ENGLISH

lumiraDx SARS-CoV-2 Ag Test

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

REF	**Test strips and swabs**	L01600060902A, L01600060904B
REF	**Test strips no swabs**	L01600010901Z, L01600010902A, L01600010904B
IVD	℞ Only	

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LumiraDx SARS-CoV-2 Ag Test

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

Intended use

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

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

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

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

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of a patient's recent exposures, history and presence of clinical signs and symptoms consistent with COVID-19.

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

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

Caution: For *in vitro* diagnostic use.

Before you start testing, if you are new to the LumiraDx Instrument and LumiraDx Platform, you must read the LumiraDx Platform User Manual, the LumiraDx SARS-CoV-2 Ag Test Quick Reference Instructions and this entire Product Insert. In addition please watch the LumiraDx Platform Training Video 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'. 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[1].

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

Principle of the assay

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

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

Materials provided

- LumiraDx Test Strips packed individually in sealed desiccant foil pouches.
- LumiraDx Test Product Insert
- RFID (Radio frequency ID) Tag held inside the Test Strip carton
- Extraction Buffer Vials
- Dropper Lids
- LumiraDx SARS-CoV-2 Ag Test Quick Reference Instructions
- Sterile Nasal Collection Swabs (Provided only with the following product codes L01600060902A, L01600060904B)

Materials required but not provided with the Test Strip carton

- LumiraDx Instrument
- LumiraDx SARS-CoV-2 Ag Quality Controls (as required to meet local and organisational compliance)
- LumiraDx Connect if connectivity required (refer to LumiraDx Connect User Manual)
- Standard nasal or nasopharyngeal collection equipment is required if using a LumiraDx SARS-CoV-2 Ag Test kit without swabs (L01600010901Z, L01600010902A, L01600010904B). Please visit **lumiradx.com** for information on LumiraDx validated swabs for use with the LumiraDx SARS-CoV-2 Ag test.

Note: If using a LumiraDx SARS-CoV-2 Ag test kit which does not include swabs, please note that the swabs listed on lumiradx.com may have only been internally validated by LumiraDx.

Warnings and precautions

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

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

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

Storing the Test Strips

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

Handling the Test Strips

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

Sample material

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

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

The Test device contains

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

Preparing the Instrument to perform a Test

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

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

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

Lot Calibration File installation

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

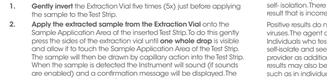
RFID strip code reader

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.

Sampling from a nasopharyngeal swab

1. Tilt patient's head back 70°. Remove swab from the swab packet. Hold the Swab by the shaft while gently rotating the swab, insert swab less than one inch into the first nostril until resistance is met at Turbinates. (Turbinates are the small structures inside the nose).
2. Gently rub and roll the Swab, leaving it in place for several seconds to absorb secretions. If a deviated septum or blockage creates difficulty in obtaining a sample from one nostril, use the same swab to obtain the sample from the other nostril.
3. Slowly remove the swab while rotating it. Samples can be collected from both nostrils, but it is not necessary if the swab is saturated with fluid from the first nostril. Remove and then place the swab in the extraction vial. See instructions for Sample Extraction.

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

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

Instructions for sample collection

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

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

Swabs provided in the kit (L01600060902A, L01600060904B).For anterior nasal sampling where swabs are provided please use the swabs within the kit.

Swabs not provided in the kit (L01600010901Z, L01600010902A, L01600010904B)

Where a swab is not provided within the kit, please visit lumiradx.com for information on LumiraDx validated swabs for use with the LumiraDx SARS-CoV-2 Ag test.

Sampling from an anterior nasal swab

1. Tilt patient's head back 70°

2. A swab sample is needed from both nostrils, and this is taken using the same swab. Remove swab from the swab packet. Hold the swab by the shaft, while gently rotating the swab, insert swab less than one inch into the first nostril until resistance is met at Turbinates. (Turbinates are the small structures inside the nose).

3. Rotate the swab at least 4 times against the nasal wall for 10-15 seconds. Remove and repeat this process by using the same swab into the second nostril. Then place the Swab into the Extraction Vial. See instructions for Sample Extraction.

Sampling from a nasopharyngeal swab

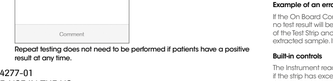
1. Tilt patient's head back 70°. Remove swab from the swab packet. Hold the Swab by the shaft while gently rotating the swab, insert swab less than one inch into the first nostril until resistance is encountered.The swab should reach depth equal to distance from nostrils to outer opening of the ear.
2. Gently rub and roll the Swab, leaving it in place for several seconds to absorb secretions. If a deviated septum or blockage creates difficulty in obtaining a sample from one nostril, use the same swab to obtain the sample from the other nostril.

