lumiraDx™ SARS-CoV-2 & Flu A/B

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

SPEC-34351 R1 ART-01225 R2

Product Name	Product Description	REF	Σ
LumiraDx SARS-CoV-2 & Flu A/B	EN,FR,DE,IT,NL,ES Test Strips and Swabs	L019000201012	12
LumiraDx SARS-CoV-2 & Flu A/B	EN,FR,DE,IT,NL,ES Test Strips and Swabs	L019000201024	24
LumiraDx SARS-CoV-2 & Flu A/B	EN,FR,DE,IT,NL,ES Test Strips and Swabs	L019000201048	48
LumiraDx SARS-CoV-2 & Flu A/B	EN,FR,DE,IT,NL,ES Test Strips (No swabs included)	L019000101012	12
LumiraDx SARS-CoV-2 & Flu A/B	EN,FR,DE,IT,NL,ES Test Strips (No swabs included)	L019000101024	24
LumiraDx SARS-CoV-2 & Flu A/B	EN,FR,DE,IT,NL,ES Test Strips (No swabs included)	L019000101048	48

ENGLISH

lumiraDx™ SARS-CoV-2 & Flu A/B

LumiraDx SARS-CoV-2 & Flu A/B

The LumiraDx SARS-CoV-2 & Flu A/B 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 and to view results quickly on the Instrument touchscreen.

Intended use:

The LumiraDx SARS-CoV-2 & Flu A/B test is an automated rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform, for near-patient testing, intended for the qualitative detection and differentiation of SARS-CoV-2, Influenza A and/or Influenza B viral antigens from nasal swab samples. Samples are collected from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider.

The LumiraDx SARS-CoV-2 & Flu A/B test is intended for use as an aid in the differential diagnosis of SARS-CoV-2, Influenza A, and Influenza B in humans and is not intended to detect Influenza C.

The LumiraDx SARS-CoV-2 & Flu A/B test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification and differentiation of SARS-CoV-2, Influenza A and/or Influenza B nucleocapsid viral antigens. Viral antigens are generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of active infection but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. The agent detected may not be the definite cause of disease.

Negative results do not rule out SARS-CoV-2, Influenza A, and/or Influenza B infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. 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, and confirmed with a molecular assay, if necessary, for patient management.

The LumiraDx SARS-CoV-2 & Flu A/B test is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings, and proficient in performing tests using the LumiraDx Instrument.

Caution: For *in vitro* diagnostic use.

Before you start testing, if you are new to the LumiraDx Instrument and LumiraDx Platform, you must read the LumiraDx Platform User Manual, the LumiraDx SARS-CoV-2 & Flu A/B test Quick Reference Instructions, available online, 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[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].

Influenza (commonly known as `flu') is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus. Influenza outbreaks occur each year during the fall and winter months. Type A viruses are typically more prevalent than type B viruses and are associated with most serious Influenza epidemics, while type B infections are usually milder.[3]

The use of a LumiraDx SARS-CoV-2 & Flu A/B test will enable the physician to help verify infection quickly, differentiate between SARS-CoV-2 and Influenza infection, begin appropriate treatment and to initiate isolation precautions helping prevent further spread of infection.

Principle of the assay:

The LumiraDx SARS-CoV-2 & Flu A/B test is a rapid microfluidic immunofluorescence assay for use with the LumiraDx instrument for the qualitative detection and differentiation of SARS-CoV-2, influenza type A, and influenza type B viral antigens. The LumiraDx SARS-CoV-2 & Flu A/B test uses nasal swab specimens. The test procedure involves taking a sample and adding to an extraction buffer. Then one drop of sample from the extraction buffer vial is added to the sample application area of the Test Strip. The LumiraDx Instrument is programmed to perform the analysis when the specimen has reacted with the reagents. The analysis is based on the amount of fluorescence the Instrument detects within the measurement area of the Test Strip. The concentration of the analyte in the specimen is directly proportional to the fluorescence detected. The results are displayed on the Instrument touchscreen within 12 minutes from the addition of specimen.

Materials provided:

- LumiraDx SARS-CoV-2 & Flu A/B test strips packed individually in sealed desiccant foil pouches.
- LumiraDx SARS-CoV-2 & Flu A/B Product Insert
- RFID (Radio frequency ID) Tag held inside the Test Strip carton
- Extraction Buffer Vials
- Dropper Lids
- Nasal swabs (provided only with product codes L019000201012, L019000201024, L019000201048)

Materials required but not provided with the Test Strip carton:

- LumiraDx Instrument
- LumiraDx SARS-CoV-2 & Flu A/B Quick Reference Instructions (available online at www.lumiradx.com)
- LumiraDx SARS-CoV-2 & Flu A/B Quality Controls (as required to meet local and organisational compliance)
- LumiraDx Connect if connectivity required (refer to LumiraDx Connect User Manual)
- Standard nasal swab collection equipment if using LumiraDx SARS-CoV-2 & Flu A/B kits which do not include swabs (L019000101012, L019000101024, L019000101048). Please refer to the Limitations section of this product insert for information on recommended swabs.

