing devices may be used to collect fingerstick whole blood.

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.

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.



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 Ab Test results should be evaluated by a Healthcare Professional in the

context of all available clinical and laboratory data.

Testing fingerstick whole blood samples – Directly applying blood from a hanging blood drop

1. Increasing the blood flow in the finger will help to get a good drop of blood. Before lancing the finger, the following techniques can be used until the fingertip has increased colour:
   - Ask the patient to rinse their hands with warm water.
   - Ask the patient to hold his or her arm straight down at their side
   - Massage the finger from its base, and if required, immediately after lancing, very gently squeeze the finger from its base to encourage blood flow.
2. **Use a high flow lancet** (20uL) on the selected finger to obtain a blood sample.
3. **Immediately apply the sample** by holding the finger and the hanging blood drop over the Sample Application Area of the strip already inserted into the instrument (see **Preparing the Instrument to perform a Test** above). Allow the blood drop to touch the Sample Application Area of the Test Strip. Blood will then be drawn by capillary action into the Test Strip. When the sample is detected the Instrument will sound (if sounds are enabled) and a confirmation message will be displayed. The touch-screen of the LumiraDx Instrument will request the user to close the door.
4. **Do not add more blood**. Do not open the door while the test is in progress. The touch-screen will indicate test progress.
5. **The result** will appear on the Instrument touch-screen within approximately 11 minutes of applying the sample and starting the test. Examples of the result screens display:-

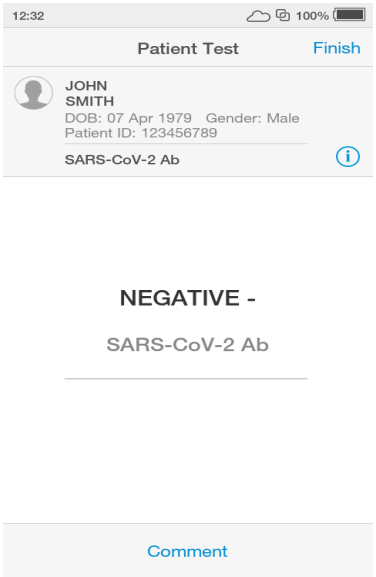


Fig.1 Negative Result for SARS-CoV-2 Antibody

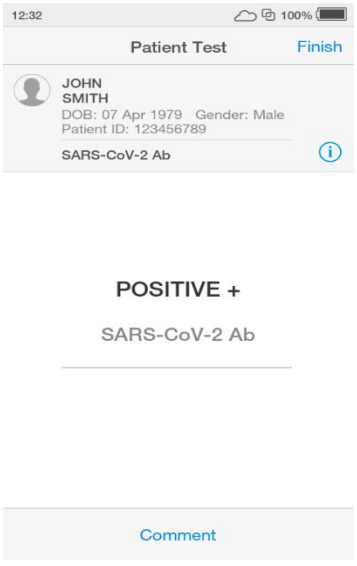


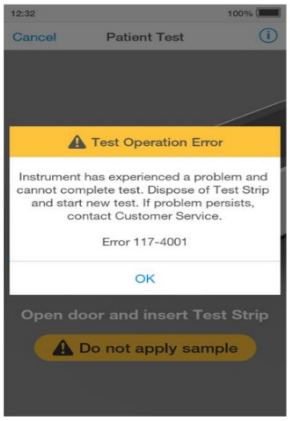
Fig.2 Positive Result for SARS-CoV-2 Antibody

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

8. If you need to retest, use a new Test Strip and lancet, and a different finger.

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 LumiraDx Customer Services on telephone number 1-888-586-4721.



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 Services.

Transfer of fingerstick whole blood samples using transfer tube (optional)

Alternatively, the Sarstedt Minivette POCT 20µl transfer pipette (cat. No. 17.2111.020, not included) can be used to transfer the fingerstick whole blood sample to the Sample Application Area of the Test Strip. To do this follow the procedure above for lancing the finger to obtain a blood sample. Immediately, use the Transfer Tube by placing it into the blood droplet on the finger without blocking the air ventilation hole at the end of the tube piston (the piston should not be pushed down), and the blood should quickly move into the tube. Stop collecting blood when it has reached the filter at the other end of the capillary tip. Ensure there are no air bubbles present. Then hold the Transfer Tube over the Sample Application Area of the Test Strip already inserted into the instrument (see **Preparing the Instrument to perform a Test** above) and press down the piston to dispense the sample. This should be enough just to fill the Sample Application Area. Take care not to introduce air bubbles into the sample. When the sample is detected the Instrument will sound (if sounds are enabled) and a confirmation message will be displayed. The touch-screen of the LumiraDx Instrument will request the user to close the door. Dispose of the Transfer Tube in the appropriate clinical waste. Follow instructions from step 4.

Testing from venous blood, serum or plasma sample

Mix the sample well before testing. You may use K_2-EDTA venous blood, K_2-EDTA plasma or serum samples for testing. Use a micropipette to remove 20µl of sample from the tube. Hold the micropipette over the Sample Application Area of the Test Strip already inserted into the instrument (see **Preparing the Instrument to perform a Test** above) and dispense the sample. This should be enough just to fill the Sample Application Area. Take care not to introduce air bubbles into the sample. When the sample is detected the Instrument will sound (if sounds are enabled) and a confirmation message will be displayed. The touch-screen of the LumiraDx Instrument will request the user to close the door. Dispose of the pipette in the appropriate clinical waste. Follow instructions step 4 and 5.

Testing patient specimens procedural notes:

- Refrigerated whole blood, serum or plasma specimens must be allowed to reach room temperature before testing.
- Before use, mix whole blood venous, plasma and serum specimens thoroughly by gently inverting the tube several times.

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 Ab Test Strips have several quality control functions integrated to ensure validity of each test run. These checks ensure that the volume of sample added is sufficient, the hematocrit level of whole blood sample test is within the range that can be used with the Test Strip and 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 Quality Control Tests using LumiraDx Quality Control solutions to meet regulatory compliance requirements.

Quality controls:

Liquid Quality Controls for the LumiraDx SARS-CoV-2 Ab Test are available for purchase from LumiraDx (Catalogue# L017080109002). Details can be found via the website (lumiradx.com) or at the Customer Services telephone number 1-888-586-4721. Good laboratory practice recommends the use of control materials. Follow the appropriate federal, state and local guidelines concerning the frequency of testing quality control material. To complete Quality Control assessment of the LumiraDx Instrument and SARS-CoV-2 Ab Test Strips, you must use the LumiraDx SARS-CoV-2 Ab Quality Control Pack. The Quality Controls come as Positive and Negative controls.

SARS-CoV-2 Ab Positive Control (2 x 0.5mL): heat-treated convalescent plasma positive for antibodies to SARS-CoV-2 in human plasma matrix containing 5% 1,2,3-propanetriol, 0.1% sodium azide and 0.1% ProClin 950.

SARS-CoV-2 Ab Negative Control (2 x 0.5mL): heat-treated SARS-CoV-2 antibody negative plasma matrix containing 5% 1,2,3-propanetriol, 0.1% sodium azide and 0.1% ProClin 950.

Quality controls should be run for:

- each new kit lot
- each new operator
- as required by internal quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.

If the LumiraDx Antibody Quality Controls do not perform as expected, repeat the QC Test and if the problems persists, do not report patient results and contact LumiraDx Customer Services on telephone number 1-888-586-4721.

Cleaning and Disinfection.

It is recommended to disinfect the Instrument after each patient sample, or if contamination is suspected. Details of LumiraDx approved disinfectant materials can be found at www.lumiraDx.com. 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. Alcohol wipes alone are not sufficient to disinfect the Instrument for blood-based samples, due to the potential presence of bloodborne pathogens

1.Using a LumiraDx recommended disinfecting material (Please see www.lumiradx.com for further details), wipe the external surfaces of the Instrument while taking care to avoid the door hinges, Test Strip inlet, power cord, vents and USB port.

2.Allow the disinfectant at least 5 minutes contact time with the Instrument before testing the next sample.

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

Limitations of the procedure:

- Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
- Test results should be considered in the context of all available clinical and diagnostic information, including patient history and other test results.
- There is the possibility that factors such as technical or procedural errors, as well as additional substances in blood specimens that are not listed below, may interfere with the test and cause erroneous results.
- Blood specimen types, draw methods or anticoagulants different from those described in this product insert have not been evaluated.
- Interference may be observed when plasma biotin concentration is greater than 0.007 mg/dL.
- Samples should only be tested from individuals that are 15 days or more post-symptom onset.
- Hematocrit values between 25-55% do not significantly affect test results. Hematocrit values outside the range 25-55% will generate an error message showing 'Hct Out of Range' and no SARS-CoV-2 Ab Test result will be reported.
- Any unusual result must always be followed up to identify the potential cause.
- Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection.
- Results that do not match the clinical symptoms should be repeated to rule out a procedural error.
- When performing a new test or repeating a patient test, always use a new lancet to obtain a fresh drop of blood from a different finger and use a new Test Strip.
- Information regarding approved cleaning wipes can be found at www.lumiradx.com.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
- A negative result for an individual subject indicates absence of detectable anti-SARS-CoV-2 antibodies. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. The sensitivity of this assay early after infection is unknown.

- A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
- The performance of this test has not been established in individuals that have received a COVID-19 vaccine. The clinical significance of a positive or negative antibody result following COVID-19 vaccination has not been established, and the result from this test should not be interpreted as an indication or degree of protection from infection after vaccination.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. The samples for the negative agreement study were collected in the United States and United Kingdom either prior to November 2019 or between May 2020 and August 2020. The samples for the positive percent agreement study were collected in the United States and United Kingdom between April 2020 and May 2020. 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.

Conditions of Authorization for the Laboratory

The LumiraDx SARS-CoV-2 Ab Test Letter of Authorization*, along with the authorized Fact Sheet forHealthcare 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 Ab Test ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

A. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

B. Authorized laboratories must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instrument, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

C. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

D. 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.

E. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and to you (email: customerservices.US@lumiradx.com or telephone 1-888-586-4721) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

F. All laboratory personnel using your product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.

G. LumiraDx, authorized distributor(s), 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.

*The letter of authorization refers to, "authorized laboratories" as the following: Testing of serum, plasma and venous whole blood is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests.

Testing of fingerstick whole blood specimens 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 high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens 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.

Performance characteristics

Clinical Agreement

Positive agreement was evaluated using plasma samples collected from symptomatic subjects in the USA and UK between April 2020 and May 2020. All subjects were confirmed positive for 2019 Novel Coronavirus by RT-PCR.

Days from RT-PCR to Blood Collection	Number of Samples	2019-nCoV RT-PCR Result	LumiraDx SARS-CoV-2 Ab Test Result as compared to RT-PCR
0-7 days	17	Positive	**15/17 = 88.2%** (95%CI = 65.7% - 96.7%)
8-14 days	6	Positive	**6/6 = 100%** (95%CI = 61.0% - 100.0%)
≥ 15 days	49	Positive	**49/49 = 100%** (95%CI = 92.7% - 100.0%)
Total	**72**	**Positive**	**70/72 = 97.2%** (95% CI= 90.4% - 99.2%)

Negative agreement of the LumiraDx SARS-CoV-2 Ab Test was evaluated using plasma samples from endemic symptomatic and asymptomatic subjects collected between May 2020 and August 2020, and asymptomatic subjects collected prior to November 2019 in the UK and USA. All samples were confirmed negative for 2019 Novel Coronavirus by RT-PCR. The resulting Negative Agreement of the LumiraDx SARS-CoV-2 Ab Test compared to the expected result is presented below.

Number of Samples	Origin	Test Population	LumiraDx SARS-CoV-2 Ab Test Result as compared to RT-PCR
15	UK	*PCR negative, Symptomatic Subjects*	15/15 = 100% (95% CI = 79.6% - 100%)
13	UK	*PCR negative, Asymptomatic Subjects*	13/13 = 100% (95% CI = 77.2% - 100%)
99	USA	*Collected prior to December'2019*	99/99 = 100% (95% CI = 96.3% - 100%)
163	UK	*Collected prior to December'2019*	163/163 = 100% (95% CI = 97.7% - 100%)
Total = 290	-	-	**290/290 = 100% 95% CI= 98.7 - 100%)**

Point-of-care study with Fingerstick Blood Samples:
Positive agreement was evaluated using fingerstick samples collected prospectively from symptomatic subjects. All subjects were confirmed positive or negative for 2019 Novel Coronavirus by RT-PCR prior to testing. Fingerstick specimens from each patient were applied directly and using Transfer tube (the Sarstedt Minivette POCT, 20µl transfer pipette; cat. No. 17.2111.020). Results presented are from subjects tested 8 - 118 days since RT-PCR test.

