ENGLISH

lumiraDx™ SARS-CoV-2 Ab Test

For Professional Use Only
For *In Vitro* Diagnostic Use Only

SPEC-32880 R3 ART-00532 R3

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 whole blood (capillary fingerstick or venous), plasma or serum. 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. At this time, it is not known for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.

Results are for the detection of SARS-CoV-2 total antibody. Antibodies (IgM, IgA, IgG) 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.

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.

The LumiraDx SARS-CoV-2 Ab Test is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings, only sufficient in performing tests using the LumiraDx Instrument.

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. All these materials are available at Lumiradx.com.

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 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 whole blood (capillary and venous), serum or plasma.

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 whole blood (capillary fingerstick and EDTA venous blood), EDTA plasma or serum samples. The test procedure involves the addition of fingerstick, venous whole blood, plasma or serum 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 concentration of the analyte in the sample is proportional to the fluorescence detected. 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.
- RFID (Radio frequency ID) Tag held inside the Test Strip carton.

Materials required but not provided with the Test Strip Carton:

- LumiraDx Instrument
- LumiraDx SARS-CoV-2 Ab Test Quick Reference Instructions (QRI)
- Standard blood collection equipment (high flow lancets, venepuncture, Transfer tubes, appropriate biowaste disposal)
- LumiraDx SARS-CoV-2 Ab Quality Controls (as required to meet local and organisational compliance)
- LumiraDx Connect if connectivity required (refer to LumiraDx Connect User Manual)

Warnings and precautions

- For *in vitro* diagnostic use only
- Do not use the kit components beyond the expiration date
- 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 local regulations and procedures.
- 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/uk-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 regulations and procedures.
- 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

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 whole blood - capillary fingerstick sample (direct or using Transfer tube)
- Anticoagulated venous whole blood (EDTA)
- Plasma (EDTA)
- Serum

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 capillary blood sample from a fingerstick. Optionally, you may use a non-anticoagulated Transfer Tube to collect the fingerstick blood sample. Details of recommended Transfer Tubes are available here https://lumiradx.com/uk-en/product-list. Only auto-disabling, single use, high flow lancing devices may be used to collect capillary 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.

Once installed, the Instrument will have all the information required to process the test, and any future tests from the same Lot of Test Strips.

Lot Calibration File installation

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

RFID strip code reader

Locate ((•)) symbol on Instrument.

Installation

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

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

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

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

Testing from a fresh capillary fingerstick sample

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 Test Strip. 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

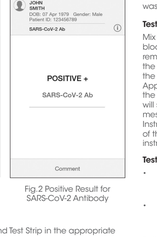

Fig.2 Positive Result for SARS-CoV-2 Antibody

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 customerservices@lumiradx.com.

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.

Using a Transfer Tube from a capillary finger stick sample

You must use a non-anticoagulated Transfer Tube to transfer the capillary sample from the fingerstick to the Sample Application Area of the Test Strip. To do this follow the procedure for collecting a capillary blood sample from a fingerstick. Use the Transfer Tube by placing it into the blood droplet on the finger, and the blood should quickly move into the tube. Then hold the Transfer Tube over the Sample Application Area of the Test Strip 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 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 EDTA venous blood, plasma or serum samples for testing. Use a pipette to remove 20µl of sample from the tube. Hold the pipette over the Sample Application Area of the Test Strip 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 Transfer Tube in the appropriate clinical waste. Follow instructions from 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 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.

Hematocrit (Hct) range:

The Hct level is determined by the Instrument for each blood sample applied to the Test Strip. The LumiraDx SARS-CoV-2 Ab Test can be used with blood samples with Hct levels of 25-55% Hct. Samples with Hct levels outside this range are shown as 'Hct Out of Range' on the Instrument touch-screen. No SARS-CoV-2 Ab value is reported in samples with Hct 'Out of Range'.

Quality controls:

Liquid Controls for SARS-CoV-2 Ab are available from LumiraDx. Details can be found via the website (lumiradx.com). Quality Control testing policy is at the discretion of your organization. Good laboratory practice recommends the use of control materials. Follow the appropriate 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 comprise as Positive and Negative controls.

LumiraDx recommends controls be run once for:

- each new kit lot
- each new operator
- as required by internal quality control procedures and in accordance with 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.

Cleaning and disinfection:

It is recommended to disinfect the Instrument after each patient sample, or if contamination is suspected. 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, wipe the external surfaces of the Instrument while taking care to avoid the door hinges, Test Strip inlet, power cord, 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 present when plasma biotin concentration is greater than 0.007 mg/dL.
- 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 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 lumiradx.com.

