ENGLISH

SARS-CoV-2 Ag Surveillance Test Product Insert

For surveillance purposes only - not for use in diagnostic procedures

SPEC-34434 R1 ART-01478 R1 Date of Revision 2021/07

LumiraDx SARS-CoV-2 Ag Surveillance Test Strip

The LumiraDx Severe Acute Respiratory Syndrome (SARS) CoV-2 Antigen (Ag) Surveillance Test Strips (hereafter referred to as Test Strips) are to be used with the LumiraDx Platform. The LumiraDx Instrument can be used in conjunction with the SARS-CoV-2 Ag Surveillance Test for COVID-19 surveillance testing. This test allows users to perform COVID-19 surveillance tests using small specimen volumes and to view results quickly on the Instrument touchscreen.

Intended use:

The LumiraDx SARS-CoV-2 Ag Surveillance Test is a rapid microfluidic immunofluorescence assay for use with the LumiraDx Instrument and is intended for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 in de-identified a) individual specimens from professionally supervised & self-collected nasal swab samples or professionally collected nasal or nasopharyngeal swab samples, or b) professionally supervised & self-collected nasal swab specimens or professionally collected nasal or nasopharyngeal swab specimens (2-5 specimens) which are then pooled for testing. The test aids in the surveillance of COVID-19 in populations by detecting SARS-CoV-2 antigen.

Individual results should not be reported based on the SARS-CoV-2 Ag Surveillance Test. Results should not be used as diagnostic information on an individual basis.

The LumiraDx SARS-CoV-2 Ag Surveillance Test is intended for use by individuals proficient in performing tests using the LumiraDx Instrument.

The SARS-CoV-2 Ag Surveillance Test is for surveillance purposes only and not for use in diagnostic procedures.

Before you start testing, if you are new to the LumiraDx Instrument, you must read the LumiraDx Platform User Manual and this entire Product Insert. In addition, please watch the LumiraDx Platform Training Video available at **lc.lumiradx.com.**

Summary and explanation of the Test:

The World Health Organization (WHO) has 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].

Use of a LumiraDx SARS-CoV-2 Ag Surveillance Test will enable surveillance of a population to make population-level health decisions to prevent further spread of infection.

Principle of the assay:

The LumiraDx SARS-CoV-2 Ag Surveillance Test is a fluorescence immunoassay device designed to detect the presence of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab and nasopharyngeal swab specimens. The Test Strip is single use.

The test procedure involves collecting up to 5 nasal swab or nasopharyngeal swab specimens using a recommended swab which are then eluted into a vial containing Extraction Buffer. A single drop of the specimen in Extraction Buffer is added to the Test Strip using the vial dropper cap provided. The LumiraDx Instrument is programmed to perform the test protocol using the dried reagents contained within the Test 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 specimen is proportional to the fluorescence detected. The results are displayed on the Instrument touchscreen within 12 minutes from the addition of the specimen.

In specimen pooling, the collected nasal or nasopharyngeal swab specimens are identified and between two to five individual specimens are then combined into one pool by eluting each individual specimen sequentially into a single vial containing Extraction Buffer. Attach the dropper cap, invert the sample 5x, and squeeze to place a single drop of the pooled specimen from the Extraction Buffer to the Test Strip. The LumiraDx Instrument is programmed to perform the Pooled Surveillance Test Protocol within 12 minutes from the addition of the pooled specimen. If the pool is positive, then SARS-CoV-2 antigen was detected in one or more specimens in the pool. If the pool is negative, then SARS-CoV-2 antigen was not detected in the specimen pool.