Direct sample collection and testing

Days from RT-PCR to Sample Collection	Number of Samples	2019-nCoV RT-PCR Result	LumiraDx SARS-CoV-2 Ab Test Result as compared to RT-PCR (95% CI)
≤7 days	0	N/A	N/A
8-14 days	3	Positive	**3/3 = 100%** (95% CI = 43.85% - 100.0%)
> 14 days	54	Positive	**54/54 = 100%** (95% CI = 93.4% - 100.0%)
Total	**57**	**Positive**	**57/57 = 100% (95% CI = 93.7% - 100.0%)**

Sample collection by transfer tube (Sarstedt Minivette POCT) and testing:

Days from RT-PCR to Sample Collection	Number of Samples	2019-nCoV RT-PCR Result	LumiraDx SARS-CoV-2 Ab Test Result as compared to RT-PCR (95% CI)
≤7 days	0	N/A	N/A
8-14 days	3	Positive	**3/3 = 100%** (95% CI = 43.85% - 100.0%)
> 14 days	54	Positive	**54/54 = 100%** (95% CI = 93.4% - 100.0%)
Total	**57**	**Positive**	**57/57 = 100% (95% CI = 93.7% - 100.0%)**

Negative agreement was evaluated using fingerstick samples samples collected from symptomatic and asymptomatic subjects. All subjects were confirmed negative for 2019 Novel Coronavirus by RT-PCR. Fingerstick specimens from each patient were applied directly and using Transfer tube.

Sample collection method	Number of Samples	2019-nCoV RT-PCR Result	LumiraDx SARS-CoV-2 Ab Test Result as compared to RT-PCR (95% CI)
Direct Transfer of Fingerstick Blood	53	Negative	53/53 = 100% (95% CI = 93.24% - 100%)
Fingerstick Blood via Transfer Tube	55	Negative	55/55 = 100% (95% CI = 93.47% - 100%)

Independent Clinical Agreement Evaluation Study:
The LumiraDx SARS-CoV-2 Ab Test from LumiraDx UK Ltd was tested on 2022-07-27 through 2022-07-28 at the Frederick National Laboratory for Cancer Research (FNLCR), a Federally Funded Research and Development Center (FFRDC) sponsored by the National Cancer Institute (NCI). The test was validated against a panel of previously frozen samples consisting of 30 SARS-CoV-2 antibody-positive serum samples and 80 antibody-negative anticoagulant Citrate Dextrose Solution

Formula A (ACD-A) plasma samples. Each of the 30 antibody-positive samples were confirmed with a nucleic acid amplification test (NAAT) and both IgM and IgG antibodies were confirmed to be present in all 30 samples. The presence of antibodies in the samples was confirmed by several orthogonal methods prior to testing with LumiraDx SARS-CoV-2 Ab Test Antibody Test. The presence of IgM and IgG antibodies specifically was confirmed by one or more comparator methods. Antibody-positive samples were selected at different antibody titers.

All antibody-negative samples were collected prior to 2020 and include i) Seventy (70) samples selected without regard to clinical status, "Negatives" and ii) Ten (10) samples selected from banked serum from HIV+ patients, "HIV+".

Testing was performed by one operator using 1 lot of LumiraDx SARS-CoV-2 Antibody tests. Confidence intervals for sensitivity and specificity were calculated per a score method described in CLSI EP12-A2 (2008). For the evaluation of cross-reactivity with HIV+, it was determined whether an increased false positive rate among antibody-negative samples with HIV was statistically higher than the false positive rate among antibody-negative samples without HIV (for this, a confidence interval for the difference in false positive rates was calculated per a score method described by Altman). The results and data analysis are shown in the tables below.

Summary Results

	Comparator Method			Collected pre-2020		Total
	Antibody Positive			Antibody Negative		
LumiraDx SARS-CoV-2 Ab Test	IgM+, IgG+	IgM+, IgG-	IgM-, IgG+	Negative	HIV+	Total
Pan Ig+	30			1		31
Pan Ig-				69	10	79
Total	30			70	10	110

Summary Statistics

Measure	Estimate	Confidence Interval
Pan Ig Sensitivity	100% (30/30)	(88.7%; 100%)
Pan Ig Specificity	98.8% (79/80)	(93.3%; 99.8%)
Combined Sensitivity	100% (30/30)	(88.7%; 100%)
Combined Specificity	98.8% (79/80)	(93.3%; 99.8%)
Combined PPV for prevalence = 5.0%	80.8%	(40.9%; 96.0%)
Combined NPV for prevalence = 5.0%	100%	(99.4%; 100%)
Cross-reactivity with HIV+	0.0% (0/10), not detected	

Important limitations:

1) Samples were not randomly selected, and sensitivity and specificity estimates may not be indicative of the real-world performance of the device.
2) These results are based on serum and plasma samples only and may not be indicative of performance with other sample types, such as whole blood, including finger stick blood.
3) The number of samples in the panel is a minimally viable sample size that still provides reasonable estimates and confidence intervals for test performance, and the samples used may not be representative of the antibody profile observed in patient populations.

Matrix Equivalency

A matrix equivalency study was performed to evaluate K_2-EDTA venous and serum matrices against the K_2-EDTA plasma matrix used for determination of the clinical performance. Each matrix set (K_2-EDTA venous blood, K_2-EDTA plasma and serum) was tested from the same donor and paired samples were used. Negative, low positive and moderate positive were evaluated by running five different

samples, in duplicate for each concentration. The study demonstrated 100% agreement across the 3 matrix types (K_2-EDTA venous blood, K_2-EDTA plasma and serum) therefore clearly demonstrating that the performance between the matrices can be considered equivalent.

Analytical Sensitivity and Specificity

Reactivity/Inclusivity: Although mutations in the SARS-CoV-2 genome have been identified as the virus has spread, no serologically unique strains have been described relative to the originally isolated virus (this research is exceptionally limited at present).

Cross-Reactivity: Cross-reactivity of the LumiraDx SARS-CoV-2 Ab Test was evaluated by testing serum and plasma samples collected from individuals with underlying diseases in the acute or convalescent stages of infection for the underlying condition. No reactivity was detected with the potential cross reactants as shown in the table below:

Potential cross-reactant	LumiraDx SARS-CoV-2 Ab Test Result		
	No. of samples	Positive	Negative
Influenza A	14	0	14
Influenza B	9	0	9
Hepatitis C Virus	10	0	10
Hepatitis B Virus (Genotype D)	9	0	9
Haemophilus influenzae	5	0	5
Human Coronavirus 229E	5	0	5
Human Coronavirus NL63	12	0	12
Human Coronavirus OC43	18	0	18
Human Coronavirus HKU1	9	0	9
Anti-Nuclear Antibody	6	0	6
Respiratory Syncytial Virus	7	0	7
HIV	10	0	10
Epstein Barr Virus	5	0	5
Mycoplasma pneumoniae	3	0	3
Streptococcus pneumoniae	3	0	3
Bordetella pertussis	3	0	3
Mycobacterium tuberculosis	3	0	3
Legionella pneumophila	3	0	3
Total	**134**	**0**	**134**

Interference

The following substances were tested at the concentrations shown with no observed interference:

Interferent	Test Concentration
Acetaminophen	15.6 mg/dL
Ascorbic Acid	5.25 mg/dL
Bilirubin (unconj)	40 mg/dL
Haemoglobin (via Hemolysis)	1000 mg/dL
Lipemia	1500 mg/dL
Total Protein	16.7 g/dL
Uric Acid	23.5 mg/dL

Gentisic Acid	0.5 mg/dL
Ethanol	200 mg/dL
Caffeine	10.8 mg/dL
Acetylsalicylic acid	3.0 mg/dL
Biotin	0.007 mg/dL
Diphenhydramine	0.0774 mg/dL
Fluticasone	0.000126 mg/dL

Point of Care Use

The LumiraDx SARS-CoV-2 Ab Test was used by 7 untrained users in 3 sites across the United States. Untrained users tested 420 subject tests. The user error rate was 3.1%.

References:

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

Symbols glossary:

Symbol	Meaning
	Temperature limitation
	Manufacturer
	*In Vitro* Diagnostic Medical Device
	Catalogue Number
	Batch code/Lot Number

	Use by
	Consult Instructions for Use
Rx Only	Prescription Use Only
	Do Not Re-use

LumiraDx customer services:

For product inquiries please contact LumiraDx Customer Services by email: customerservices.US@lumiradx.com or telephone 1-888-586-4721 or at lumiradx.com

For return policy

If there is a problem with the **LumiraDx SARS-CoV-2 Ab Tests** you may be asked to return them. Before returning tests please obtain a return authorization number from LumiraDx Customer Services. This return authorization number must be on the shipping carton for return. For ordinary returns following purchase, please contact LumiraDx Customer Services for terms and conditions.

Limited warranty

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

Unused Test 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 Ab 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.

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 lumiradx.com/IP.

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

LumiraDx US Office. 221 Crescent St, Suite 502, Waltham, MA 02453. Telephone: (617) 621-9775

LumiraDx™

LumiraDx SARS-CoV-2 Ab Test Quick Reference Instructions for Fingerstick Whole Blood.

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

SPEC-32783 R1 S-COM-ART-00408 Rev3 Date of Rev 2021/07

The LumiraDx SARS-CoV-2 Ab Test is a rapid microfluidic immunofluorescence assay for use on the LumiraDx Platform intended for qualitative detection of total antibodies to SARS-CoV-2 in human serum, plasma (dipotassium EDTA), venous whole blood (dipotassium EDTA), and fingerstick whole blood samples. Samples should only be tested from individuals that are 15 days or more post-symptom onset. The LumiraDx SARS-CoV-2 Ab Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.
Study the **LumiraDx Platform User Manual** and **LumiraDx SARS-CoV-2 Ab 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% - 90% relative humidity. Refrigerated samples must be allowed to reach room temperature and be mixed thoroughly 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 Ab Test Strip Product Insert for Specimen Collection, Warning and Precautions, and Limitations.
Warning and Precautions - 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 lumiradx.com/us-en/what-we-do/diagnostics/test-technology/antibody-test. 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 specimens, used Test Strips and used transfer tubes 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 and where any component is of animal origin, the source is certified as free from infectious or contagious material – however, should any reagent become exposed it should be treated as potentially infectious.

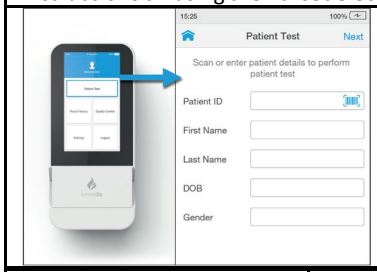
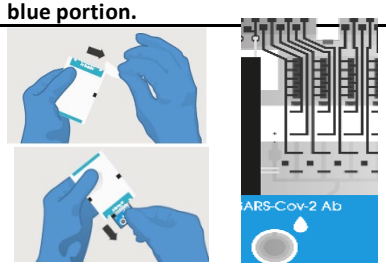
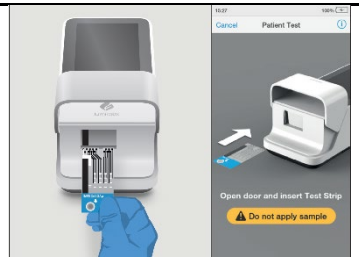
Kit Contents:

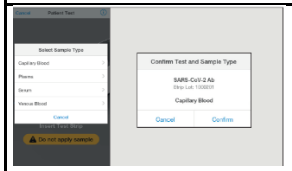
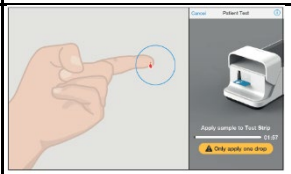
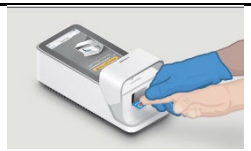
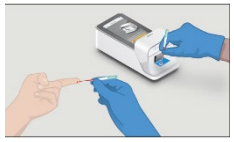
- 48 x LumiraDx SARS-CoV-2 Ab Test Strips packed individually in sealed desiccant foil pouches.
- 1 x LumiraDx SARS-CoV-2 Ab Test Product Insert
- 1x LumiraDx SARS-CoV-2 Ab Test Quick Reference Instructions (QRI)
- 1 x RFID (Radio frequency ID) Tag held inside the Test Strip carton

Item not included but may be required

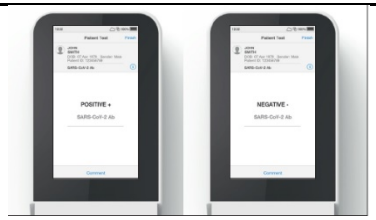
- Sarstedt Minivette POCT 20µl transfer pipette (Catalogue# 17.2111.020), if using the alternative transfer tube method to apply a fingerstick whole blood sample to the Test Strip.
- LumiraDx Instrument (available for purchase separately; Catalogue# L001000330001)
- LumiraDx SARS-CoV-2 Ab Quality Controls (available for purchase separately from LumiraDx UK Ltd; Catalogue# L017080109002)
- LumiraDx Connect, if connectivity required (refer to LumiraDx Connect User Manual)