Warnings and precautions

- For *in vitro* diagnostic use only
- Do not open the test strip until ready for immediate use.
- Discard and do not use any damaged or dropped Test Strips or other materials.
- Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results.
- 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.
- Samples must be processed as indicated in the Sample 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 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 laboratory safety techniques should be followed at all times when working with SARS-CoV-2 and/or Influenza 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 regulations and procedures.
- For additional information on safety, handling, and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at lumiraDx.com.

Storing the Test Strips:

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

Handling the Test Strips:

When you are ready to perform a test, open the Test Strip carton, take out a Test Strip, and remove it from the foil pouch. Hold the Test Strip by gripping the blue label end with the label 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 & Flu A/B test strip:

- Anterior Nasal Swab Sample (NS)

The Test device contains:

- Mouse monoclonal antibodies
- Fluorescent particles
- Magnetic particles
- Buffer and stabilising 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 with the SARS-CoV-2 & Flu A/B test 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 the information needed to perform diagnostic tests. This only needs to be completed once for each Test Strip Lot. The Instrument will prompt to install the Lot Calibration File when inserting a new Test Strip Lot.

RFID strip code reader

Locate ((•)) symbol on Instrument.

Installation

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

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

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

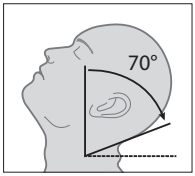
The LumiraDx SARS-CoV-2 & Flu A/B test results should be evaluated by a Healthcare Professional in the context of all available clinical and laboratory data.

Instructions for sample collection:

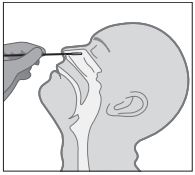
When collecting any type of sample, follow universal collection precautions and guidelines according to your organization. Users should be trained in appropriate sample collection and handling procedures. If swab packaging is damaged, do not use.

The steps that follow apply to an anterior nasal swab. Where provided, (Refer to Materials Provided Section for product codes which include swabs) please use the swab within the kit. Where a swab is not provided (Refer to Materials Not Provided Section for product codes which do not include swabs) within the kit please refer to the Limitations section of this Product Insert for information on recommended swabs to use with the LumiraDx SARS-CoV-2 & Flu A/B test.

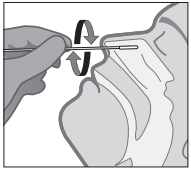
Sampling from an anterior nasal swab:



1. Tilt patient's head back 70°



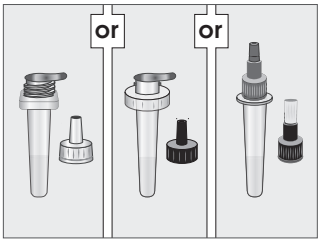
2. A swab sample is needed from both nostrils, and this is taken using the same swab. While gently rotating the swab, insert swab less than one inch into the first nostril until resistance is met at Turbinates. (Turbinates are the small structures inside the nose).



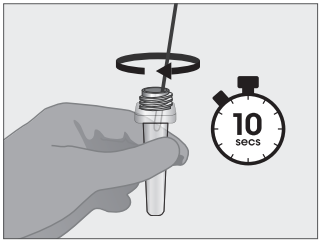
3. Rotate the swab at least 4 times against the nasal wall for 10-15 seconds. Remove and repeat this process by using the same swab into the second nostril. Then place the Swab into the Extraction Vial. See instructions for Sample Extraction.

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.

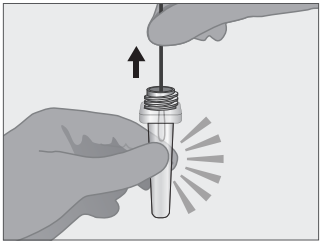
Instructions for sample extraction:



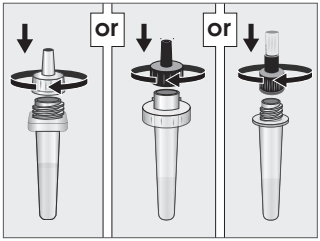
1. **Remove the seal or blue screw cap** from the top of the Extraction Vial containing the Extraction Buffer.



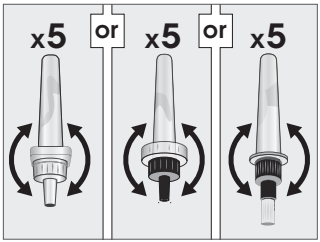
2. **Place and soak the Patient Swab** in the Extraction Buffer for 10 seconds and then stir well by rotating the swab against the side of the vial 5 times.



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 five hours when stored at room temperature. Extracted nasal swab samples may be frozen at -80°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 Guide 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. **Apply the extracted sample from the Extraction Vial** onto the Sample Application Area of the inserted Test Strip. To do this gently 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).**
2. **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.
3. **The result** will appear on the Instrument touchscreen within 12 minutes of applying the sample and starting the test. Positive or negative results will be displayed for each of **SARS-CoV-2, Flu A** and **Flu B** on the Instrument screen. (see Fig 1 and Fig 2).
4. **Dispose** of the swab, Extraction Vial and Test Strip in the appropriate biohazard waste.
5. **Disinfection** of the Instrument with LumiraDx approved materials is recommended if contamination is suspected and at least once per day when in use. A list of approved disinfecting materials 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.
6. **If you need to retest,** you will use a new Test Strip. Use the same extraction vial and repeat the test. The extracted sample must be used within five hours when stored at room temperature.. Extracted nasal swab samples may be frozen at -80°C and used up to 5 days after freezing.