Performance characteristics

Clinical agreement

Positive agreement was evaluated using plasma samples collected from symptomatic subjects in the US and UK. 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
≤6 days	13	Positive	11/13 = 84.6%
7-13 days	7	Positive	7/7 = 100%
14-20 days	6	Positive	6/6 = 100%
≥ 21 days	46	Positive	46/46 = 100%
Total	72	Positive	70/72 = 97.2% (95% confidence interval: 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, and non-endemic asymptomatic subjects in the UK and USA. Endemic samples were collected during the 2020 COVID-19 pandemic and all 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	Specificity: LumiraDx SARS-CoV-2 Ab Test result as compared to RT-PCR
15	UK	Endemic, Symptomatic subjects (PCR –ve)	15/15 = 100%
13	UK	Endemic, Asymptomatic subjects (PCR –ve)	13/13 = 100%
99	USA	Non-endemic, asymptomatic subjects	99/99 = 100%
163	UK	Non-endemic, asymptomatic subjects	163/163 = 100%
Total 290	UK/USA	Endemic PCR -ves and Non-endemic asymptomatics	290/290 = 100% (95% confidence interval of 98.7 to 100%.)

Positive agreement was evaluated using finger stick samples collected prospectively from symptomatic and asymptomatic 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. Results presented are from subjects tested 8 - 118 days since PCR test.

Sample	Number of samples	2019-nCoV RT-PCR result	LumiraDx SARS-CoV-2 Ab Test result as compared to RT-PCR
Direct fingerstick	62	Positive	62/62 = 100%
Fingerstick via Transfer Tube	62	Positive	62/62 = 100%

Negative agreement was evaluated using finger stick 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. It is important to note that the negative agreement is being determined during the Covid-19 Pandemic and therefore there is potential for some patients to be antibody positive and PCR negative.

Sample	Number of samples	2019-nCoV RT-PCR result	LumiraDx SARS-CoV-2 Ab Test result as compared to RT-PCR (> 14 days from PCR)
Direct Fingerstick	54	Negative	54/54 = 100%
Fingerstick via Transfer Tube	56	Negative	56/56 = 100%

Matrix equivalency

A matrix equivalency study was performed to evaluate venous and serum matrices against the plasma matrix used for determination of the clinical performance. Each matrix set (whole blood, plasma, serum) was tested from the same donor and paired samples were used. Negative, low positive and moderately positive were evaluated by running five different samples, in duplicate for each concentration. The study demonstrated 100% agreement across the 3 matrix types (venous, 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:

The LumiraDx SARS-CoV-2 Ab Test did not cross react with samples positive for antibody to Influenza A, Influenza B, Hepatitis C Virus, Hepatitis B Virus (Genotype 3), Hemophilus influenzae, human coronaviruses (HKU1, NL63, OC43 and 229E), Anti-Nuclear Antibody, Respiratory Syncytial Virus (RSV), Human Immunodeficiency Virus (HIV), Mycoplasma pneumoniae, Streptococcus Pneumoniae, Bordella Pertussis, Mycobacterium Tuberculosis and Legionella Pneumophila.

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 LumiraDx SARS-CoV-2 Ab Test was shown to be easy to use, with a low user error rate of 3.1%.

References:

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

Symbols glossary

	Temperature limitation
	Manufacturer
IVD	*In vitro* diagnostic medical device
REF	Catalogue number
LOT	Batch code/Lot Number
	Use-by date
	Refer to instructions for use.
EC REP	Authorized Representative in the European Union
Σ	Contains sufficient for 12 or 24 or 48 Tests
CE	"CE Mark ". This product fulfils the requirements of the European Directive 98/79/EC on *in vitro* diagnostic medical devices.
	Do Not Re-use

LumiraDx customer services:

For product enquiries please contact LumiraDx Customer Services at customerservices@lumiradx.com or find telephone contact details at lumiradx.com.

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@lumiradx.com 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 abuse, misuse, improper storage or use, inconsistent with the LumiraDx Platform User Manual or Product Insert, fraud, tampering, unusual physical stress, negligence or accidents, and any modifications 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 Platform is owned at LumiraDx. Details of relevant Intellectual Property regarding our products can be found at lumiradx.com/IP.

Legal notices:

Manufacturer information:

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

EC REP LumiraDx AB, Västra Vägen 5A, 16961 Solna, Sweden

CE mark applies to LumiraDx Instrument,Test Strips, Quality Controls and Connect Hub only.