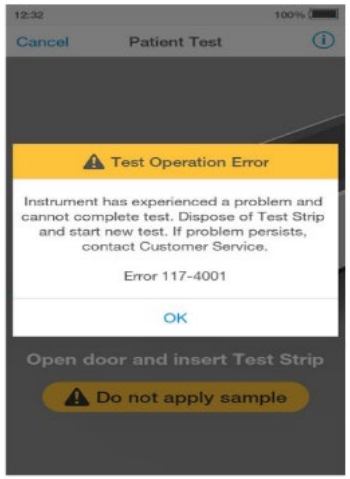
Running the Test

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. When prompted to apply the sample by the **Instrument** use a high-flow lancet on the finger to create a hanging blood drop if using a capillary sample.	6. Apply **one whole drop** of blood onto the **Test Strip Sample Application Area** when prompted by the **Instrument** directly from the hanging blood drop.	7. Alternatively the Sarstedt Minivette POCT 20µl transfer pipette (cat. No. 17.2111.020, not included) can be used. a) Hold the Minivette POCT 20 uL transfer pipette in a horizontal, slightly declined position, under the wings. The air ventilation hole at the end of the piston should not be covered, nor should the piston be pushed down. Touch the blood drop with the capillary tip of the pipette. The blood will automatically flow into the tube. b) Wait until the blood fills the capillary tip reaches the filter at the other end of the tip. (ensuring there are no air bubbles present. c) Hold the Minivette POCT 20 uL transfer pipette over the Sample Application Area of the Test Strip and slightly press down the piston to dispense the sample. Take care not to introduce bubbles into the sample
			

8. Close the door when prompted to continue the test.	9. Results are displayed within 11 minutes of applying the sample. The left-hand image here shows a positive result for SARS-CoV-2 Ab and the right-hand image shows a negative result for SARS-CoV-2 Ab. 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.





Example of an error screen: If the OnBoard 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 Services.

INTERPRETATION OF RESULTS

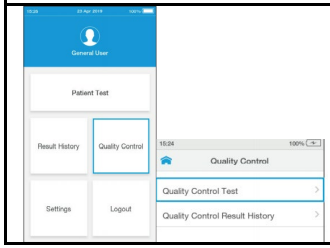
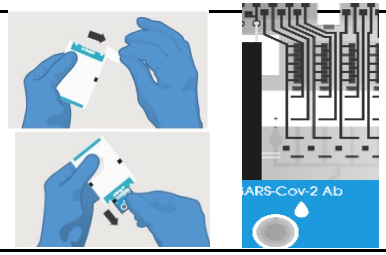
Positive Test Results – A positive result indicates the presence of SARS-CoV-2 antibodies.

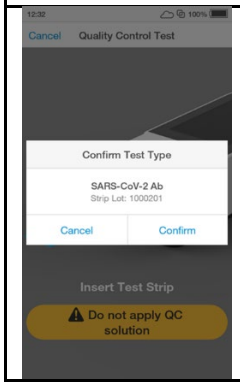
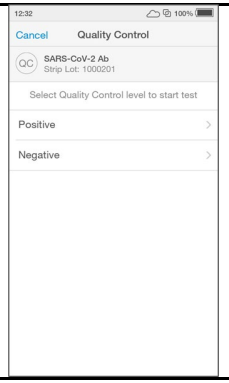
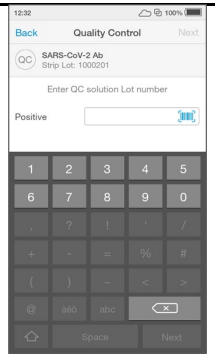
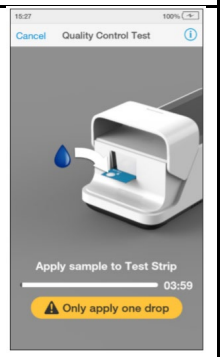
Negative Test Results – A negative result indicates that no SARS-CoV-2 antibodies are present. Negative results do not rule out SARS-CoV-2 infection.

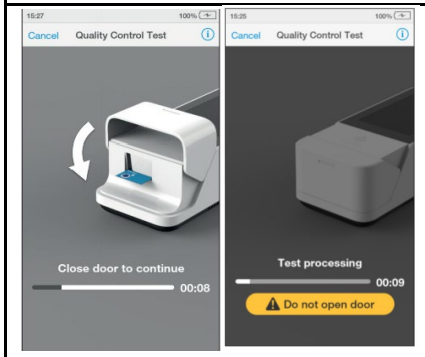
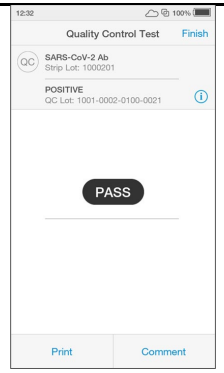
Invalid Results - If an issue occurs, a message will be displayed on the Instrument touch-screen. Alert messages include useful information and are highlighted by an orange banner. Error messages also include a ⚠ symbol. All messages will contain a description of the Instrument status or error and an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

Quality Controls - To complete Quality Control assessment of the LumiraDx Instrument and SARS-CoV-2 Ab Test Strips, you must use the LumiraDx SARS-CoV-2 Ab Quality Control Pack which are available separately (Catalogue# L017080109002). If the LumiraDx Antibody Quality Controls do not perform as expected, do not report patient results. Retest using a new Test Strip – if problems persist contact LumiraDx Customer Services on telephone number 1-888-586-4721.

Running the QC Test

1. Select *Quality Control* from the **Instrument** *Home Screen* and next tap ap 'Quality Control Test' from the Quality Control menu.	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 quality control 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. Check the test type is correct and tap '*Confirm*' to proceed.	5. Select the intended Quality Control, *Positive* or *Negative* from the list displayed.	6. 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	7. 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.
			

8. The Instrument display will display a prompt to close the door	9. When the QC test is complete the result,, PASS or FAIL will be displayed on the screen. An example result is shown here. Review the result then tap 'Finish' or tap 'Comment' to add a comment, if required.
	

In the USA:

This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

This product has been authorized only for detecting the presence of total antibodies to 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 diagnostics 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.

Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. Testing of fingerstick whole blood 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.

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 between each patient test or if contamination is suspected using LumiraDx approved materials. Details of LumiraDx approved disinfectant materials can be found at www.LumiraDx.com. Use the wipe until the surface of the Instrument is visibly wet. Allow the surface to remain wet for **5 minutes** 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.

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

Customer Services

If the **LumiraDx SARS-CoV-2 Ab Test** or the **LumiraDx Instrument** do not perform as expected, contact LumiraDx Customer Services **1-888-586-4721 or** customerservices.us@lumiradx.com

LumiraDx SARS-CoV-2 Ab Quality Controls

For Professional Use Only

For Use under Emergency Use Authorization (EUA) only

For In Vitro Diagnostic Use

Rx Use only

SPEC- 34696 Rev 1 ART-01515 Rev 1 Date of Revision: 2021/08

The LumiraDx SARS-CoV-2 Ab 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 Test Ab Test (hereafter referred to as SARS-CoV-2 Ab 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 Ab Test and the Quality Controls correctly, read the appropriate Platform User Manual, SARS-CoV-2 Ab Test Product Insert and this entire pack insert. In addition, please watch the LumiraDx Platform Training video available at lumiradx.com. 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 Ab 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 Ab Quality Controls are normal human plasma-based reagents:

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 Ab 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.
- For Emergency Use Authorization only.
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product is authorized for use with a test authorized only for detecting the presence of total antibodies to 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 diagnostics 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.
- This control contains human source material that was tested and found nonreactive for the Human Immunodeficiency Virus (HIV 1 and 2) antibody, Hepatitis B Surface Antigen (HbsAg) and Hepatitis C Virus (Anti-HCV) at the donor stage. This product, 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 Ab Positive Quality Control: heat-treated convalescent plasma positive for antibodies to SARS-CoV-2 in human plasma matrix with 5% 1,2,3-propanetriol, 0.1% Sodium Azide and 0.1% ProClin 950
- 2 x 0.5ml vial SARS-CoV-2 Ab Negative Quality Control: heat-treated SARS-CoV-2 antibody negative plasma matrix containing 5% 1,2,3-propanetriol, 0.1% sodium azide and 0.1% ProClin 950
- 40 Transfer pipettes (20µl)
- LumiraDx SARS-CoV-2 Ab Quality Control Pack Insert

Materials required but not provided with the Control Carton:

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

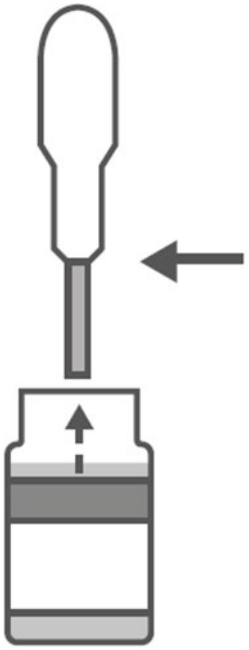
Preparing the Quality Controls:

The liquid controls are supplied ready to use.

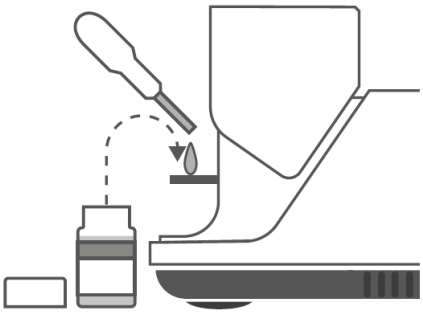
Handling the LumiraDx SARS-CoV-2 Ab Test Strips: To ensure that you are using the SARS-CoV-2 Ab Test and the Instrument correctly, read the appropriate SARS-CoV-2 Ab Test Strip Product Insert and Platform User Manual.

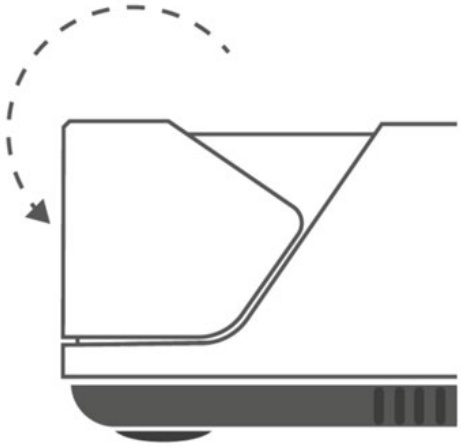
Procedure/Performing a Test: Consult the LumiraDx Platform User Manual for instructions on how to analyse a Quality Control sample. Open the foil pouch of the SARS-CoV-2 Ab Test Strip just before use and insert the Test Strip into the LumiraDx Instrument. The Instrument will indicate when ready for the 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 Ab 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 11 minutes of applying the Quality Control solution and starting the test. The results will be displayed as a **PASS** or **FAIL** QC result 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 a **PASS**.

If the LumiraDx Antibody Quality Controls do not perform as expected, do not report patient results. Retest using a new Test Strip – if problems persist contact LumiraDx Customer Services on telephone number 1-888-586-4721.

Symbols glossary:

Symbol	Meaning

	Temperature limitation
	Manufacturer
	For In Vitro Diagnostic Use Only
	Catalogue Number
	Lot Number
	Use-by Date – indicates the date after which the unopened IVD/Quality Control Material cannot be used
Rx Only	Prescription Use Only
	Emergency Use Authorization
	Indicates a negative control
	Indicates a positive control
	Indicates that potential biological risks are associated with the Quality Control material.
	Refer to instructions for use

LumiraDx customer services:

For product inquiries please contact LumiraDx Customer Services by email: customerservices.US@lumiradx.com or telephone 1-888-586-4721.

Any adverse results experienced with the use of this product, and/or quality problems should also be reported to LumiraDx Customer Services by email: customerservices.US@lumiradx.com or at lumiradx.com.

For return policy

If there is a problem with the **LumiraDx SARS-CoV-2 Ab Quality Controls Pack** you may be asked to return them. Before returning tests please obtain a return authorization number from LumiraDx Customer Services. This return authorization number must be on the shipping carton for return. For ordinary returns following purchase, please contact LumiraDx Customer Services for terms and conditions.

Limited warranty

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

Unused Test 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 Ab Quality Controls Pack 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 lumiradx.com/IP.

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

LumiraDx US Office. 221 Crescent St, Suite 502, Waltham, MA 02453. Telephone: (617) 621-9775

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 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 test has been authorized only for the detection of antibodies to SARS-CoV-2, not for any other viruses or pathogens. In the USA, 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 authorization is terminated or revoked sooner.