Result interpretation:

The results will be displayed on the Instrument screen - **examples of result screen display:**

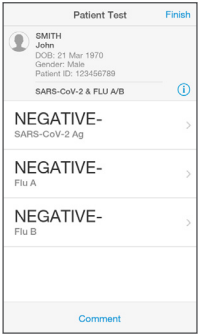


Fig 1: Negative result for SARS-CoV-2 Ag and Flu A and Flu B

Fig 2: Positive result for SARS-CoV-2 Ag, negative for Flu A and Flu B

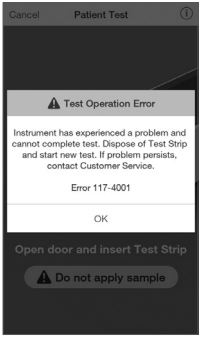
NOTE: A negative result should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. A negative result for Flu should be treated as presumptive for Influenza A and B and, if necessary, these results may be confirmed by an Influenza A and B molecular assay.

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.

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

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

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

External Quality Controls:

External liquid Quality Controls for LumiraDx SARS-CoV-2 & Flu A/B 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 operator. External Quality Control requirements should be established in accordance with local and organizational compliance. It is recommended that external control testing be performed with each new operator and before using a new lot or shipment of the LumiraDx SARS-CoV-2 & Flu A/B. Refer to the LumiraDx SARS-CoV-2 & Flu A/B Quality Controls pack insert available at lumiradx.com for detailed instructions.

LumiraDx SARS-CoV-2 & Flu A/B Quality Controls are purchased separately.

If the LumiraDx SARS-CoV-2 & Flu A/B Quality Controls do not perform as expected, repeat the QC Test and if the problems persist, do not report patient results and contact LumiraDx Customer Services

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 with LumiraDx approved materials if contamination is suspected and at least once per day when in use. 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. 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. Do not spray or pour solution 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, SARS-CoV-2, Influenza A and Influenza B. 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.
- Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
- Test results should be considered in the context of all available clinical and diagnostic information, including patient history and other test results.
- 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 or Influenza viral or bacterial infections.
- Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed.
- If the differentiation of specific 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.
- Extracted anterior nasal 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
- 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 RT-PCR.
- The contents of this kit are for qualitative detection of SARS-CoV-2 and Influenza antigens from nasal swab samples only.
- For information on swabs that have been validated for use with the LumiraDx SARS-CoV-2 & Flu A/B test please visit **lumiradx.com**.

Performance Characteristics

Clinical performance – Anterior Nasal Swab

The performance of the LumiraDx SARS-CoV-2 & Flu A/B test was established with anterior nares nasal swabs prospectively collected from individual subjects up to 12 days since symptom onset. For SARS-CoV-2, the samples were collected in the US between June and September 2020 during the SARS-CoV-2 pandemic. Influenza samples were collected in the US between January and March 2020, ahead of the SARS-CoV-2 pandemic. Samples were collected from sequentially enrolled subjects who presented with symptoms of Influenza A/B (159) or COVID-19 (188). For SARS-CoV-2, dual nasal swabs were simultaneously collected for testing with the LumiraDx test or the reference test (EUA authorized PCR method). For Influenza, dual nasal swabs were randomised and collected for testing with the LumiraDx test or the reference test (510K cleared PCR method). Swabs were collected and extracted into the LumiraDx Extraction Buffer. Samples were 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 reference test result. The performance of LumiraDx SARS-CoV-2 & Flu A/B test was compared to the results from nasal swabs collected into 3ml universal transport medium (UTM) and tested with the reference methods.

Patient demographics

Patient demographics (age) are available for the samples used in the study. The following table shows the number of positive subjects correctly identified by the LumiraDx device (LDx).

Assay	Age	Total N	Positive	Prevalence
SARS-CoV-2 (N=42 LDx Positive)	≤ 5 years	49	0	0.0%
	6 to 21 years	114	5	4.4%
	22 to 59 years	157	34	21.7%
	≥ 60 years	27	3	11.1%
Flu A (N=25 LDx Positive)	≤ 5 years	49	5	10.2%
	6 to 21 years	114	13	11.4%
	22 to 59 years	157	7	4.5%
	≥ 60 years	27	0	0.0%
Flu B (N=24 LDx Positive)	≤ 5 years	49	5	10.2%
	6 to 21 years	114	17	14.9%
	22 to 59 years	157	2	1.3%
	≥ 60 years	27	0	0.0%

Clinical performance

The following table shows the agreement between the LumiraDx SARS-CoV-2 & Flu A/B test and the Reference RT-PCR assay for Detection of **SARS-CoV-2**

	RT-PCR					95% Wilson Score CI		
		POS	NEG	Total	Measure	Estimate	LCI	UCI
LumiraDx SARS-CoV-2 & Flu A/B	POS	42	9	51	PPA	95.5%	84.9%	98.7%
	NEG	2	294	296	NPA	97.0%	94.5%	98.4%
	TOTAL	44	303	347	PPV	82.4%	69.7%	90.4%
					NPV	99.3%	97.6%	99.8%
					Prevalence	12.7%	9.6%	16.6%
					OPA (% Agreement)	96.8%	94.4%	98.2%