3. Slowly remove the swab while rotating it. Samples can be collected from both nostrils, but it is not necessary if the swab is saturated with fluid from the first nostril. Remove and then place the swab in the extraction vial. See instructions for Sample Extraction.

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

Instructions for sample extraction

1. **Remove the seal or blue screw cap** from the top of the Extraction Vial containing the Extraction Buffer.
2. **Place and soak the Patient Swab** in the Extraction Buffer for 10 seconds and then stir well by rotating the swab against the side of the vial 5 times.



3. **Squeeze Swab** Remove the Patient Swab while squeezing the middle of the Extraction Vial to remove the liquid from the swab. Discard the swab in biohazard waste.
4. **Firmly attach the clear or purple Dropper Lid** to the top of the Extraction Vial. The extracted sample must be used within 8 hours of preparation when stored at room temperature. Extracted nasal or nasopharyngeal swab samples may be frozen at -60°C and used up to 5 days after freezing.
5. **Gently invert the Extraction Vial** five times just before applying the sample to the Test Strip.

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

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

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

Interpretation of Results

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

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

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

COVID-19 Positive (+)

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

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

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

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the LumiraDx SARS-CoV-2 Ag test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary. If there is a low likelihood of COVID-19 (such as in a healthy) and even asymptomatic exposures to COVID-19 or residing in communities with low prevalence of infection.

COVID-19 Negative (-)

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

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

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

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

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

Invalid test results

If an issue occurs, a message will be displayed on the instrument touch-screen. Alert messages include useful information and are highlighted by an orange banner. Error messages also include a ⚠ symbol. All messages will contain a description of the Instrument status or error and an instruction. Error messages contain an identifying code that may be used for further troubleshooting purposes.Refer to the LumiraDx Platform User Manual if an error message is displayed on the LumiraDx Instrument touch-screen and contact 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 with a new Test Strip and a new drop of extracted sample. If the problem persists, contact Customer Services.

Built-in controls

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

The LumiraDx Instrument and LumiraDx SARS-CoV-2 Ag Test Strips have several quality control functions integrated to ensure validity of each test run.These checks ensure that the volume of sample added is sufficient 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 touchscreen.

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

- Automated checks of the correct functioning of the Instrument at power on and during operation.
- This includes electrical, mechanical 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.

External Quality Controls

External liquid Quality Controls for SARS-CoV-2 Ag are available from LumiraDx and may be used to demonstrate that the Test is functioning properly by demonstrating the expected Quality Control results and correct test performance by the user.External Quality Control assessments should be established in accordance with local, state, and federal regulations or accreditations requirements. It is recommended that external control testing be performed with each new shipment of Test Strips, when using a new lot or shipment of the LumiraDx SARS-CoV-2 Ag Test. Refer to the LumiraDx SARS-CoV-2 Ag Quality Controls pack insert available at **lumiradx.com** for detailed instructions.

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

If the Lumiradx SARS-CoV-2 Ag Quality Control results are not 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

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

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

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

Limitations

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

For information on swabs that have been validated by LumiraDx for use with the LumiraDx SARS-CoV-2 Ag Test please visit lumiradx.com.

There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give a negative result in an individual with COVID-19 as compared to a molecular test especially in samples with low viral loads.

Conditions of Authorization for the Laboratory

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

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

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

- Authorized laboratories[2] using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.
- Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: **CDRH-EUA-Reporting@fda.hhs.gov**) and to you (via email: **customerservices.US@lumiradx.com**) 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.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- You, authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1] The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet the requirements to perform 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," as "authorized laboratories."

Clinical performance – Anterior Nasal Swab

The performance of the LumiraDx SARS-CoV-2 Ag Test was established with 257 direct nasal swabs prospectively collected from individual subjects between June 2020 and July 2020 during the 2020 COVID-19 pandemic. Samples were collected from sequentially enrolled subjects who presented with symptoms of COVID-19 (159 or key workers (98) at increased risk of infection. No positive results were observed from patients without symptoms or beyond 12 days of symptom onset. Dual nasal swabs were simultaneously collected and then randomly allocated to testing with the LumiraDx test or an EUA RTPCR assay. Samples were collected from 6 sites across the United States (5) and United Kingdom (1), including four sites in which minimally trained operators collected and tested fresh samples.

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

Patient demographics

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

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

Positive results broken down by days since symptom onset

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

Final data analysis is presented below

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

PPA - Positive Percent Agreement (Sensitivity) CI - Confidence Interval

NPA – Negative Percent Agreement (Specificity) LCI – Lower Confidence Interval

UCI – Upper Confidence Interval

Clinical Performance – Nasopharyngeal Swabs

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

Patient demographics

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

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

Positive and negative results broken down by days since symptom onset

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

Final data analysis is presented below

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

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

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

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

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

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

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

Note: This study was not performed using LumiraDx assay.