Materials provided:

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

Materials required but not provided:

- Swabs and collection tubes
- Please refer to list of approved swabs on website
- Collection tubes, if needed
- Use a dry, clean, and sterile tube
- LumiraDx Instrument
- LumiraDx SARS-CoV-2 Ag Surveillance Test Quick Reference Instructions
- LumiraDx SARS-CoV-2 Ag Quality Controls (as required to meet local and organizational compliance)

Materials not required but available:

- LumiraDx Connect if connectivity required (refer to LumiraDx Connect User Manual)
- LumiraDx Barcode Scanner
- LumiraDx How to Use Platform video

'How to' videos are accessible at www.lumiradx.com

Warnings and precautions

- For surveillance purposes only - not for use in diagnostic procedures
- 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 specimen collection, storage, and transport can result in incorrect results.
- All specimens in a single pool must be of the same specimen type (nasal or nasopharyngeal)
- 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
- Do not reuse any kit components.
- Specimens must be processed as indicated in the Specimen Extraction and Performing a Test sections of this Product Insert. Failure to follow the instructions for use can result in inaccurate results.
- All components of this kit should be discarded as biohazard waste according to local regulations and procedures.
- Refer to the product safety data sheet for risk and safety phrases and disposal information. The product safety data sheet is available via our website at lumiradx.com.
- Exercise the normal precautions required for handling all laboratory reagents. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when samples are collected and evaluated.
- Proper safety techniques should be followed at all times when working with specimens that may contain SARS-CoV-2. Specimen 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 regulations and procedures.
- For additional information on safety, handling, and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at lumiradx.com

Storing the Test Kit:

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 Ag Surveillance Test Strip:

- Nasal Swab Specimens (NS)
- Nasopharyngeal Swab Specimens (NP)

The Test device contains:

- Rabbit and Mouse Monoclonal antibodies
- Fluorescent Latex 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. Check that "Pooled Test" is available on the Instrument home screen. If it is not, enable "Pooled Test" in the Instrument settings menu.

Refer to the section on **Performing a Test** in this Product Insert for information on how to test a specimen. The LumiraDx SARS-CoV-2 Ag Surveillance Test 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 for the first time. 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 the information needed to perform a surveillance test. 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. To install, locate the ((•)) symbol on the instrument and touch it to the same symbol on the back of the Test Strip Carton to install.

RFID strip code reader
Locate ((•)) symbol on Instrument.

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

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

When indicated by the touchscreen, open the foil pouch just before use and insert the LumiraDx Test Strip into the LumiraDx Instrument. The Instrument will indicate when it is ready for the sample to be applied. The LumiraDx SARS-CoV-2 Ag Surveillance Test results should not be used to make individual-level diagnoses.

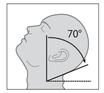
Instructions for specimen collection:

When collecting any type of specimen, follow universal collection precautions and guidelines according to your organization. For collection of nasal swabs and nasopharyngeal swabs, follow appropriate Swab Collection Guidelines and swab manufacturers' recommendations. Users should be trained in appropriate specimen collection and handling procedures.

The steps that follow apply to a nasal swab and a nasopharyngeal swab. For information on recommended swabs to use with the LumiraDx SARS-CoV-2 Ag Surveillance Test, please see the 'SARS-CoV-2 Ag Test Technical Bulletin – Swabs' available at Lumiradx.com.

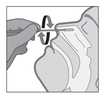
Collecting a nasal swab:

Individual specimens should be collected and either placed directly into the extraction buffer vial or placed into a dry, clean, and sterile tube separately. The steps that follow apply to a nasal swab.



1. Tilt individual's head back 70°.

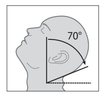
2. A swab sample is needed from both nostrils and this is taken using the same swab. While gently rotating the swab, insert swab less than one inch into the nostril until resistance is met at Turbinates. (Turbinates are the small structures inside the nose).



3. Rotate the swab several times against the nasal wall. Remove and repeat this process by using the same swab into the second nostril. Place swab in dry, clean, and sterile tube or process the swab directly in the extraction buffer vial as per instructions for sample extraction of pooled samples outlined below.