The following table shows the performance measures, and 95% confidence intervals, as calculated with the Wilson Score method for subsets of the results above. Reference method used to determine Ct was the Roche Cobas® 6800 SARS-CoV-2:

Grouping	N	PPA	95% CI
Ct < 33 (all)	44	95.5%	84.9-98.7
Ct < 30 (all)	40	100%	91.2-100
Ct < 25 (all)	25	100%	86.7-100

The following table shows the number of positive subjects correctly identified by the LumiraDx device vs RT-PCR across days since symptom onset:

Days Since Symptom Onset	Cumulative PCR Positive (+)	LumiraDx Positive (+)	Sensitivity (PPA)	LCI	UCI
0	3	3	100.0%	43.9%	100.0%
1	8	8	100.0%	67.6%	100.0%
2	19	19	100.0%	83.2%	100.0%
3	24	24	100.0%	86.2%	100.0%
4	32	31	96.9%	84.3%	99.4%
5	34	33	97.1%	85.1%	99.5%
6	37	36	97.3%	86.2%	99.5%
7	39	38	97.4%	86.8%	99.5%
8	40	38	95.0%	83.5%	98.6%
9	40	38	95.0%	83.5%	98.6%
10	41	39	95.1%	83.9%	98.7%
11	43	41	95.3%	84.5%	98.7%
12	44	42	95.5%	84.9%	98.7%

The following table shows the agreement between the LumiraDx SARS-CoV-2 & Flu A/B test and the Reference RT-PCR assay for Detection of **Influenza A**

	RT-PCR					95% Wilson Score CI		
		POS	NEG	Total	Measure	Estimate	LCI	UCI
LumiraDx SARS-CoV-2 & Flu A/B	POS	25	8	33	PPA	83.3%	66.4%	92.7%
	NEG	5	309	314	NPA	97.5%	95.1%	98.7%
	TOTAL	30	317	347	PPV	75.8%	59.0%	87.2%
					NPV	98.4%	96.3%	99.3%
					Prevalence	8.6%	6.1%	12.1%
					OPA (% Agreement)	96.3%	93.7%	97.8%

The following table show the agreement between the LumiraDx SARS-CoV-2 & Flu A/B test and Reference RT-PCR assay for Detection of **Influenza B**

	RT-PCR				95% Wilson Score CI		
		POS	NEG	Total	Measure	Estimate	LCI	UCI
LumiraDx SARS-CoV-2 & Flu A/B	POS	24	15	39	PPA	80.0%	62.7%	90.5%
	NEG	6	302	308	NPA	95.3%	92.3%	97.1%
	Total	30	317	347	PPV	61.5%	45.9%	75.1%
					NPV	98.1%	95.8%	99.1%
					Prevalence	8.6%	6.1%	12.1%
					OPA (% Agreement)	93.9%	90.9%	96.0%

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

Clinical performance 2 – Anterior Nasal Swab

The performance of the LumiraDx SARS-CoV-2 & Flu A/B test was further analysed for SARS-CoV-2 antigen with anterior nares nasal swabs prospectively collected from individual subjects and study samples combined to create a larger sample set. The samples were collected in the US and UK between June and September 2020 during the SARS-CoV-2 pandemic. Samples were collected from sequentially enrolled subjects. Dual nasal swabs were simultaneously collected for testing with the LumiraDx test or the reference test (RT- PCR method). Swabs were collected and extracted into the LumiraDx Extraction Buffer. Samples were 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 reference test result. The performance of the LumiraDx SARS-CoV-2 & Flu A/B test was compared to the results from nasal swabs collected into 3ml universal transport medium (UTM) and tested with the reference methods.

Patient demographics

Patient demographics (age) are available for the samples used in the study. The following table shows the number of positive subjects correctly identified by the LumiraDx device (LDx).

Assay	Age	Total N	Positive	Prevalence
SARS-CoV-2 (N=131 LDx Positive)	≤ 5 years	54	2	3.7%
	6 to 21 years	132	13	9.8%
	22 to 59 years	322	102	31.7%
	≥ 60 years	81	9	11.1%

The following table shows the agreement between the LumiraDx SARS-CoV-2 & Flu A/B test and the Reference RT-PCR assay for Detection of **SARS CoV-2**

	Grouping	PCR +ve	LDx	PPA	CI	PCP	LDX -ve	NPA	CI
DSSO	5	103	95	92.2%	85.4%-96.0%	246	244	99.2%	97.1%-99.8%
	6	116	107	92.2%	85.9%-95.9%	252	250	99.2%	97.2%-99.8%
	7	126	115	91.3%	85.0%-95.1%	271	268	98.9%	96.8%-99.6%
	10	134	120	89.6%	83.2%-93.7%	284	281	98.9%	96.9%-99.6%
	Ct < 33 (all)	122	-	88.5%	81.7%-93.0%				
	Ct < 30 (all)	110	-	91.8%	85.2%-95.6%				
	Ct < 25 (all)	64	-	96.9%	89.3%-99.1%				

DSSO = days since symptom onset.