LumiraDx Platform User Manual Copy (Master)

LumiraDx

Confidential

Purpose of this document

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

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

Platform User Manual

• 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 the 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

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
	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
	Catalogue Number
	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
'Cloud icons'	Indicates whether the Instrument has an active connection to an EHR
	Notification - Highlights an area which requires attention
	Caution - Highlights an error or precautionary statement which requires attention. Refer to safety-related warnings and precaution notes in the Instructions for Use accompanying this product, e.g. Platform User Manual, Test Strip Product Insert or Quality Control Pack Insert
	Indicates the status of the battery
	Displayed when the battery is in a charging state
	Icon which acts as a button - clears the text input field of all data
	Indicates the high end of the touch-screen brightness slider
	Indicates the low end of the touch-screen brightness slider

	Volume (high)
	Volume (low)
	Indicates a text field which can perform a search function
	Indicates confirmation of a completed action

Abbreviations

CDC	Centers for Disease Control and Prevention
EHR	Electronic Health Record
HCP	Health Care Professional
ID	Identification
QC	Quality Control
RFID	Radio-Frequency Identification
UK	United Kingdom
USB	Universal Serial Bus
WHO	World Health Organization
HIS	Hospital Information System
LIS	Laboratory Information System
DOB	Date of Birth

Important safety information

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

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

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

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 Connect diagnostic connectivity solution:

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

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

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

About this Platform User Manual

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

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

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

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

This Platform User Manual highlights cautions and important information:

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

1. Introduction

1.1 Intended use

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

1.2 Important information

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

1.3 Summary of the test procedure

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

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

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

1.4 Principles of operation

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

1.4.1 Quality Assurance

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

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

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

1.5 Storage and operating conditions

1.5.1 LumiraDx Test Strips

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

1.5.2 LumiraDx Instrument

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

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

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

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

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

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

1.6 Warnings

Inserting Test Strips

- **Do NOT** touch Test Strip Sample Application Area.
- **Do NOT** bend or fold the Test Strip.
- **Do NOT** touch Test Strip contacts.
- **Do NOT** apply sample until prompted.

Performing a patient test

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

Performing a Quality Control test

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

- **Do NOT** touch the Test Strip until the test has finished and the result is displayed.
- **Do NOT** open the door or move the Instrument during the test or an error will result and the test result will not be saved.
- Dispose of all Test Strips used for Quality Control testing safely in accordance with local regulations and procedures.
- Follow the test operating conditions in the LumiraDx Test Strip Product Insert.
- Follow the information on correct handling of Test Strips in the LumiraDx Test Strip Product Insert.

Cleaning and disinfecting

- **Do NOT** attempt to put any objects or cleaning materials inside the Test Strip slot.
- Always wear gloves whilst cleaning and disinfecting the Instrument.
- Only use LumiraDx recommended cleaning and disinfecting materials on the Instrument surfaces.
- Only use a damp and not wet swab or cloth for cleaning. Excess liquid may damage the Instrument.
- Always use LumiraDx approved wipes to disinfect the Instrument. Details of LumiraDx approved wipes can be found at lumiradx.com.
- **Do NOT** spray or pour solution directly onto the Instrument.
- Following cleaning and disinfection, and before performing a patient test, change gloves and wash hands.

Instrument disposal

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

FCC Radiation Exposure

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

- The transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
- Avoid direct contact to the antenna, or keep contact to a minimum while using the Instrument.

1.7 Precautions

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

Avoidance of electrical shock, fire and explosions

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

Safe disposal

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

Electromagnetic interference

- Do not use the Instrument near strong electromagnetic fields, which could interfere with the proper operation of the Instrument.

Electromagnetic compatibility

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

1.8 Help and support

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

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

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

2. Getting Started

2.1 Unpacking

The LumiraDx Instrument package includes the following contents:

1. LumiraDx Instrument
2. LumiraDx Power Supply Unit
3. Platform User Manual
4. Platform Quick Reference Guide (including passwords for Standalone operation)

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.

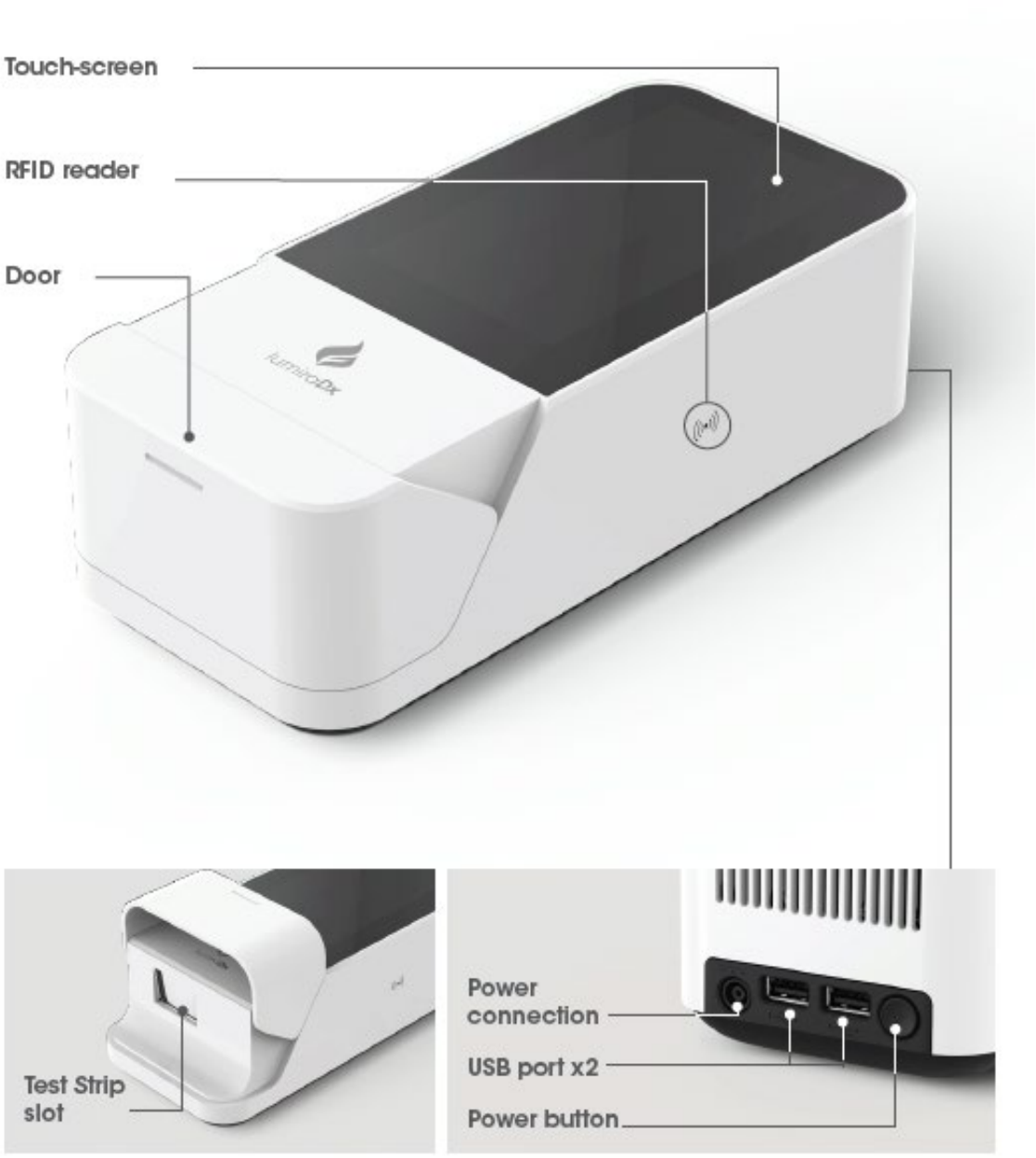
2.5 Operating mode and first time setup

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.

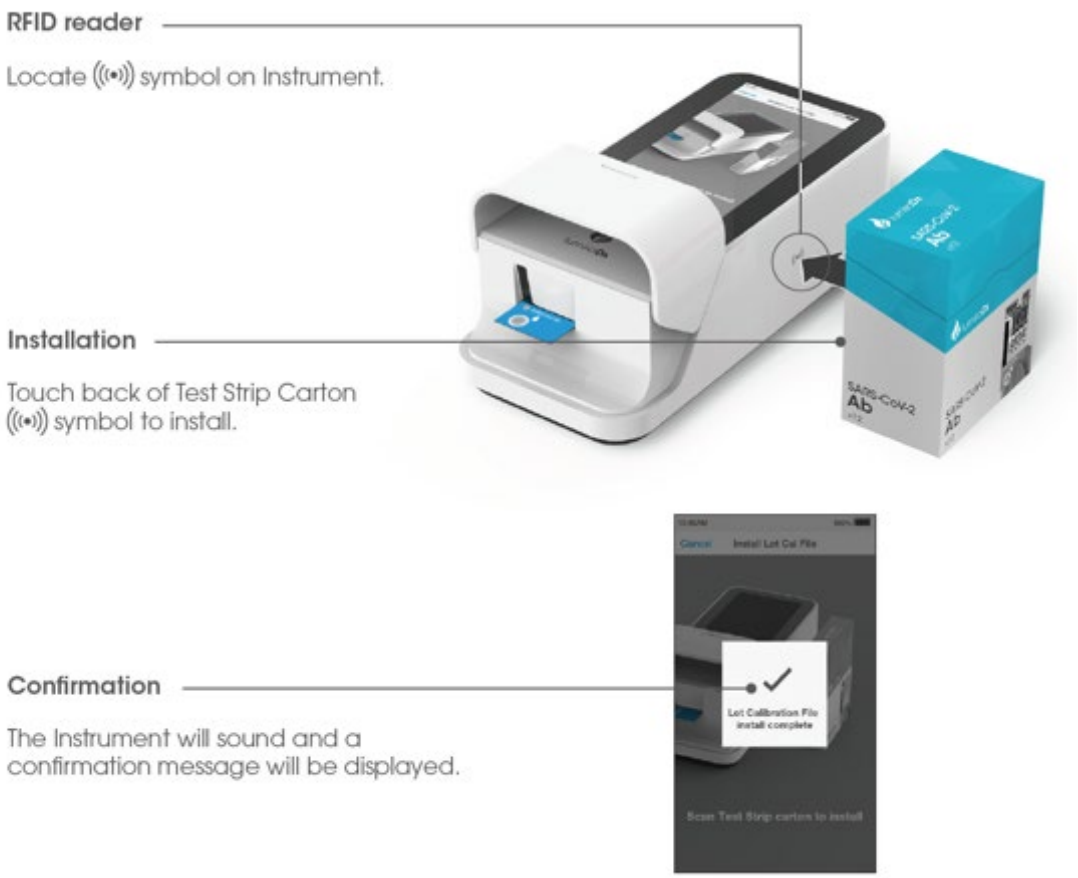
Refer to the "Instrument Specifications" chapter of this Platform User Manual for additional information on operating conditions and complete Instrument specifications.

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.