Collecting a nasopharyngeal swab:

Individual specimens should be collected and either placed directly into the extraction buffer vial or placed into a dry clean, and sterile tube separately. The steps that follow apply to a nasopharyngeal swab.



1. Tilt individual's head back 70°.

2. Hold the swab firmly between the fingers and insert Swab into nostril. The swab should reach a depth equal to distance from nostrils to outer opening of the ear. Leave Swab in place for several seconds to absorb secretions.

3. Slowly remove the swab while rotating it. Remove and then place the swab in a dry, clean, and sterile tube or process the swab directly in the extraction buffer vial as per instructions for sample extraction of pooled samples outlined below.

NOTE: After collecting the swab specimen, process the Swab(s) in the Extraction Buffer Vial as soon as possible. Freshly collected specimens should be processed in the Extraction Buffer vial within 1 hour of collection. If the specimen is not processed immediately, the swab may be stored at room temperature (15° - 30°/59° - 86°) for up to 1 hour prior to testing in a dry, clean and sterile tube.

Do not place the swab back into the swab packaging sleeve after sample collection.

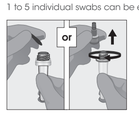
Specimen pooling for the LumiraDx SARS-CoV-2 Ag Surveillance Test

Users may consider changing the pool size to test fewer than 5 pooled specimens based on a variety of factors. Pools of up to 5 swab specimens may be tested using the SARS-CoV-2 Ag Surveillance Test.

Process pooled specimens as described in the instructions below for sample extraction of pooled samples.

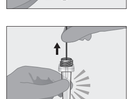
Instructions for specimen extraction:

1 to 5 individual swabs can be eluted sequentially into a single Extraction Buffer v



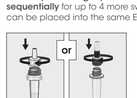
1. **Remove the seal or blue screw cap** from the top of the Extraction Buffer Vial containing the Extraction Buffer.

2. **Place and soak the 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 and remove** the Swab while squeezing the middle of the Extraction Buffer Vial to remove the liquid from the swab. Discard the swab in biohazard waste.

NOTE: If performing a pooled surveillance test. repeat steps 2 and 3 sequentially for up to 4 more swabs. Up to and including a total of 5 specimens can be placed into the same Extraction Buffer Vial.



4. **Firmly attach the clear or purple Dropper Lid** to the top of the Extraction Buffer Vial. The extracted specimen must be used within 5 hours of preparation when stored at room temperature. Extracted nasal swab or nasopharyngeal swab samples may be frozen at -80°C and used up to 5 days after freezing.

5. Gently **invert the Extraction Buffer Vial** 5 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).

1. **Gently invert** the Extraction Vial five times (5x) just before applying the sample to the Test Strip.
2. **Squeeze and apply the extracted sample from the Extraction Buffer Vial** onto the Sample Application Area of the inserted Test Strip. To do this gently press the sides of the extraction buffer vial until **one whole drop** is visible and allow it to touch the Sample Application Area of the Test Strip. The specimen will then be drawn by capillary action into the Test Strip. When the specimen 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 specimen.** 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 specimen and starting the test.

a. **For pooled specimen surveillance tests** the results will be displayed as a **"Pooled Positive" or "Pooled Negative" result SARS-CoV-2-Ag** on the Instrument screen. (see Fig 1 and Fig 2).

b. **For individual specimen surveillance tests** the results will be displayed as a **"Positive" or "Negative" result SARS-CoV-2-Ag** on the Instrument screen. (see Fig 3 and Fig 4).

5. **If you need to retest**, you will use a new Test Strip. Use the same Extraction Buffer Vial and repeat the test. The extracted sample must be used within 5 hours of preparation when stored at room temperature. Extracted nasal swab or nasopharyngeal swab samples may be frozen at -80°C and used up to 5 days after freezing.
6. **Dispose** of the swab, Extraction Buffer Vial and Test Strip in the appropriate clinical waste.
7. **Disinfection** of the Instrument with LumiraDx approved materials is recommended if contamination is suspected. Details of approved disinfecting materials is available at lumiradx.com. Allow the Instrument to air dry before testing the next sample. The disinfectant should remain in contact for at least 1 minute.