Analytical performance

Limit of Detection – LoD (Analytical sensitivity)

Limit of Detection (LoD) studies determine the lowest detectable concentration of SARS-CoV-2, Flu A and/or Flu B at which at least 95% of all (true positive) replicates test positive. The LoD for the LumiraDx SARS-CoV-2 & Flu A/B test was established using limiting dilutions of gamma-irradiated SARS-CoV-2 (BEI Resources NR-52287), Influenza A H1N1 California 07/2009 (BEI Resources VR-1894)), Influenza A H3N2 Perth/16/09 (Zeptometrix 0810251CF), Influenza B Victoria/2/87 (Zeptometrix 0810517CF) and Influenza B Wisconsin/1/10 (Zeptometrix 0810241CF) viruses.

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.

The Influenza viruses are all live viruses and were supplied frozen at concentrations of 4.17 x10^5 (Flu A California/07/2009), 5 x 10^4 (Flu A H3N2 Hong Kong/6/68) 5 x 10^3 (Flu B Brisbane 60/08) and 3.89 x 10^4 (Flu B Wisconsin/1/10) $TCID_{50}$/mL respectively.

LoD Screening

An initial LoD screening study was performed using 5-fold serial dilutions of each virus made in pooled negative human nasal matrix starting at a test concentration of 10x the expected LoD 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.

LoD Range Finding

Using the selected concentration for each virus from LoD Screening, the LoD was further refined using a 2-fold dilution series of each virus made in pooled negative human nasal matrix. These dilutions were tested in triplicate. The lowest concentration at which all (3 out of 3) were positive was treated as the tentative LoD for the LumiraDx SARS-CoV-2 & Flu A/B test.

LoD Confirmation

The LoD of the LumiraDx SARS-CoV-2 & Flu A/B test for each virus was then confirmed by testing 20 replicates with concentrations at the tentative Limit of Detection. The final LoD of the LumiraDx SARS-CoV-2 & Flu A/B 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 specimens was confirmed as:

Virus Material	Starting Concentration	Estimated LoD	No. Positive/ Total	% Positive
SARS-CoV-2 USA-WA1/2020	2.8 x 10^5 $TCID_{50}$ /mL	80 $TCID_{50}$/mL	20/20	100
Flu A H1N1 California/07/2009	4.17 x10^5 $TCID_{50}$ /mL	200 $TCID_{50}$ /mL	20/20	100
Flu A H3N2 Hong Kong/6/68	5 x 10^4 $TCID_{50}$/mL	100 $TCID_{50}$ /mL	20/20	100
Flu B Brisbane 60/08	5 x 10^3 $TCID_{50}$/mL	100 $TCID_{50}$ /mL	20/20	100
Flu B Wisconsin/1/10	3.89 x 10^4 $TCID_{50}$ /mL	40 $TCID_{50}$ /mL	20/20	100

Cross-reactivity (analytical specificity) studies

Cross-reactivity of the LumiraDx SARS-CoV-2 & Flu A/B test was evaluated by testing a panel of related pathogens, high prevalence disease agents and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen and could potentially cross-react with the LumiraDx SARS-CoV-2 & Flu A/B test, including various microorganisms, viruses and negative matrix. Each organism and virus were tested in triplicate in the absence SARS-CoV-2, Flu A and Flu B virus. The final concentration of the organisms and viruses are documented in the Table below:

Microorganism	Source	Concentration tested	Cross Reactivity (Yes/No, replicates)		
			SARS-CoV-2	Flu A	Flu B
Human Coronavirus 229E	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Human Coronavirus OC43	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Human Coronavirus NL63	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Adenovirus Type 1	Zeptometrix ATCC	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Adenovirus Type 7	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Human Metapneumovirus	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Parainfluenza Type 1	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Parainfluenza Type 2	ATCC	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Parainfluenza Type 3	ATCC	1 x 105 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Parainfluenza Type 4a	ATCC	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Enterovirus	Zeptometrix	1.58 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Respiratory Syncytial Virus Type A	ATCC	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Respiratory Syncytial Virus Type B	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Rhinovirus Type 1A	ATCC	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Rhinovirus Type 2	ATCC	8.89 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Hemophilus influenzae	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Hemophilus parainfluenzae	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)

Microorganism	Source	Concentration tested	Cross Reactivity (Yes/No, replicates)		
			SARS-CoV-2	Flu A	Flu B
Streptococcus pneumoniae	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Streptococcus pyogenes	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Candida Albicans	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Pooled human nasal wash	LumiraDx	14% (v/v)	No (3/3)	No (3/3)	No (3/3)
Bordetella pertussis	Zeptometrix	1 x 10^8 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Mycoplasma pneumoniae	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Chlamydia pneumoniae	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Legionella pneumophila	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Cytomegalovirus	ATCC	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Epstein Barr Virus	Zeptometrix	1.4 x 10^5 cp/mL	No (3/3)	No (3/3)	No (3/3)
Escherichia coli	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Herpes Simplex Virus	ATCC	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Kingella kingae	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Klebsiella oxytoca	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Lactobacillus sp.	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Measles	Zeptometrix	1 x 10^5 pfu/mL	No (20/20)	No (19/20)	No (20/20)
Mumps	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Moraxella catarrhalis	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Neisseria elongata	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Nocardia asteroides	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Pseudomonas aeruginosa	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Serratia marcescens	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)