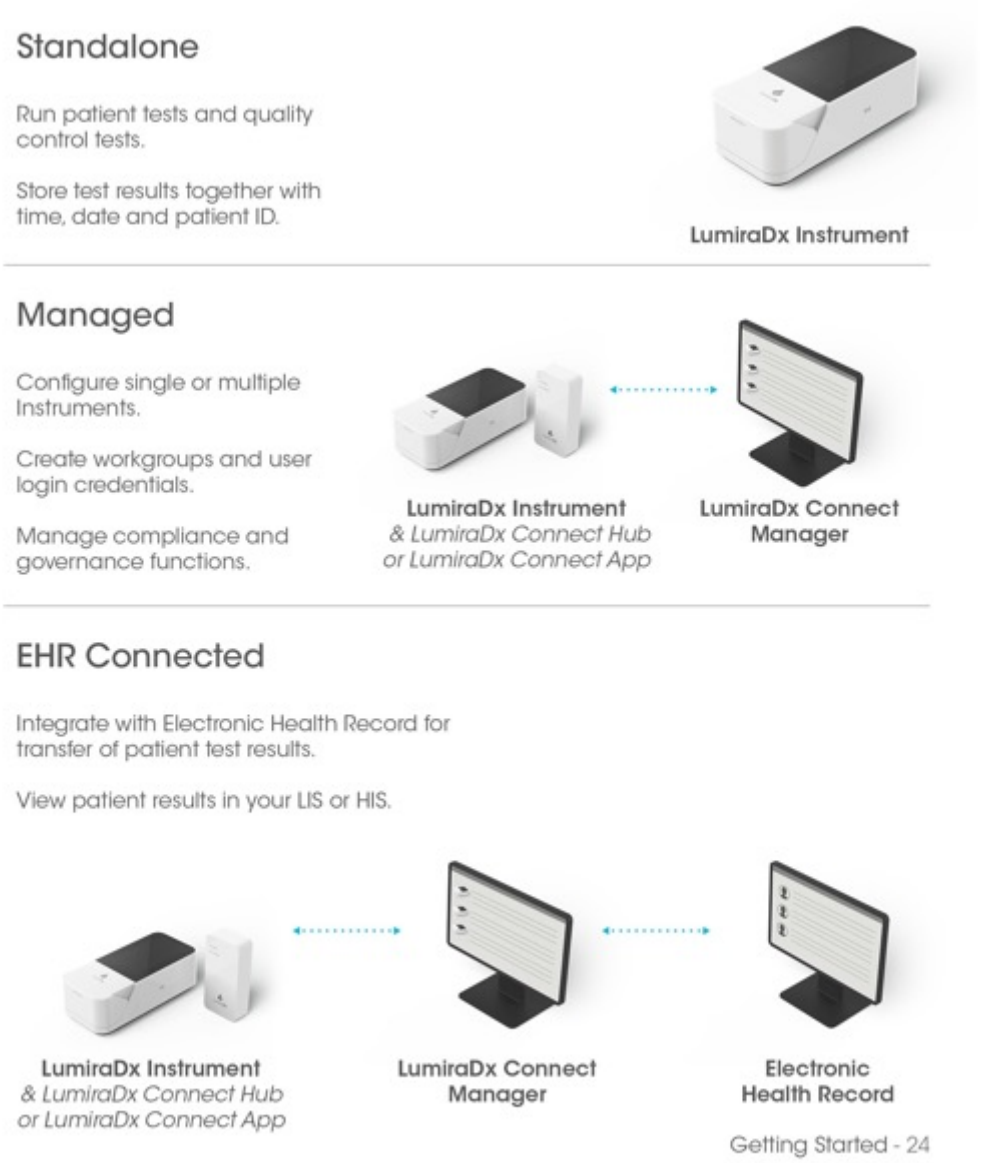
Lot Calibration File installation is performed manually. Locate the RFID reader by looking for the **RFIDICON** symbol on the side of the Instrument. To install a new Lot Calibration File, touch the back of the Test Strip Carton to the **RFIDICON** symbol to install. When the Lot Calibration File is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

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



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.

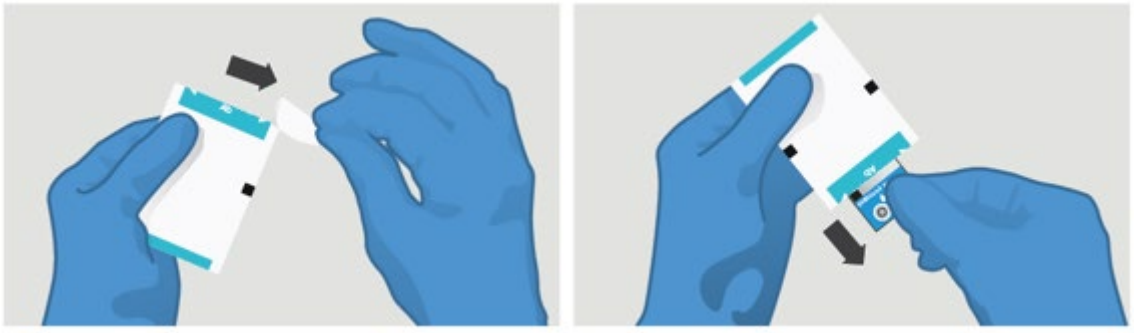


3. Preparation for Testing

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.	⚠

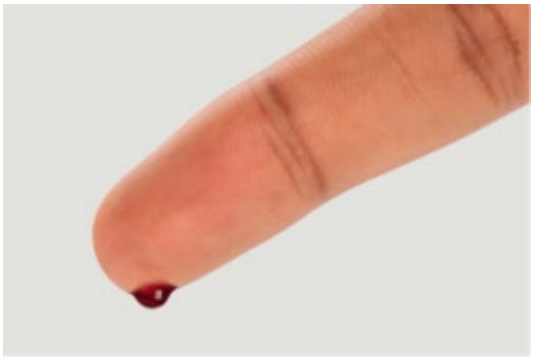
3.3 Capillary sample collection and application

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

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

Collecting a capillary blood sample from a finger stick

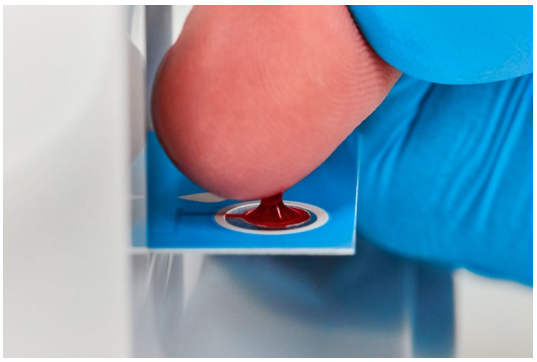
Use a lancet near the finger tip on the side which faces down.



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. Holding their arm straight down at their side, or massaging the finger from its base also increases blood flow to produce a sufficiently large hanging blood drop.

Applying a finger stick sample to the Test Strip

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



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

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

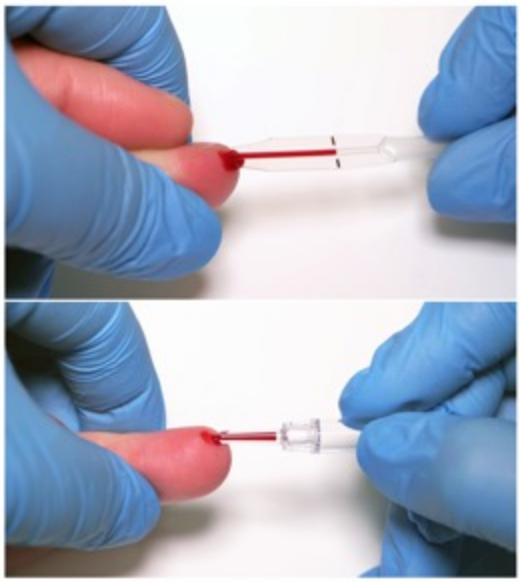
When the sample is detected, the Instrument will sound and a confirmation message will be displayed.

Collecting a capillary blood sample using a transfer tube

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

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

- **Do NOT** squeeze the bulb of the transfer tube before or during sample collection.
- **Do NOT** allow the transfer tube to touch the finger.
- Ensure the transfer tube is filled to the black fill line or to the end of the collection tube depending on what type of transfer tube is being used.
- If air bubbles are seen discard the transfer tube and start again.



Applying a transfer tube sample to the Test Strip

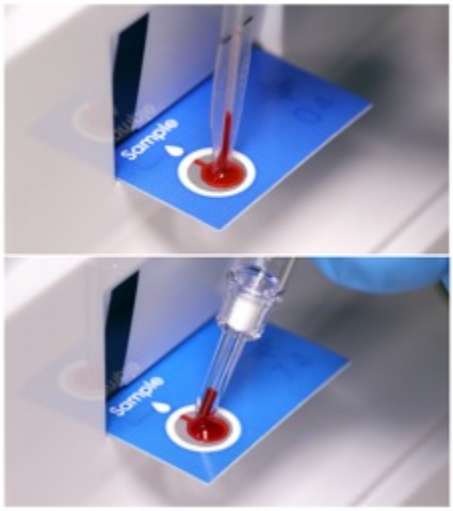
Hold the filled transfer tube vertically over the Sample Application Area and gently squeeze the bulb or depress the plunger to move the sample to the tip of the transfer tube.

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

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

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

If you need to retest, use a new Test Strip and lancet, and a different finger.



Do NOT apply more than one drop of sample. **Do NOT** touch the Test Strip until the test has finished and the result is displayed.	

3.4 Sample application using other sample types

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

3.5 Quality Control solution application

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

4. Instrument Operation

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

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

Please note:

- Instructions are combined with example screenshots. Some screens may appear differently depending on the test or mode of operation. All screens, test names and results displayed in this Platform User Manual are intended only as examples.
- You can only hear the sounds on the LumiraDx Instrument when they are turned on. This Platform User Manual presumes that the sounds are turned on.

4.1 Home Screen

4.2 Settings Menu

General user settings menu

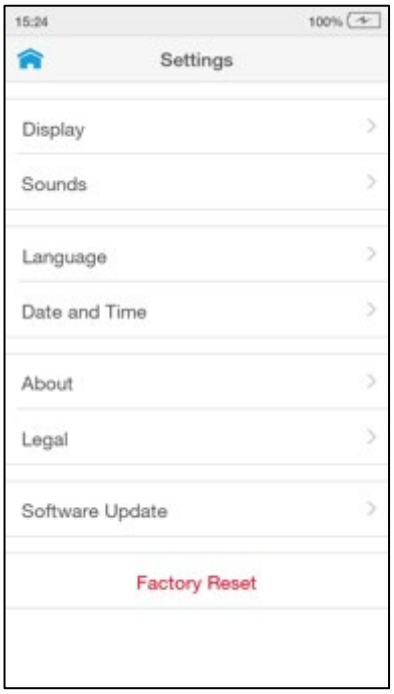
All users can set display and sound preferences in the Settings menu. Refer to the “Instrument Operation” chapter in this Platform User Manual for instructions.

Administrator settings menu

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

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

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



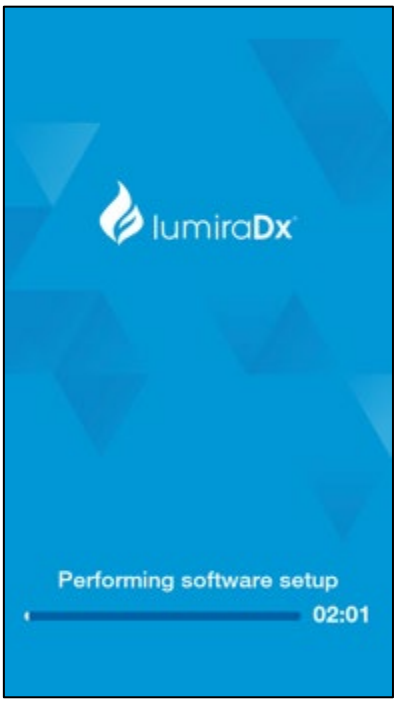
4.3 Standalone Instrument First Time Setup

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

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

1. Power on

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



2. Enter Password

Tap the password field to display the keyboard.

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

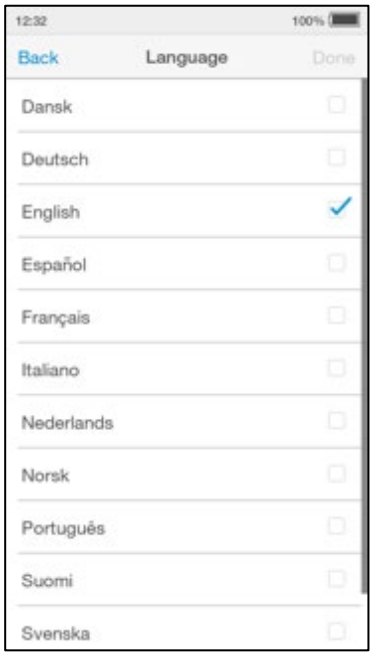
Note: Administrator password is provided on a tear out sheet in the Platform Quick Reference Guide.

3. Set language

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

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

Tap ‘Done’ to save and return to the Settings menu.



4. Set date and time

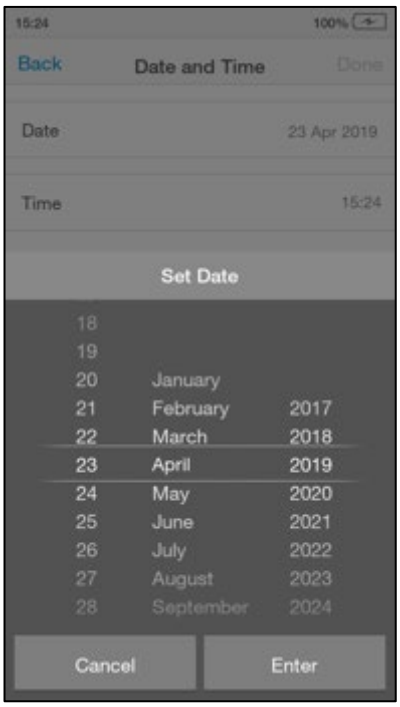
Go to ‘Settings’ and tap ‘Date and Time’.

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

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

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

Return to the home screen and tap ‘Logout’.