Result interpretation:

The results will be displayed on the Instrument screen as **shown below:**

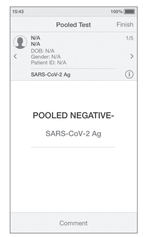


Fig 1: Negative pooled result for SARS-CoV-2 Ag Surveillance Test

Fig 2: Positive pooled result for SARS-CoV-2 Ag Surveillance Test

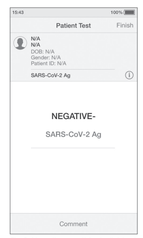


Fig 3: Negative result for individual specimen SARS-CoV-2 Ag Surveillance Test

Fig 4: Positive result for individual specimen SARS-CoV-2 Ag Surveillance Test

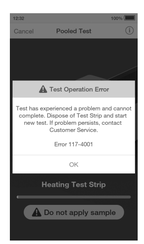
NOTE: Results from the SARS-CoV-2 Ag Surveillance Test should not be used to make individual-level health decisions or diagnoses. All results should be considered in the context of the population.

Error Messages:

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

Example of an error screen:

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



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

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

- Automated checks of the correct functioning of the Instrument at power on and during operation.
- This includes electrical component operation, heater operation, battery charge state, mechanical actuators and sensors and optical system performance.
- Monitoring of Test Strip performance and controls during test run time.
- Ability to perform Quality Control Tests using LumiraDx Quality Control solutions to meet regulatory compliance requirements.

Cleaning and disinfection

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

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

It is recommended to disinfect the Instrument if contamination is suspected and at least once per day when in use with LumiraDx approved materials. Details of LumiraDx approved disinfectant materials can be found at www.lumiradx.com. Allow the Instrument to air dry before testing the next sample. The disinfectant should remain in contact for at least 1 minute.

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

Avoid USB ports and power inlet. Do not spray or pour solution directly into the Instrument. Do not put any objects or cleaning materials into the Test Strip slot.

Limitations:

- This test detects both viable (live) and non-viable, SARS-CoV and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- Test results should only be used to make population-level health decisions and should not be used to make individual level diagnoses
- Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- When considering surveillance strategies, the appropriateness of the strategy should be considered based on the positivity rate in the testing population, efficiency of the surveillance workflow, and surveillance test specificity.
- Users should test specimens as quickly as possible after specimen collection.
- Specimens extracted into the same Extraction Buffer should all be of the same specimen type (nasal or nasopharyngeal).
- Extracted nasal specimens or nasopharyngeal specimens may be frozen at -80°C and used up to 5 days after freezing.
- Swab specimens and Extraction Buffer must be at room temperature before testing.
- Positive test results do not rule out co-infection with the presence of other pathogens
- A false negative result may occur if the level of viral antigen in a specimen is below the detection limit of the test or if the specimen was collected inappropriately, therefore a negative test result does not rule out the possibility of the presence of SARS-CoV-2 in the specimen.
- The contents of this kit are for qualitative detection of SARS-CoV-2 antigens from nasal swab and nasopharyngeal swab specimens only.
- For information on swabs have been validated for use with the LumiraDx SARS-CoV-2 Ag Surveillance Test please visit lumiradx.com.
- Only dry, clean, and sterile tubes have been validated for use with the LumiraDx SARS-CoV-2 Ag Surveillance Test.

Clinical Performance

Clinical Performance – 1 Nasal Specimen from Symptomatic Patients

Note: This clinical performance data was generated using the EUA LumiraDx SARS-CoV-2 Ag IVD test and is provided for illustration purposes only. The LumiraDx SARS-CoV-2 Ag Surveillance Test should not be used to make individual level diagnoses.