Microorganism	Source	Concentration tested	Cross Reactivity (Yes/No, replicates)		
			SARS-CoV-2	Flu A	Flu B
Staphylococcus aureus	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Staphylococcus epidermis	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Varicella-Zoster Virus	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
SARS-CoV-2 (WA1/2020)	Zeptometrix	7.55 x 10^5 $TCID_{50}$/mL	Yes (5/5)	No (5/5)	No (5/5)
Influenza A H1N1 (Denver/1/57)	Zeptometrix	1.5 x 10^7 $TCID_{50}$/mL	No (3/3)	Yes (3/3)	No (3/3)
Influenza A H3N2 (Hong Kong/8/68)	Zeptometrix	6.33 x 10^5 $TCID_{50}$/mL	No (5/5)	Yes (5/5)	No (5/5)
Influenza B (Victoria/2/87)	Zeptometrix	1 x 10^4.93 $TCID_{50}$/mL	No (4/4)	No (4/4)	Yes (4/4)
Lactobacillus casei	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Corynebacterium bovis	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Mycobacterium tuberculosis	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
MERS-CoV	Zeptometrix	4095 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Pneumocytis jiroveci	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)

To estimate the likelihood of cross-reactivity of the SARS-CoV-2 assay channel in the LumiraDx SARS-CoV-2 & Flu A/B test with related 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.

Due to the differences between the viral species and protein sequences, no cross-reactivity between the Influenza A and B channels of the LumiraDx SARS-CoV-2 & Flu A/B test would be expected with either Human Coronavirus HKU1 or SARS-Coronavirus No cross-reactivity was observed in these channels using SARS-CoV-2.

Microbial Interference Studies

Microbial interference in the LumiraDx SARS-CoV-2 & Flu A/B test was evaluated by testing a panel of related pathogens, high prevalence disease agents and normal or pathogenic flora to demonstrate that false negatives do not occur when SARS-CoV-2, Flu A or Flu B is present in a specimen with other microorganisms including various microorganisms, viruses, and negative matrix. Each organism and virus were tested in triplicate in the presence of heat inactivated SARS-CoV-2 (WA-1/2020 Zeptometrix 0810587CFHI), Flu A (A/California/07/09 Zeptometrix 0810165CF) and Flu B (B/Wisconsin/1/10 Zeptometrix 0810241CF) virus at 3 x LoD. The final concentration of the organisms and viruses are documented in the Table below.

Microorganism	Source	Concentration tested	Cross Reactivity (Yes/No, replicates)		
			SARS-CoV-2	Flu A	Flu B
Human Coronavirus 229E	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Human Coronavirus OC43	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Human Coronavirus NL63	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Adenovirus Type 1	Zeptometrix ATCC	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Adenovirus Type 7	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Human Metapneumovirus	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Parainfluenza Type 1	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Parainfluenza Type 2	ATCC	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)

Microorganism	Source	Concentration tested	Cross Reactivity (Yes/No, replicates)		
			SARS-CoV-2	Flu A	Flu B
Parainfluenza Type 3	ATCC	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Parainfluenza Type 4a	ATCC	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Enterovirus	Zeptometrix	1.58 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Respiratory Syncytial Virus Type A	ATCC	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Respiratory Syncytial Virus Type B	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Rhinovirus Type 1A	ATCC	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Rhinovirus Type 2	ATCC	8.89 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Hemophilus influenzae	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Hemophilus parainfluenzae	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Streptococcus pneumoniae	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Streptococcus pyogenes	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Candida Albicans	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Pooled human nasal wash	LumiraDx	14% (v/v)	No (3/3)	No (3/3)	No (3/3)
Bordetella pertussis	Zeptometrix	1 x 10^8 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Mycoplasma pneumoniae	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Chlamydia pneumoniae	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Legionella pneumophila	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Cytomegalovirus	ATCC	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Epstein Barr Virus	Zeptometrix	1.4 x 10^5 cp/mL	No (3/3)	No (3/3)	No (3/3)
Escherichia coli	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Herpes Simplex Virus	ATCC	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)

Microorganism	Source	Concentration tested	Cross Reactivity (Yes/No, replicates)		
			SARS-CoV-2	Flu A	Flu B
Kingella kingae	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Klebsiella oxytoca	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Lactobacillus sp.	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Measles	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Mumps	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Moraxella catarrhalis	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Neisseria elongata	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Nocardia asteroides	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Pseudomonas aeruginosa	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Serratia marcescens	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Staphylococcus aureus	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Staphylococcus epidermis	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Varicella-Zoster Virus	Zeptometrix	1 x 10^5 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Lactobacillus casei	ATCC	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Corynebacterium bovis	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
Mycobacterium tuberculosis	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)
MERS-CoV	Zeptometrix	4095 pfu/mL	No (3/3)	No (3/3)	No (3/3)
Pneumocytis jiroveci	Zeptometrix	1 x 10^6 cfu/mL	No (3/3)	No (3/3)	No (3/3)

Competitive Interference (Co-infection)

A study was performed to confirm there is no Competitive Interference between the test channels on the LumiraDx SARS-CoV-2 & Flu A/B test. This was completed by testing SARS-CoV-2 at 2-3 x LOD level in the presence of high levels of Influenza A or B and Influenza A or B at 2-3x LOD in the presence of high levels of SARS-CoV-2. Each condition was tested in triplicate. In this testing there does not appear to be any competitive interference.