4.4 Connected Instrument First Time Setup

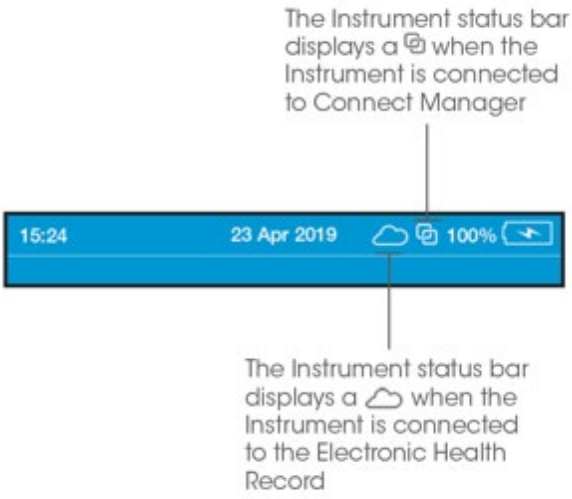
Connected system setup should be completed by the administrator on Connect Manager. Refer to the LumiraDx Connect User Manual for further information.

Power on by pressing the power button at the rear of the Instrument. You will hear the Instrument powering on and the display will be blank for several seconds before starting up. Follow the steps for Standalone first-time setup to set the language.

To download other Instrument settings, ensure the Instrument is within range of a LumiraDx Connect Hub or a device running the LumiraDx Connect App (within approximately 10 metres). If **LINKICON** appears at the top of the screen, the Instrument is connected to Connect Manager and the Instrument settings will download and install automatically. Time, date, and language settings will be set automatically if the Instrument is in range of a LumiraDx Connect Hub and these settings will be greyed out in the settings menu.

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

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


The Instrument status bar displays a when the Instrument is connected to Connect Manager
15:24
23 Apr 2019
100%
The Instrument status bar displays a when the Instrument is connected to the Electronic Health Record

4.5 Display and Sound Preferences

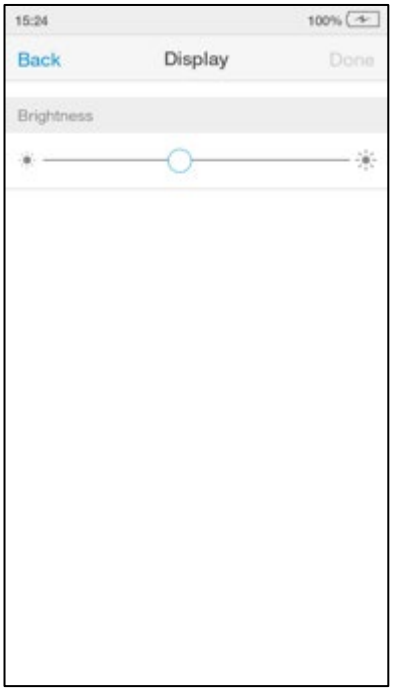
All users can set display and sound preferences in the Settings menu.

Display

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

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

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



Sounds

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

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

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

4.6 Performing a Patient Test

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

Important Notes

ALWAYS

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

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

To cancel a patient test tap 'Cancel' at the top of the touch-screen and follow the Instrument prompts.

1. Power on and login

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

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

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

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

Tap the password field to display the keyboard.

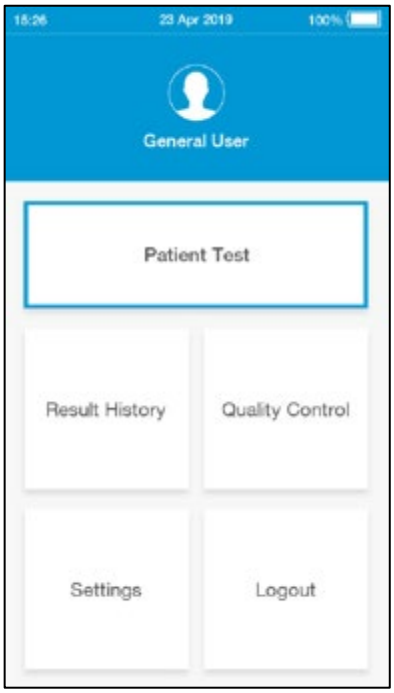
Enter password and tap 'Login' to complete the login.

2. Check date and time

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

3. Tap Patient Test

Tap the ‘Patient Test’ button on the home screen.



4. Enter patient details

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

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

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

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

5. Using the Instrument in EHR Connected mode

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

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

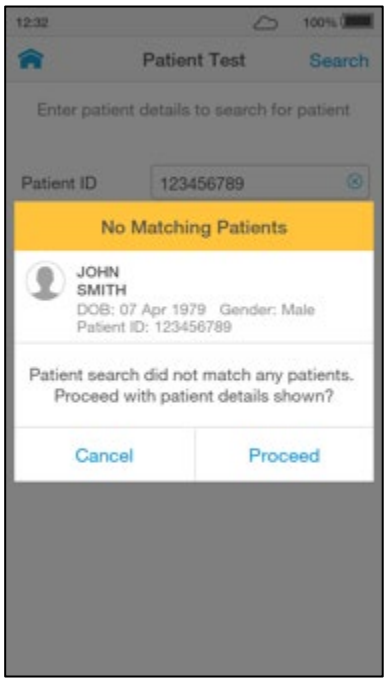
EHR Connect patient search

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

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

No patient match

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



6. Confirm patient details

Check patient details are correct and tap ‘Confirm’ to proceed.

7. Open door and Insert Test Strip

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

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

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

The Instrument will sound when the Test Strip is detected.

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

8. Select sample type

Select the intended sample type from the list displayed.

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

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

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

9. Confirm test and sample type

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

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

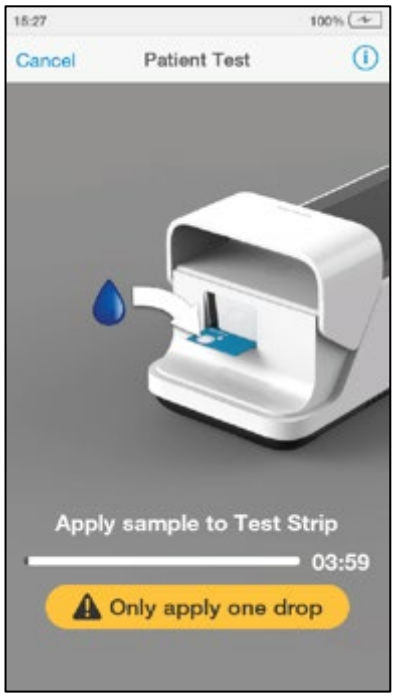
10. Apply sample

The Instrument display will prompt when to apply the sample.

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

The Test Strip draws up the sample by capillary action.

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



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

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

11. Immediately close door to continue

The Instrument display will prompt to close the door.

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

12. Test processing

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

Note: Each test type has a different processing time.

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

13. Review result

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

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

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

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

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

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

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

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

Close the Instrument door.

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

4.7 Quality Control

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

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

- LumiraDx Instrument
- LumiraDx Test Strips
- LumiraDx Quality Controls

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

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

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

4.8 Performing a Quality Control test

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

Important Notes

ALWAYS

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

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

To cancel a QC test tap 'Cancel' at the top of the touch-screen and follow the Instrument prompts.

1. Power on and login

2. Check date and time

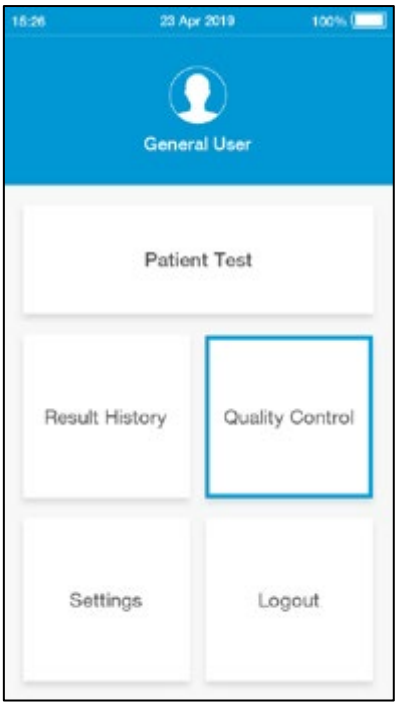
Check that the date and time are correct. If not correct, the current date and time will need to be set by the administrator. (Refer to "First time setup" in this chapter for more information).

3. Prepare Quality Control solution

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

4. Tap Quality Control

Tap the ‘Quality Control’ button on the home screen.



5. Select Quality Control Test

Tap ‘Quality Control Test’ from the Quality Control menu.

6. Open door and Insert Test Strip

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

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

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

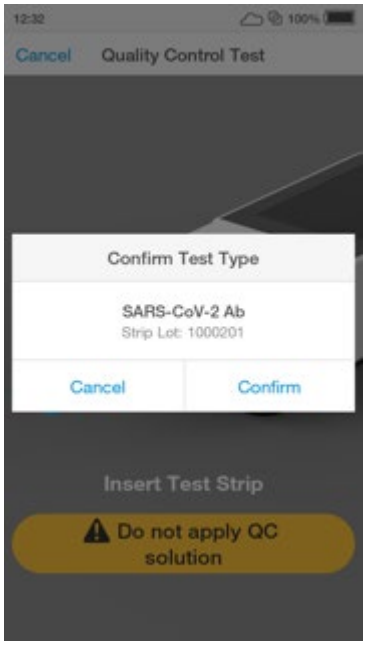
The Instrument will sound when the Test Strip is detected.

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

7. Confirm test type

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

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

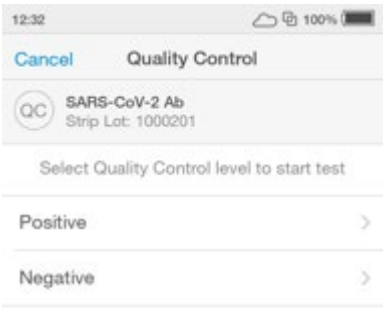


8. Select Quality Control level

Select the intended Quality Control from the list displayed.

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

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



9. Enter Quality Control Lot number

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

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

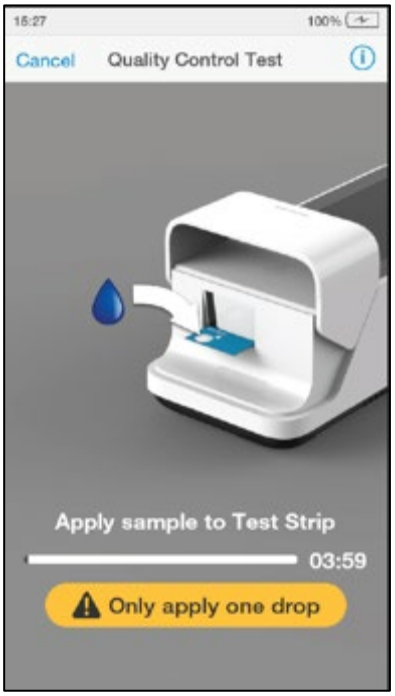
Note: If the barcode from a different QC level or test from the one selected on the previous screen is entered an error message will display.

10. Apply Quality Control solution

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

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

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



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

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

11. Immediately close door to continue

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

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

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

12. QC test processing

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

Note: Each test type has a different processing time.

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

13. Review QC result

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

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

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

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

14. Remove and dispose of Test Strip

The Instrument will prompt to remove the Test Strip.

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

Close the instrument door.

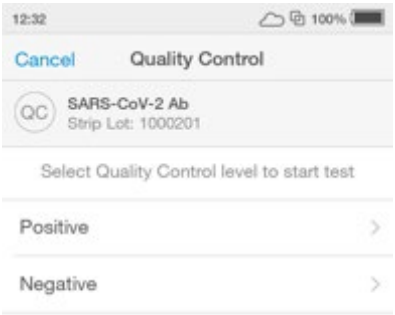
Dispose of all Test Strips used for Quality Control testing safely in accordance with local regulations and procedures.	⚠

15. Complete remaining QC levels

Multiple QC levels may be required depending on test type.

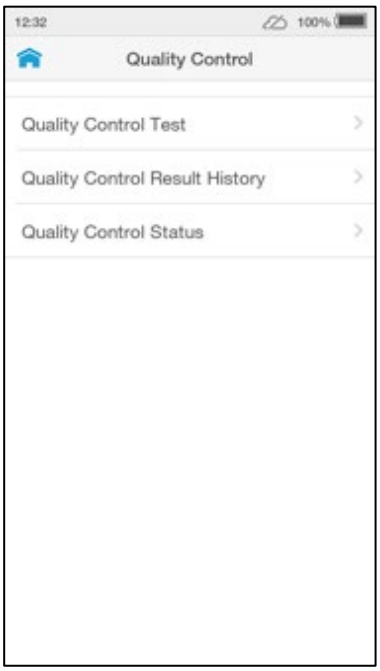
Refer to the LumiraDx Quality Control Pack Insert for more information on QC levels.