The performance of the LumiraDx SARS-CoV-2 Ag Test was established with 257 direct nasal swabs prospectively collected from individual subjects during the 2020 COVID-19 pandemic. Samples were collected from sequentially enrolled subjects who presented with symptoms of COVID-19 ('19') 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 the Roche Cobas 6800. 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 PCR result. The performance of the LumiraDx SARS-CoV-2 Ag Test was compared to the results from nasal swabs collected into 3ml universal transport medium (UTM) and tested with the Roche Cobas 6800 PCR method.

Patient demographics

Patient demographics (gender, 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	0.0%
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	PPV	93.1%	85.8%	96.8%
	TOTAL	83	174	257	NPV	98.8%	95.8%	99.7%
					Prevalence	32.3%	26.9%	38.2%
					OPA	96.9%	94.0%	98.4%

PPA - Positive Percent Agreement (Sensitivity)
NPA – Negative Percent Agreement (Specificity)
PPV – Positive Predictive Value
NPV- Negative Predictive Value
OPA – Overall Percent Agreement
CI - Confidence Interval
LCI – Lower Confidence Interval
UCI – Upper Confidence Interval

Clinical Performance – 1 Nasopharyngeal Sample from Symptomatic Patients

Note: This clinical performance data was generated using the EUA LumiraDx SARS-CoV-2 Ag IVD test and is provided for illustration purposes only. The LumiraDx SARS-CoV-2 Ag Surveillance Test should not be used to make individual level diagnoses.

The performance of the SARS-CoV-2 Ag Test was established with 255 nasopharyngeal swabs prospectively collected from individual subjects 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 (gender, 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 RT-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	PPV	88.6%	76.0%	95.0%
	TOTAL	40	215	255	NPV	99.5%	97.4%	99.9%
					Prevalence	15.7%	11.7%	20.7%
					OPA	97.6%	95.0%	98.9%

Clinical Performance – Nasal and Nasopharyngeal Swabs Symptomatic and Asymptomatic Subjects with 1 Sample

Note: This clinical performance data was generated using the EUA LumiraDx SARS-CoV-2 Ag test and is provided for illustration purposes only. The LumiraDx SARS-CoV-2 Ag Surveillance Test should not be used to make individual level diagnoses.

Clinical studies were continued to include asymptomatic and symptomatic positive individuals across sites in the United Kingdom, the United States and Norway*. Studies were conducted with individual subjects.

The performance of the LumiraDx SARS-CoV-2 Ag Test was established with direct nasal swabs prospectively collected from asymptomatic and symptomatic individual subjects during the 2020 COVID-19 pandemic. Samples were collected from 676 subjects in the US and Norway (109 positive by PCR). Dual NP swabs were collected and then randomly allocated to testing with the LumiraDx Test or the RT-PCR reference. Swabs were collected and extracted into the LumiraDx Extraction Buffer and used fresh within 1h of collection. The performance of the LumiraDx SARS-CoV-2 Ag Test was compared to the results from NP swabs collected into 3ml universal transport medium (UTM) and tested with RT-PCR.

* SKUP (Scandinavian evaluation of laboratory equipment for point of care testing) independent evaluation of the LumiraDx SARS-CoV-2 Ag test. www.skup.org .