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

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

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

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

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

Analytical performance

Limit of Detection - LOD (analytical sensitivity)

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

Limit of Detection (LoD) screening

An initial LoD screening study was performed using a 5-fold serial dilutions (six dilutions in total) of the gamma-irradiated virus made in pooled negative human nasal matrix starting at a test concentration of 2 x 10^4 $TCID_{50}$/mL (as shown in table below) and processed for each study as described above. These dilutions were tested in triplicate.The volume of solution spiked onto each swab was 50µL.The lowest concentration at which all (3 out of 3 replicates) were positive was chosen for LoD Range finding.This was 32 $TCID_{50}$/mL. Based upon the testing procedure for this study the LoD of 32 $TCID_{50}$/mL equates to 1.6 $TCID_{50}$/swab.

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

Limit of Detection range finding

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

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

Limit of Detection (LoD) confirmation

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

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

Omicron Testing

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

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

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

Cross-reactivity (analytical specificity) and microbial interference studies

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

Microorganism	Source	Concentration	Cross-Reactivity (Yes/No)	Interference (Yes/No)
Human coronavirus 229E	Zeptometrix	1 x 10^5 PFU/mL	No (3/3 negative)	No (3/3 Negative, 3/3 Positive)
Human coronavirus OC43	Zeptometrix	1 x 10^6 PFU/mL	No (3/3 negative)	No (19/20 positive)
Human coronavirus NL63	Zeptometrix	9.87 x 10^5 PFU/mL	No (3/3 negative)	No (3/3 Positive)
MERS coronavirus	Zeptometrix	7930 PFU/mL	No (2/2 negative)	No (3/3 Positive)
Adenovirus (e.g. C1 Ad. 71)	Zeptometrix	1 x 10^5 PFU/mL	No (3/3 negative)	No (3/3 Positive)
Human Metapneumovirus (hMPV)	Zeptometrix	1 x 10^5 PFU/mL	No (3/3 negative)	No (3/3 Positive)
Parainfluenza virus Type 1	Zeptometrix	1 x 10^6 PFU/mL	No (3/3 negative)	No (3/3 Positive)
Parainfluenza virus Type 2	Zeptometrix	1 x 10^5 PFU/mL	No (3/3 negative)	No (3/3 Positive)
Parainfluenza virus Type 3	Zeptometrix	1 x 10^6 PFU/mL	No (3/3 negative)	No (3/3 Positive)
Parainfluenza virus Type 4a	Zeptometrix	1 x 10^6 PFU/mL	No (3/3 negative)	No (3/3 Positive)
Influenza A H3N2 (Wisconsin/67/05)	Zeptometrix	8.82 x 10^4 PFU/mL	No (3/3 negative)	No (3/3 Positive)
Influenza A H1N1	Zeptometrix	1 x 10^6 PFU/mL	No (3/3 negative)	No (3/3 Positive)
Influenza B (Malaysia/2506/04)	Zeptometrix	2.92 x 10^5 PFU/mL	No (3/3 negative)	No (19/20 positive)
Enterovirus	Zeptometrix	1 x 10^5 PFU/mL	No (3/3 negative)	No (3/3 Positive)
Respiratory syncytial virus	Zeptometrix	1 x 10^6 PFU/mL	No (3/3 negative)	No (3/3 Positive)
Rhinovirus	Zeptometrix	4.17 x 10^5 PFU/mL	No (3/3 negative)	No (3/3 Positive)
Haemophilus influenzae	Zeptometrix	1 x 10^8 CFU/mL	No (3/3 negative)	No (3/3 Positive)
Streptococcus pneumoniae	Zeptometrix	1 x 10^8 CFU/mL	No (3/3 negative)	No (3/3 Positive)
Streptococcus pyogenes	Zeptometrix	1 x 10^8 CFU/mL	No (3/3 negative)	No (3/3 Positive)
Candida albicans	Zeptometrix	1 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 Positive)
Pooled human nasal wash	LumiraDx	14% v/v	No (3/3 negative)	No (3/3 Positive)
Bordetella pertussis	Zeptometrix	1 x 10^8 CFU/mL	No (3/3 negative)	No (3/3 Positive)
Mycoplasma pneumoniae	ATCC	1 x 10^8 CFU/mL	No (3/3 negative)	No (3/3 Positive)
Chlamydia pneumoniae	ATCC	1 x 10^8 CFU/mL	No (3/3 negative)	No (3/3 Positive)
Legionella pneumophila	Zeptometrix	1 x 10^8 CFU/mL	No (3/3 negative)	No (3/3 Positive)
Mycobacterium tuberculosis	Zeptometrix	1 x 10^8 CFU/mL	No (3/3 negative)	No (3/3 Positive)
Pneumocystis jirovecii	Zeptometrix	1 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 Positive)
Pseudomonas Aeruginosa	Zeptometrix	1 x 10^8 CFU/mL	No (3/3 negative)	No (3/3 Positive)
Staphylococcus Epidermidis	Zeptometrix	1 x 10^8 CFU/mL	No (3/3 negative)	No (3/3 Positive)
Streptococcus Salivarius	Zeptometrix	1 x 10^8 CFU/mL	No (3/3 negative)	No (3/3 Positive)
Staphylococcus aureus	ATCC	1 x 10^8 CFU/mL	No (3/3 negative)	No (3/3 Positive)

