ENGLISH

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 R1 ADT-01514 R1 Date of Rev 2021/08

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 venous blood (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 the 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 Organization (WHO) have named the disease caused by SARS-CoV-2 virus as coronavirus 2019 or COVID-19[1]. The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, headache, conjunctivitis, sore throat, diarrhea, loss of taste or smell, or a rash on skin or discoloration of fingers or toes. These symptoms are usually mild and begin gradually. Some people become infected but do not develop any symptoms and do not feel unwell. However, the disease can develop rapidly and have high morbidity in certain populations, especially those with underlying health conditions. The disease can spread from person to person through small droplets from the nose or mouth which are spread when a person with COVID-19 coughs or exhales. Most estimates of the incubation period for COVID-19 range from 2-14 days[2]. The SARS-CoV-2 Ab Test uses a combination of SARS-CoV-2 antigen (RBD and S1 spike) coated magnetic particles and fluorescent particles for the detection of total antibody (Ab) present 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 using the 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, such as 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 from this test and this result 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 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 7 hours 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. Further specimen collection of 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.

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 Scan 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 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. Once 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:-

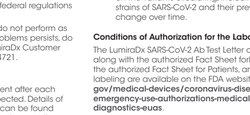


Fig.1 Negative Result for SARS-CoV-2 Antibody

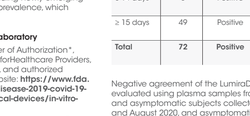
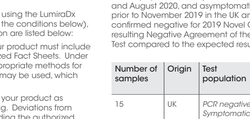


Fig.2 Positive Result for SARS-CoV-2 Antibody

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 the 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 (plan the tube should not be pushed down), and the blood should quickly move into the tube. Stop collecting blood when it has reached the filler at the other end of the capillary.Tip the transfer tube over the sample 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. Once 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 prompt.

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 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 touch-screen.

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 a 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 methods 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 bloodborne pathogens, 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 open 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 laboratory 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.**
- 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 from this test and this result 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 assure 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 collection tube 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 specimen 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 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%)

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 and tested by a CLIA laboratory and 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	LumiraD 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)
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%)

Independent Clinical Agreement Validation Study:

The LumiraDx SARS-CoV-2 Ab Test from LumiraDx UK Ltd was tested on 2021-06-17 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 serum and 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 IgM and IgG antibodies 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 5 Severity (70) samples selected without regard to clinical status, "Negatives" and (1) Item (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 Test Strips. 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					30
Pan Ig-				70	10	80
Total	**30**			**70**	**10**	**110**

Summary Statistics

Measure	Estimate	Confidence Interval
Pan Ig Sensitivity	100% (30/30)	(88.7%; 100%)
Pan Ig Specificity	100% (80/80)	(95.4%; 100%)
Combined Sensitivity	100% (30/30)	(88.7%; 100%)
Combined Specificity	100% (80/80)	(95.4%; 100%)
Combined PPV for prevalence = 5.0%	100%	(50.5%; 100%)
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

	Temperature limitation
	Manufacturer
IVD	*In vitro* diagnostic medical device
REF	Catalogue number
LOT	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.

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