Grouping	Nasal Swabs					NP Swabs				
	N	PPA	95% CI	NPA	95% CI	N	PPA	95% CI	NPA	95% CI
All Subjects	**782**	**93.8%**	**89.2-96.5**	**98.8%**	**97.6-99.4**	**676**	**92.7%**	**86.2-96.2**	**98.1%**	**96.6-98.9**
DSSO* ≤ 12	473	95.0%	90.4-97.4	98.4%	96.3-99.3	484	93.9%	87.6-97.2	97.9%	96.0-98.9
DSSO ≤ 10	465	95.4%	90.9-97.9	98.4%	96.3-99.3	479	93.9%	87.3-97.2	98.2%	96.3-99.1
DSSO ≤ 7	451	95.3%	90.6-97.7	98.3%	96.2-99.3	463	94.7%	88.1-97.7	98.4%	96.5-99.3
Ct < 33 (all)**	146	97.9%	94.1-99.3	-	-	103	97.1%	91.8-99.0	-	-
Ct < 30 (all)	129	99.2%	95.7-99.9	-	-	93	97.8%	92.5-99.4	-	-
Ct < 25 (all)	91	100%	95.9-100	-	-	73	98.6%	92.6-99.8	-	-
Asymptomatic	309	82.4%	59.0-93.8	99.3%	97.5-99.8	192	80.0%	49.0-94.3	98.4%	95.3-99.4
Ct < 33 (asymptomatic)	13	100%	77.2-100	-	-	7	100%	64.6-100	-	-

* DSSO = Days Since Symptom Onset

** Ct < [X] (all) = includes all subjects in the study (symptomatic and asymptomatic)

SARS-CoV-2 Ag Surveillance Test with 5 Nasal Specimens (Pooled testing)

The performance of the SARS-CoV-2 Ag Surveillance Test was established during the 2020 COVID pandemic with 30 positive pools prospectively collected from 150 individual subjects, and 29 negative pools prospectively collected from 145 samples. Subjects were either presenting with symptoms of COVID-19 or key workers being screened for infection. Specimens (anterior nares) were collected by a healthcare provider or by supervised on site self-collection from 1 site each in the United States and United Kingdom. Swabs were collected and extracted into the LumiraDx extraction buffer. Specimens were extracted and tested fresh within 1h of collection. One positive swab was included in a randomized sequence with 4 negative swabs for the positive pools. For the negative pools, 5 negative swabs were extracted. The performance of the LumiraDx SARS-CoV-2 Ag Surveillance Test was compared to the results from nasal swabs collected into the LumiraDx extraction buffer and tested with the LumiraDx SARS-COV-2 Ag Test.

Final data analysis is presented below.

Classification of all evaluable pools:

		Single Swab		TOTAL
		POS	NEG	
Pooled Test	POS	30	1	31
	NEG	0	28	28
TOTAL		30	29	59

Performance measures, and 95% confidence intervals, as calculated with the Wilson Score method.

Measure	Estimate	95% Confidence Interval	
PPA	100.0%	88.6%	100.0%
NPA	96.6%	82.8%	99.4%
PPV	96.8%	83.8%	99.4%
NPV	100.0%	87.9%	100.0%
Prevalence	50.8%	38.4%	63.2%
OPA (% Agreement)	98.3%	91.0%	99.7%

PPA - Positive Percent Agreement (Sensitivity)
NPA – Negative Percent Agreement (Specificity)
PPV – Positive Predictive Value
NPV- Negative Predictive Value
OPA – Overall Percent Agreement

Analytical performance of LumiraDx SARS-CoV-2 Ag Test:

Note: This testing was generated using the LumiraDx SARS-CoV-2 Ag Test for use with single samples but is expected to be representative of the LumiraDx SARS-CoV-2 Ag Surveillance Test.

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 (BEI Resources NR-52287). The NR-52287 is a preparation of SARS-Related Coronavirus 2 (SARS-CoV2), 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 10^6 $TCID_{50}$/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 lowest concentration at which all (3 out of 3 replicates) were positive was chosen for LoD Range finding. This was 32 $TCID_{50}$/mL.

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
6.2	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 (TCIDso/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.

Starting Material Concentration	Estimated LoD	No. Positive/Total	% Positive
2.8 x 10^3 $TCID_{50}$/mL	32 $TCID_{50}$/mL	20/20	100

The Limit of Detection studies were repeated for the SARS-CoV-2 Surveillance Test with one positive swab and 4 negative swabs and demonstrated comparable results to the SARS-CoV-2 Ag Test when run across 3 test strip batches.