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



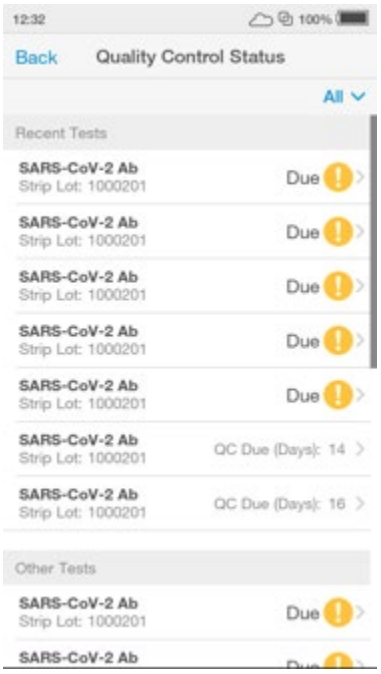
16. Mandatory Quality Control Policy

Connected Instruments with the Quality Control policy set to 'mandatory' will have an additional menu item of 'Quality Control Status'.



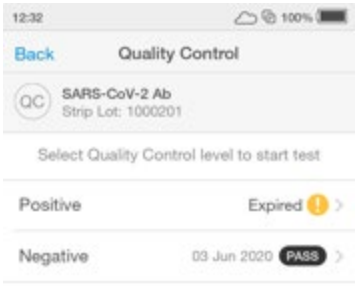
Quality Control test statuses are sorted by 'Recent Tests' meaning test lots for which patient tests or Quality Control tests have been performed recently. 'Other Tests' are test lots which have not had a patient test or QC test performed for more than 90 days.

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

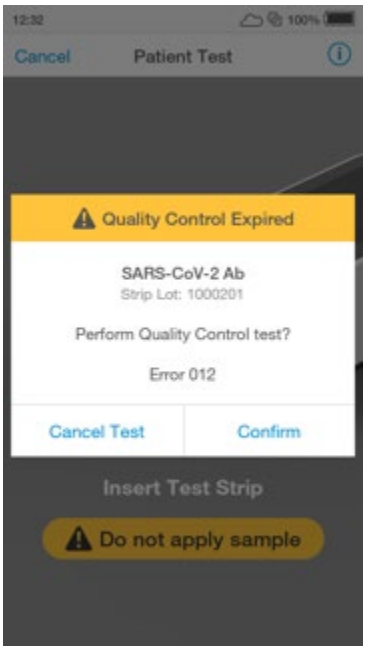


The Quality Control level selection screen will also show the status of each QC level as well as the date of any recently performed QC tests.

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



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



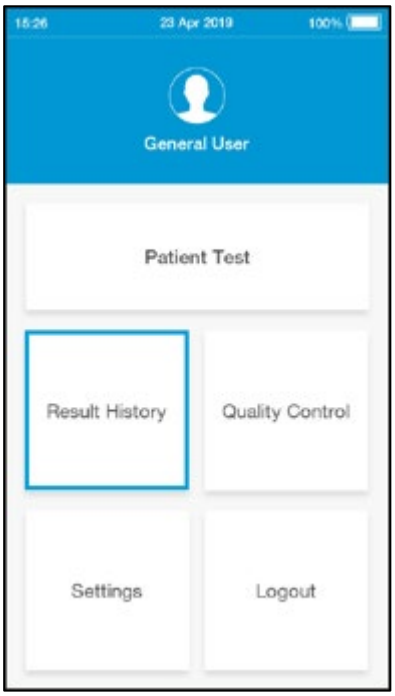
4.9 Result History

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

1. Power on and login

2. Tap Result History

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



3. Review test results

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

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

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

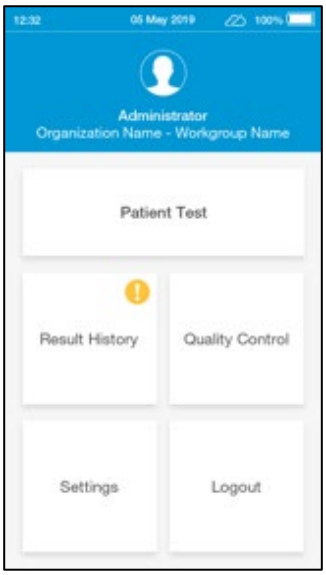
Search for a patient test result by entering the Patient ID, First Name or Last Name in the search bar from either the Patient Tests, Rejected Tests or Invalid Tests screen.

Note: A search for a partial Patient ID, First Name or Last Name will only work for the start of the search term.

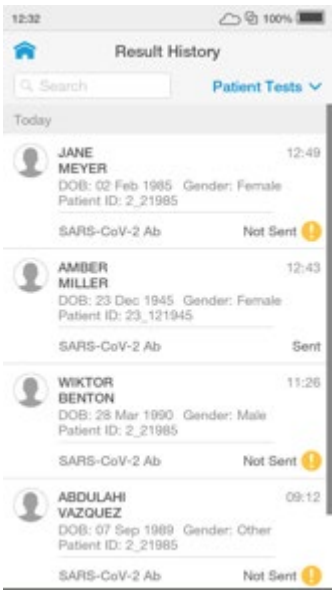
Any patient or QC test result can be printed from the test result details screen by tapping 'Print' when a LumiraDx Printer is connected to an Instrument USB port.

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

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



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

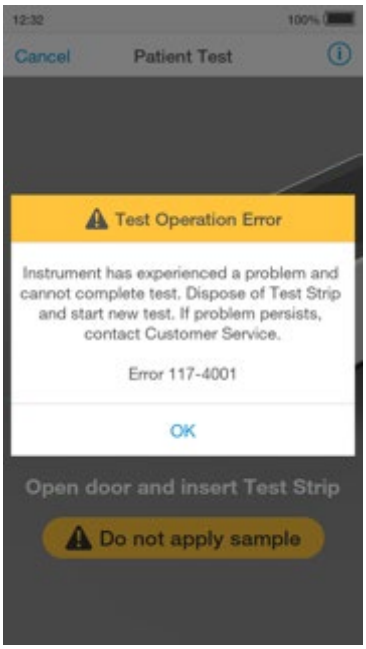


4.10 Onboard Quality Control

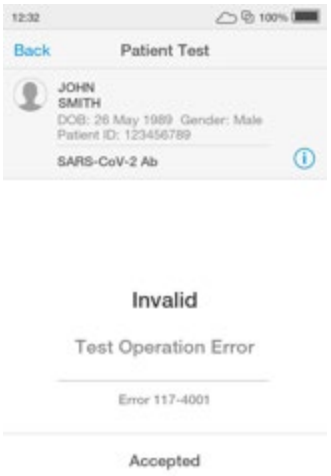
In addition to the system checks performed by the Instrument during start up and within the test procedure, LumiraDx Tests also run an onboard quality control assay alongside the patient test.

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

If the OBC fails, then an error message will be displayed and no test result will be returned. Follow the on screen instructions to dispose of the Test Strip and start a new test. If the problem persists, contact Customer Services.



A test which fails the OBC will appear in the 'Invalid' filter of the Results History.



5. Cleaning and Disinfecting

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

The difference between cleaning and disinfecting:

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

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

When should the Instrument be cleaned and disinfected?

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

What should be cleaned and disinfected?

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

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

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

Cleaning Instrument touch-screen

Cleaning the area around the Test Strip slot

Cleaning procedure

Always wear gloves to clean the Instrument.

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

Disinfection procedure

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

Always wear gloves to disinfect the Instrument.

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

Use the disinfecting material until the surface of the Instrument is visibly wet. For respiratory samples, allow the surface to remain wet for 1 minute and allow to air dry. For blood-based samples, allow the surface to remain wet for 5 minutes and allow to air dry.

Dispose of the cleaning and disinfectant materials in accordance with local procedures.

The Instrument is now ready to perform another test.

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

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

Always wear gloves whilst cleaning and disinfecting the Instrument.

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

Do NOT spray or pour solution directly onto the Instrument.

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

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

6. Software Updates

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

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

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

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

2. Power on

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

A progress bar on the Instrument display will indicate installation.

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

Remove the USB memory stick from the Instrument once completed.

7. Troubleshooting

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

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

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

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

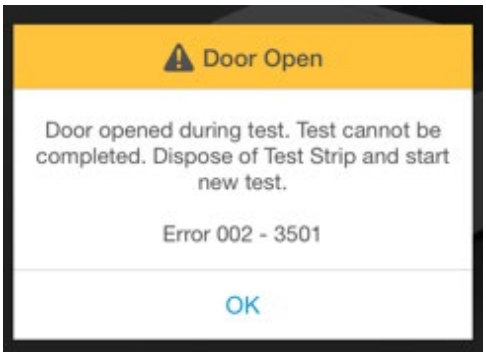
Example alert message:

Description and Instruction

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

Example error messages:

Error 002

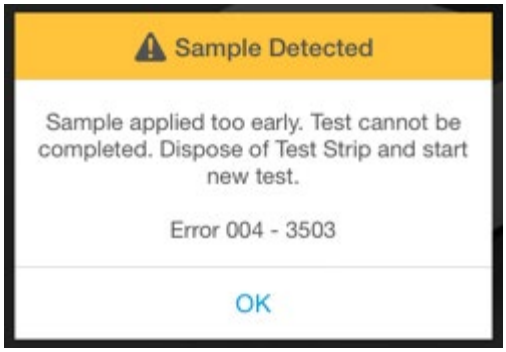


Description and instruction

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.

Error 004

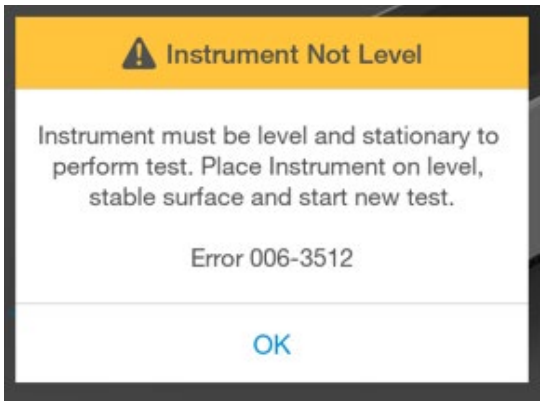


Description and instruction

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.

Error 006

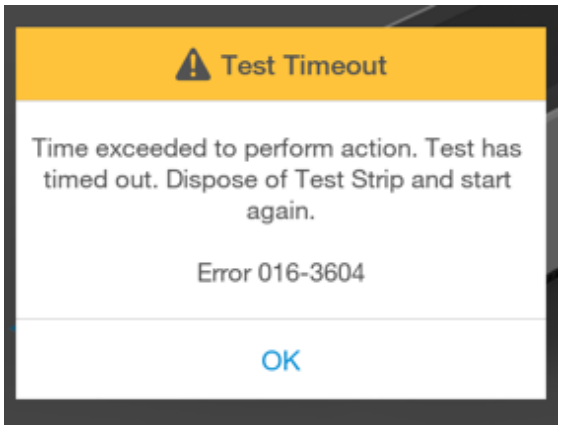


Description and instruction

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.

Error 016

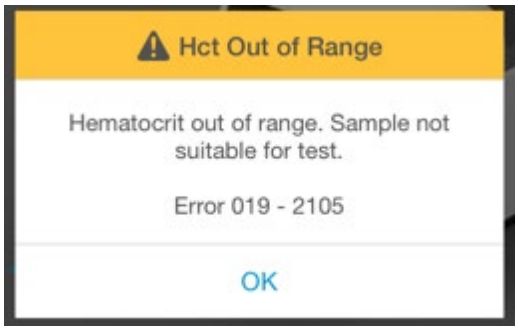


Description and instruction

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.

Error 019

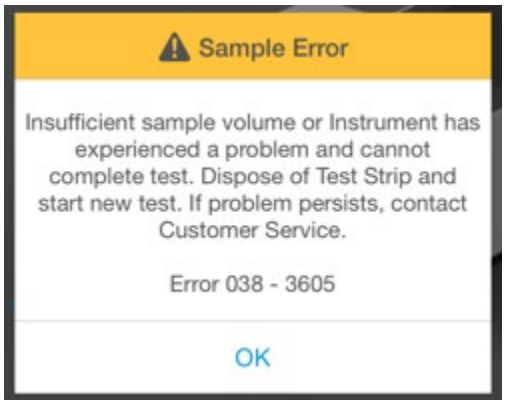


Description and instruction

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.