Competitive Virus	Strain	Concentration	Target Virus	Concentration	Target Percent Positivity
Influenza A H1N1	A/Brisbane /59/07	1 x 10^5 $TCID_{50}$/mL	SARS-CoV-2	2-3x LOD	100%
Influenza A H3N2	A/Hong Kong/8/68	1 x 10^5 $TCID_{50}$/mL	SARS-CoV-2	2-3x LOD	100%
Influenza B	B/Lee/40	1 x 10^5 $TCID_{50}$/mL	SARS-CoV-2	2-3x LOD	100%
SARS-CoV-2	WA1/2020	1 x 10^5 $TCID_{50}$/mL	Influenza A H1N1	2-3x LOD	100%
SARS-CoV-2	WA1/2020	1 x 10^5 $TCID_{50}$/mL	Influenza A H3N2	2-3x LOD	100%
SARS-CoV-2	WA1/2020	1 x 10^5 $TCID_{50}$/mL	Influenza B	2-3x LOD	100%

Endogenous/Exogenous Interference Substances Studies:

A study was performed to demonstrate that twenty six (26) 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 either SARS-CoV-2, Influenza A or Influenza B in the LumiraDx SARS-CoV-2 & Flu A/B test. Each substance was tested in triplicate in the absence or presence of SARS-CoV-2 (Zeptometrix 0810587CFHI), Influenza A (Hong Kong H3N2 virus lysate Zeptometrix Lot 319908) and Influenza B (Florida 02/06 virus lysate Zeptometrix Lot 309769 or Victoria 2/87, Zeptometrix Lot 317294) at 3x LOD.

Interfering Substance	Test Concentration	Interference (Yes/No), replicates		
		SARS-CoV-2	Flu A	Flu B
Whole Blood	5% w/v	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Mucin	500 mg/dL	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Chloraseptic / Sore Throat Phenol Spray (Menthol/ Benzocaine)	150 mg/dL	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Naso GEL (NeilMed)	5% v/v	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
CVS Nasal Drops (Phenylephrine)	15% v/v	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Afrin (Oxymetazoline)	15% v/v	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
CVS Nasal Spray (Cromolyn)	15% v/v	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Zicam	5% v/v	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Biotin	0.35 mg/dL	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Homeopathic (Alkalol)	10% v/v	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Tobramycin	0.4 mg/dL	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Mupirocin	0.15 mg/dL	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Fluticasone Propionate	0.000126 mg/dL	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Dextromethorphan	0.00156 mg/dL	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Tamiflu	500 mg/dL	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Acetylsalicylic acid	2.04 mg/dL	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)

Interfering Substance	Test Concentration	Interference (Yes/No), replicates		
		SARS-CoV-2	Flu A	Flu B
Beclomethasone	16 µg/mL	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Budesonide	6.3 x 10^{-4} mg/dL	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Dexamethasone	1.2 mg/dL	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Diphenhydramine	7.74 x 10^{-2} mg/dL	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Flunisolide	68.75 µg/mL	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Histaminum hydrochloricum	1%	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Luffa opperculata	5 % v/v	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Mometasone	2.5 µg/mL	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Triamcinolone	5.5 µg/mL	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)
Zanamivir	1 mg/mL	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)	No (3/3 Neg, 3/3 Pos)

Inclusivity (analytical reactivity):

Influenza A and B

TThe Analytical Reactivity of the LumiraDx SARS-CoV-2 & Flu A/B test was evaluated using a total of twenty one (21) strains of human influenza virus comprised of twelve (12) Influenza A and nine (9) Influenza B viruses (outwith those used in LoD testing in Section J1). Serial ten-fold dilutions for each virus with starting concentrations ranging from 5 x 10^3 to 5 x 10^4 $TCID_{50}$/mL were prepared in negative pooled nasal matrix. Five replicates of each dilution were tested. The highest dilution where 100% replicates were positive was chosen to make a series of 2-fold dilutions in negative pooled nasal matrix. Five replicates at each dilution were tested. The highest dilution that gave five out of five positive results was reported. Testing was completed across multiple lots of LumiraDx SARS-CoV-2 & Flu A/B test Strips.

Viral Strain	Viral Type	Sub-type	Minimal detectable level ($TCID_{50}$/mL) or $CEID_{50}$/mL)
A Brisbane 59/07	A	H1N1	50
A Denver 1/57	A	H1N1	125
A/New Jersey/8/76	A	H1N1	500
A/California 07/09	A	2009 H1N1	5000
A/New Caledonia 20/1999	A	H1N1	125
A/Puerto Rico 8/34	A	H1N1	62.5
A/Aichi/2/68	A	H3N2	500
A/HongKong 8/68	A	H3N2	250
A/Perth 16/09	A	H3N2	2.5
A/Wisconsin 67/05	A	H3N2	2500
A/Switzerland 9715293/2013	A	H3N2	50000
A/Swine 1976/31	A	H1N1	5000
B/Florida 78/2015	B	N/A	5000
B/GL/1739/54	B	N/A	25000
B/Taiwan/2/62	B	N/A	62.5
B/Brisbane 60/08	B	N/A	12.5
B/Lee/40	B	N/A	12500
B/Hong Kong/5/72	B	N/A	50000
B Maryland/1/59	B	N/A	5000
B/Victoria/2/87	B	N/A	50
B/Allen/45	B	N/A	9493