Cross-reactivity (analytical specificity) and microbial interference studies with 1 nasal specimen

Note: This cross-reactivity testing was generated using the LumiraDx SARS-CoV-2 Ag Test for use with single samples but is expected to be representative of the LumiraDx SARS-CoV-2 Ag Surveillance Test.

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

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

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

- For Human Coronavirus HKU1, homology exists between the SARS-CoV-2 nucleocapsid protein and Human Coronavirus HKU1. BLAST results showed 30 sequence IDs, all nucleocapsid protein, showing homology. Sequence ID AGW27840.1 had the highest alignment score and was found to be 39.1% homologous across 76% of the sequences, this is relatively low but cross-reactivity cannot be fully ruled out.
- For SARS-Coronavirus, high homology exists between the SARS-CoV-2 nucleocapsid protein and SARS-Coronavirus. BLAST results showed 68 sequence IDs, mostly nucleocapsid protein, showing homology. Sequence ID AAR87518.1, had the highest alignment score isolated from a human patient and was found to be 90.76% homologous across 100% of the sequence. This is high and cross-reactivity is likely.
- For MERS-Coronavirus, high homology exists between the SARS-CoV-2 nucleocapsid protein and MERS-Coronavirus. BLAST results showed at least 114 sequence IDs, mostly nucleocapsid protein, showing homology. Sequence IDs AHY61344.1 and AWH65950.1, 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).

Cross-reactivity (analytical specificity) and microbial interference studies with 5 nasal specimens (pooled testing)

Higher risk cross-reactant and microbial interferents were additionally tested using the LumiraDx SARS-CoV-2 Ag Surveillance Test. The following were tested:

- Human coronavirus OC43
- Adenovirus (e.g. C1 Ad. 71)
- Parainfluenza virus 1
- Parainfluenza virus 2
- Parainfluenza virus 3
- Parainfluenza virus 4b
- Influenza B
- Pneumocystis jirovecii (PJP)

Cross-reactivity and interference of the LumiraDx SARS-CoV-2 Ag Surveillance Test was evaluated by testing a panel of high-risk pathogens 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 Surveillance Test. Each organism or virus testing concentration was spiked to each of the 5 pooled swabs and tested in the absence or presence of heat inactivated SARS-CoV-2 at 3 x LoD. The results are shown below.

Microorganism	Source	Concentration	Cross-reactivity (Yes/No)	Interference (Yes/No)
Human coronavirus OC43	Zeptometrix	1 x 105 PFU/mL	No (3/3 negative)	No (3/3 positive)
Adenovirus (e.g. C1 Ad. 71)	Zeptometrix	1 x 105 PFU/mL	No (3/3 negative)	No (3/3 positive)
Parainfluenza virus Type 1	Zeptometrix	1 x 105 PFU/mL	No (3/3 negative)	No (3/3 positive)
Parainfluenza virus Type 2	Zeptometrix	1 x 105 PFU/mL	No (3/3 negative)	No (3/3 positive)
Parainfluenza virus Type 3	Zeptometrix	1 x 105 PFU/mL	No (3/3 negative)	No (3/3 positive)
Parainfluenza virus Type 4b	Zeptometrix	1 x 105 PFU/mL	No (3/3 negative)	No (3/3 positive)
Influenza B	Zeptometrix	2.72 x 104 PFU/mL	No (3/3 negative)	No (3/3 positive)
Pneumocystis jirovecii	Zeptometrix	1 x 106 CFU/mL	No (3/3 negative)	No (3/3 positive)

Endogenous interference studies with 1 nasal specimen:

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 Surveillance Test. Each substance was tested in triplicate in the absence or presence of SARS-CoV-2 at 3 x LoD. The results are shown 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 phos-phate)	500 mg/dL	No (3/3 Negative, 3/3 Positive)
Budenoside	0.00063 mg/dL	No (3/3 Negative, 3/3 Positive)
Biotin	0.35 mg/dL	No (3/3 Negative, 3/3 Positive)
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)