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

- For Human Coronavirus HKU1, homology exists between the SARS-CoV-2 nucleocapsid protein and Human Coronavirus HKU1. BLAST results showed 30 sequence IDs, of nucleocapsid protein, showing homology. Sequence ID AGW23640.1 had the highest alignment score and was found to be 39.1% homologous across 76% of the sequences, this is relatively low but cross-reactivity cannot be fully ruled out.
- For SARS-Coronavirus, high homology exists between the SARS-CoV-2 nucleocapsid protein and SARS-Coronavirus. BLAST results showed 68 sequence IDs, mostly nucleocapsid protein, showing homology. Sequence ID AAR87518.1 had the highest alignment score isolated from a human patient and was found to be 90.76% homologous across 100% of the sequence. This is high and cross-reactivity is likely.
- For MERS-Coronavirus, high homology exists between the SARS-CoV-2 nucleocapsid protein and MERS-Coronavirus. BLAST results showed at least 114 sequence IDs, mostly nucleocapsid protein, showing homology. Sequence IDs AHY61344.1 and AWH69590.1, had the highest alignment scores isolated from a human patient and were found to be 49.4% and 50.3% homologous across 88% of the sequence. Whilst this potentially represents moderate cross-reactivity testing of the MERS virus at 7930 PFU/mL showed no reactivity (see table above).

Endogenous interference studies

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

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

Interfering substance	Concentration	Interference (Yes/No)
Methanol	150 mg/dL	No (19/20 Negative, 3/3 Positive)
Acetylsalicylic Acid	3 mg/dL	No (3/3 Negative, 3/3 Positive)
Diphenhydramine	0.0774 mg/dL	No (3/3 Negative, 3/3 Positive)
Dextromethorphan	0.00156 mg/dL	No (19/20 Negative, 3/3 Positive)
Dexamethasone	1.2 mg/dL	No (3/3 Negative, 3/3 Positive)
Mucinex	5%	No (3/3 Negative, 3/3 Positive)

High dose hook effect

High Dose Hook Effect studies determine the level at which false negative results can be seen when very high levels of target are present in a tested sample. To determine if the LumiraDx SARS-CoV-2 Ag Test suffers from any high dose hook effect, increasing concentrations of gamma-irradiated SARS CoV-2 virus (BEI Resources NR-52287) were tested up to a concentration of 1.4 x 10^6 $TCID_{50}$/mL. In this study, the starting material was spiked into a volume of pooled human nasal matrix obtained from healthy donors and confirmed negative for SARS-CoV-2. At each dilution, 50 µL samples were added to swabs and the swabs processed for testing on the LumiraDx SARS-CoV-2 Ag Test as per the Product insert using the procedure appropriate for patient nasal swab samples.

No impact on test performance or high dose hook effect was observed up to 1.4 x 10^6 $TCID_{50}$/mL of gamma-irradiated SARS-CoV-2 with the LumiraDx SARS-CoV-2 Ag Test.

Test dilution	Concentration ($TCID_{50}$/mL)	Mean signal (ADC Units)
1	0	495
2	62.5	26100.6
3	250	63013.8
4	1000	83451.8
5	1.4 x 10^6	86220

Point of care use

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

References

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

Symbols glossary

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

LumiraDx customer services:

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

For return policy

If there is a problem with the **LumiraDx SARS-CoV-2 Ag Test Strips** 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: **customerservices.US@lumiradx.com**

Limited warranty

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

Unused strips and nasal collection swabs 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. Test Strip box and swab packaging. For the applicable warranty period, LumiraDx warrants that each product shall be (i) of good quality and free of material defects, (ii) functional 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 those kinds of damages might result.The Limited Warranty above shall not apply if the customer has subjected the LumiraDx SARS-CoV-2 Ag Test to physical abuse, misuse, abnormal use, use inconsistent with the LumiraDx Platform User Manual or Product Insert, fraud, tampering, unusual physical stress, negligence or accidents.Any warranty claim by Customer pursuant to the Limited Warranty shall be made in writing within the applicable Limited Warranty period.

Intellectual property

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

Legal notices

Manufacturer information

Test Strips

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

Swabs

Copan Italia S.p.A.
Sede Leg. Via F.Perrotti 10, 25125 Brescia, Italy

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