Error 038

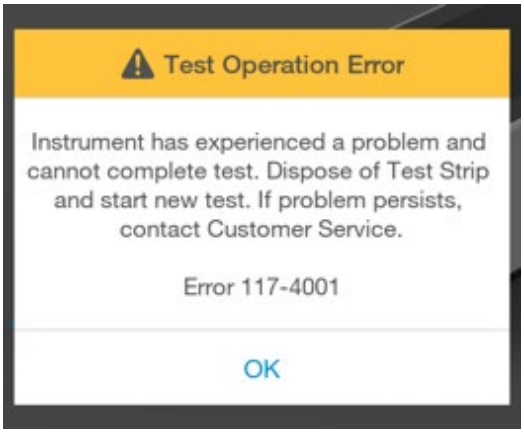


Description and instruction

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.

Error 117



Description and instruction

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

Errors and unusual behavior without error alerts

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

Instrument does not power on	
If pressing the power button does not power on the Instrument:	1. Connect the power supply unit. Wait 15 minutes and press the power button.
Cannot login	
Do not have or know where to find the correct password:	1. Check tear out sheet in the Platform Quick Reference Guide for the login password, or contact the administrator. 2. Tap the password field to bring up the keyboard and enter the password. Tap 'Login' to proceed.
Cannot connect Instrument	
The Instrument is not displaying **LINKICON symbol:**	1. Check that the Instrument is within range of the LumiraDx Connect Hub or the device running the LumiraDx Connect App. 2. Ensure the LumiraDx Connect Hub is powered on and the green Connect light is on.
Lot Calibration File is not installed	
Lot Calibration File is not installed:	1. Refer to the "Getting Started" chapter of this Platform User Manual for instructions on how to install the Lot Calibration File. 2. Ensure that the back of the Test Strip Carton is touching the **RFIDICON** symbol on the side of the Instrument continually until the Instrument sounds and a confirmation message is displayed.
Instrument does not detect the Test Strip	
If the Test Strip is not detected and no message is displayed on the touch-screen:	1. Check that the Test Strip is fully inserted. 2. Check for damage to the Test Strip. If damaged discard and insert a new Test Strip.
The Instrument will not start the test	

If the Instrument will not start the test after applying the sample or Quality Control solution:	Check the Instrument door is fully closed.
Incorrect date or time	
If the date and time is incorrect:	Contact the administrator for "Connected" Instruments, or refer to the "First time setup" section of this Platform User Manual for instructions on setting date and time.
Patient test result is red	
If the patient test result is displayed in red:	Test results that are above or below the analytic range are displayed in red and indicated by the symbols > (above) or < (below).
QC test failure	
If the Quality Control test fails unexpectedly:	1. Check the Quality Control solution type and level matches the test type and QC range information. 2. Check the expiry date of the Quality Control solution. 3. Refer to the Quality Control Pack Insert to ensure correct procedure is followed. Retest using a new Test Strip. Ensure the Test Strip and Quality Control solution are handled carefully to prevent any contamination.

8. Maintenance and Disposal

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

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

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

9. Instrument Specifications

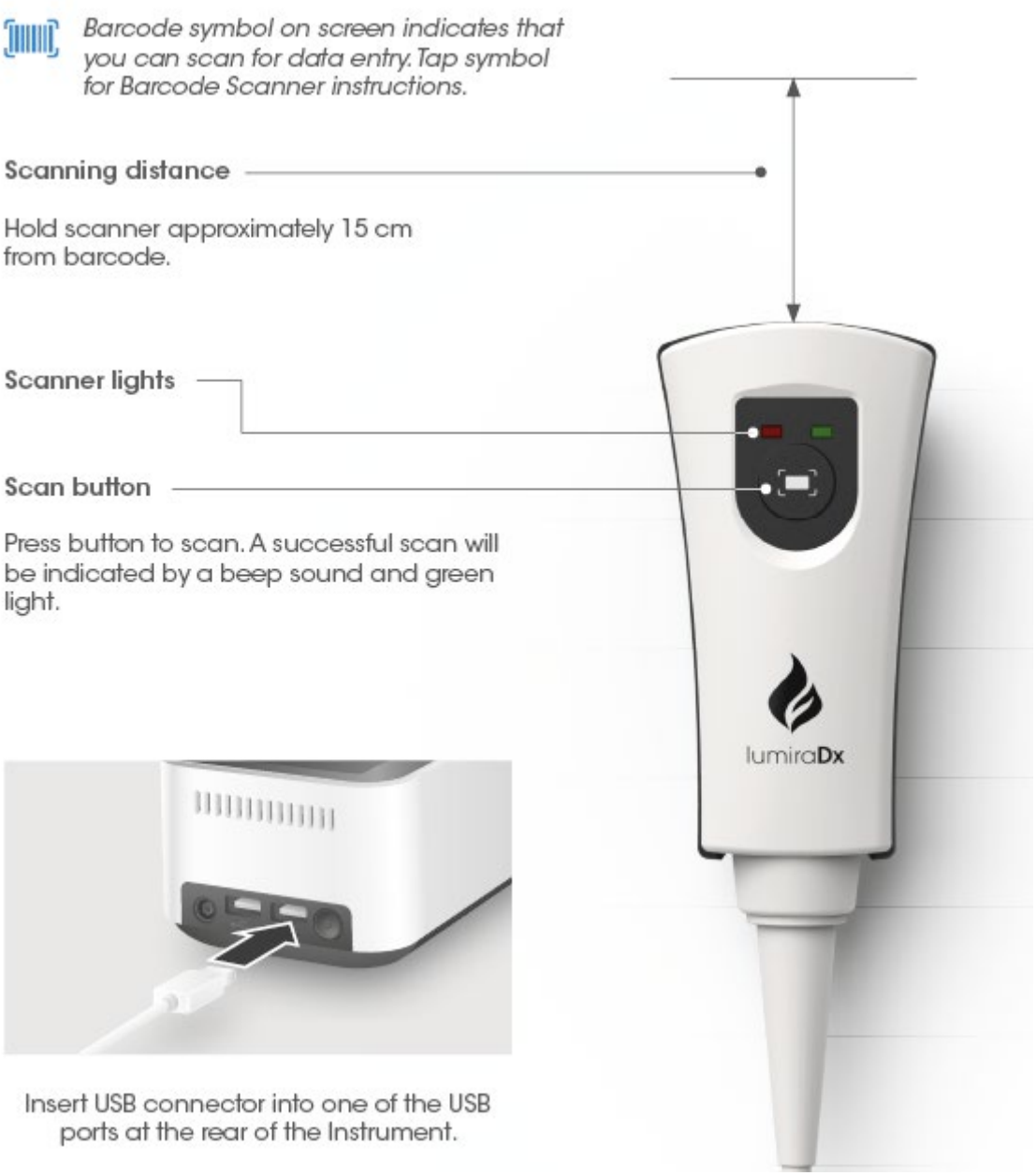
Operating temperature	15 °C to 30 °C (59 °F to 86 °F)
Storage temperature	-10 °C to 50 °C (14 °F to 122 °F)
Relative humidity	10 % to 90 % rh (non-condensing)
Maximum altitude	3,000 m (9,840 feet) operating
Data storage	1000 test results with date, time and comments Lot calibration files
Communications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

10. Ancillary Devices

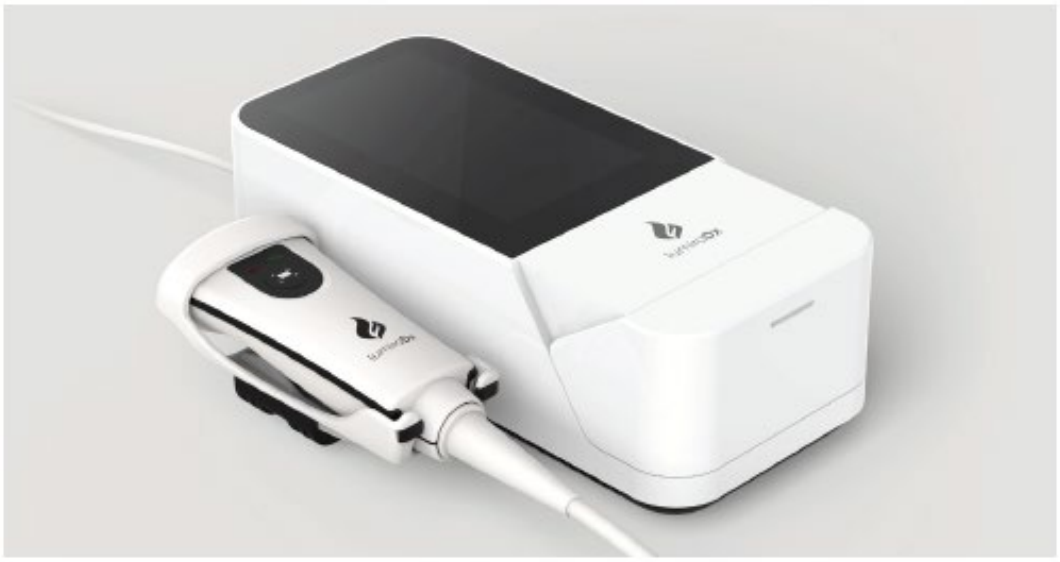
10.1 LumiraDx Barcode Scanner

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

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



LumiraDx Barcode Scanner Cradle



Attaching LumiraDx Barcode Scanner cradle to Instrument

Detaching LumiraDx Barcode Scanner cradle from Instrument

Note: Correct orientation of Barcode Scanner cradle

LumiraDx Desktop Stand

10.2 LumiraDx Printer

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

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

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

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

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

Printer status light:

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

10.3 LumiraDx USB Memory Stick

LumiraDx USB Memory Stick used for Instrument software updates.

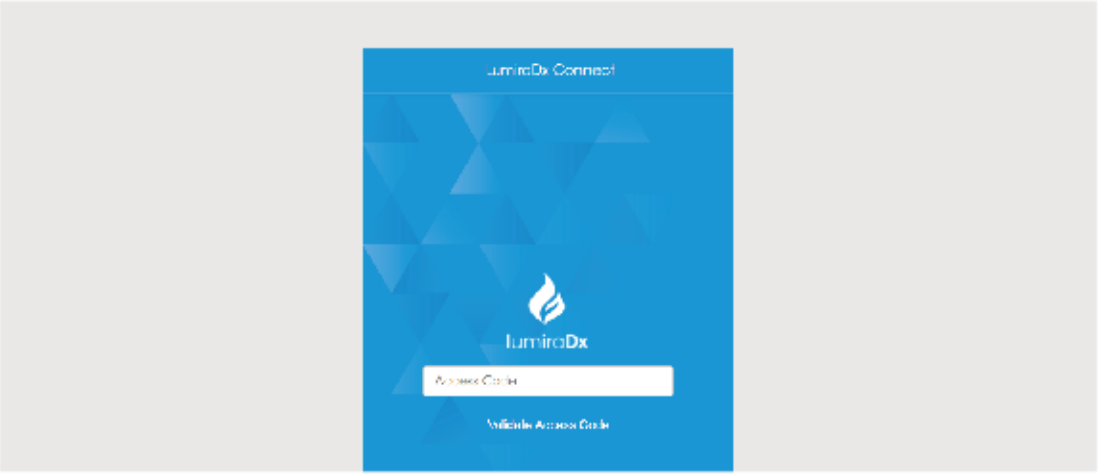
Note: Right side USB port nearest the power button at the rear of the Instrument must be used.

10.4 LumiraDx Connect Hub

10.3 LumiraDx Connect Hub

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

10.5 LumiraDx Connect App



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

11. Customer Services

For product inquires and technical support please contact LumiraDx Customer Services by email: customerservices.US@lumiradx.com, telephone 1-888-586-4721or at lumiradx.com.

11.1 Warranty

Warranty – Limited Warranty.

LumiraDx Instrument – 2 Year Warranty from date of purchase.

LumiraDx Test Strips – As per shelf life.

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

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

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

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

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

12. References

1. World Health Organization (2009) Guidelines on hand hygiene in healthcare. http://www.who.int/gpsc/5may/tools/9789241597906/en/
2. World Health Organization (2016) Guidelines on core components of infection prevention programs at the national and acute healthcare facility level. http://www.who.int/gpsc/ipc-components-guidelines/en/
3. CDC Guideline for Isolation Precautions: Preventing Transmission of infectious Agents in Healthcare Settings 2007. https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html
4. CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: https://www.cdc.gov/injectionsafety/fingerstick-devicesbgm.html

13. Compliance

13.1 Environmental Practices

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

13.2 Compliance

The LumiraDx Platform is for use under the Food and Drug Administration's Emergency Use Authorization only.

The LumiraDx Instrument has been tested and is compliant with:

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

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

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

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

Back Cover:

LumiraDx UK Ltd

Dumyat Business Park

Alloa FK10 2PB, UK

SPEC-32180 **Rev5**

ART-00410 **Rev6b**

Rev date 2021/06

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; these products 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, 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 authorization is terminated or revoked sooner.

For product inquiries and technical support please contact LumiraDx Customer Services by email: customerservices.US@lumiradx.com, telephone 1-888-586-4721or at lumiradx.com.