Endogenous interference studies with 5 nasal specimens (pooled testing):

Higher risk endogenous interferents were additionally tested using the LumiraDx SARS-CoV-2 Ag Surveillance Test. The following were tested:

- Acetylsalicylic acid
- Dexamethasone

A study was performed to demonstrate that potentially interfering substances that may be found in the upper respiratory tract in symptomatic subjects do not cross-react or interfere with the detection of SARS-CoV-2 in the LumiraDx SARS-CoV-2 Ag Surveillance Test. Each substance was tested in triplicate in the absence or presence of SARS-CoV-2 at 3 x LoD. The results are shown below.

Interfering substance	Concentration	Interference (Yes/No)
Acetylsalicylic Acid	3 mg/dL	No (6/6 Negative, 6/6 Positive)
Dexamethasone	1.2 mg/dL	No (6/6 Negative, 6/6 Positive)

High dose hook effect

Note: This testing was generated using the LumiraDx SARS-CoV-2 Ag test for use with single samples but is expected to be representative of the LumiraDx SARS-CoV-2 Ag Surveillance Test.

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

No impact on test performance or high dose hook effect was observed up to 1.4 x 10^5 $TCID_{50}$/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 10^5	86220

References:

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

Symbols glossary

Symbol	Meaning
	Temperature limitation
	Manufacturer
REF	Catalogue Number
LOT	Lot Number
	Use-by Date – indicates the date after which the unopened Surveillance Test/Quality Control Material cannot be used
	Refer to instructions for use
	Do Not Re-use
	Indicates the presence of the Radio Frequency Identification (RFID) reader/tag.

LumiraDx customer services:

For product enquiries please contact LumiraDx Customer Services at 1-888-586-4721 or customerservices.us@lumiradx.com.

The LumiraDx SARS-CoV-2 Ag Surveillance test has not been cleared, approved, or authorized by FDA under an emergency use authorization (EUA). This test should be used for surveillance purposes (i.e., to inform population or community-level decision-making) only. FDA does not regulate surveillance tests.

As with all COVID-19 tests, a negative result does not rule out the presence of COVID-19. There is a greater likelihood of a false negative result with samples used for pooling because the samples are diluted, which could result in less viral genetic material available to detect. Therefore, negative results are presumptive, and should be considered in the context of the signs and symptoms in the cohort, as well as recent exposures to COVID-19 by members of the cohort. *Risks* from a false negative result include: delay or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

For return policy

If there is a problem with the **LumiraDx SARS-CoV-2 Ag Surveillance 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.

Limited warranty:

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

Unused strips must be stored according to the required storage conditions as printed in this product insert and they can be used only up to the expiry date printed on the Test Strip pouch and Test Strip box. For the applicable warranty period, LumiraDx warrants that each product shall be (i) of good quality and free of material defects, (ii) function in accordance with the material specifications referenced in the product insert, and (iii) approved by the proper governmental agencies required for the sale of products for their intended use (the "limited warranty"). If the product fails to meet the requirements of the limited warranty, then as customer's sole remedy, LumiraDx shall either repair or replace, at LumiraDx's discretion, the Test Strips. Except for the limited warranty stated in this section, LumiraDx disclaims any and all warranties, express or implied, including but not limited to, any warranty of merchantability, fitness for a particular purpose and non-infringement regarding the product. LumiraDx's maximum liability with any customer claim shall not exceed the net product price paid by the customer. Neither party shall be liable to the other party for special, incidental or consequential damages, including, without limitation, loss of business, profits, data or revenue, even if a party receives notice in advance that these kinds of damages might result. The Limited Warranty above shall not apply if the customer has subjected the LumiraDx SARS-CoV-2 Ag Surveillance 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:

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