SARS-CoV-2

LumiraDx has been monitoring the impact of new and emerging SARS-CoV-2 viral mutations and variants on the performance of the LumiraDx SARS-CoV-2 & Flu A/B Test. Results of the latest testing can be found on our website **lumiradx.com**

CDC Panel Assessment

The analytical reactivity if the LumiraDx SARS-CoV-2 & Flu A/B test was verified against the Centers for Disease Control and Prevention (CDC) human influenza panel 2021 (VP2021 lot# 210601) to ensure adequate performance against currently circulating strains of influenza. Testing was performed as per CDC instructions with each viral stock being prepared in a 5-fold dilution series using LumiraDx Extraction buffer. 50µL of each diluted viral stock was spiked onto a swab and extracted as per the LumiraDx SARS-CoV-2 & Flu A/B Product Insert using the method appropriate for nasal swab specimens. Each extracted viral stock dilution was tested on the LumiraDx SARS-CoV-2 & Flu A/B test strip in replicates of 5 until two consecutive 5-fold dilutions showed non-reactivity (negative results for all 5 replicates tested). The last dilution that produces positive results in at least one of the five replicates is considered to be the minimum reactive concentration.

Results of the testing showed detection of all strains using the LumiraDx SARS-CoV-2 & Flu A/B test. The minimum reactive concentrations of each viral stock is shown below:

Influenza Virus (Type/ Subtype)	**Virus Strain Name**	**Stock Concen-tration (ID_{50}/mL)**	**Virus Serial Dilution Concentration (ID_{50}/mL) and Number of Positive Results at each Dilution**							
Influenza A (H1N1 pdm09)	A/CHRIST CHURCH/ 16/2010	1.58×10^9	3.17×10^8	6.34×10^7	1.27×10^7	2.54×10^6	5.07×10^5	1.01×10^5	2.03×10^4	4.06×10^3
			5/5	5/5	5/5	5/5	3/5	0/5	0/5	N/A
Influenza A (H1N1 pdm09)	A/VICT ORIA/ 2570/2019	1.58×10^8	3.17×10^7	6.34×10^6	1.27×10^6	2.54×10^5	5.07×10^4	1.01×10^4	2.03×10^3	4.06×10^2
			5/5	5/5	5/5	5/5	2/5	0/5	0/5	N/A
Influenza A (H3N2)	A/PERTH/ 16/2009	2×10^8	4×10^7	8×10^6	1.6×10^6	3.2×10^5	6.4×10^4	1.28×10^4	2.56×10^3	5.12×10^2
			5/5	5/5	5/5	5/5	4/5	0/5	0/5	N/A
Influenza A (H3N2)	A/TASM NIA/ 503/2020	3.16×10^8	6.32×10^7	1.26×10^7	2.53×10^6	5.06×10^5	1.01×10^5	2.02×10^4	4.05×10^3	8.10×10^2
			5/5	5/5	5/5	5/5	5/5	0/5	0/5	N/A
Influenza B (Victoria Lineage)	B/MICHI GAN/ 09/2011	7.94×10^6	1.59×10^6	3.18×10^5	6.35×10^4	1.27×10^4	2.54×10^3	5.08×10^2	1.02×10^2	2.03×10^1
			5/5	5/5	5/5	4/5	2/5	0/5	0/5	N/A

Influenza Virus (Type/ Subtype)	Virus Strain Name	Stock Concen-tration (ID_{50}/mL)	Virus Serial Dilution Concentration (ID_{50}/mL) and Number of Positive Results at each Dilution							
Influenza B (Victoria Lineage)	B/WASH INGTON/ 02/2019	2×10^9	4×10^8	8×10^7	1.6×10^7	$3.2 \times 1\ 0^6$	6.4×10^5	1.28×10^5	2.56×10^4	5.12×10^3
			5/5	5/5	5/5	5/5	5/5	1/5	0/5	0/5
Influenza B (Yama gata Lineage)	B/TEXAS/ 81/2016	1.26×10^8	2.52×10^7	5.04×10^6	1.01×10^6	2.01×10^5	4.03×10^4	8.06×10^3	1.61×10^3	3.22×10^2
			5/5	5/5	5/5	5/5	4/5	0/5	0/5	N/A
Influenza B (Yama gata Lineage)	B/PHUKET/ 3073/2013	7.94×10^9	1.59×10^9	3.18×10^8	6.35×10^7	1.27×10^7	2.54×10^6	5.08×10^5	1.02×10^5	2.03×10^4
			5/5	5/5	5/5	5/5	3/5	0/5	0/5	N/A

High Dose 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 & Flu A/B test suffers from any high dose hook effect, increasing concentrations of SARS-CoV-2 (Zeptometrix Heat Inactivated WA1/2020), Influenza A (A/California/07/09 and A/Hong Kong/8/68) or Influenza B (B/Victoria/2/87) were tested from near LOD up to 0.5x stock concentration as provided by the supplier. 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, Influenza A and Influenza B. At each dilution, 50µL samples were added to swabs and the swabs processed for testing on the LumiraDx SARS-CoV-2 & Flu A/B test as per the Package Insert using the procedure appropriate for patient nasal swab specimens. Samples were tested in replicates of 5. Testing was completed using one lot of LumiraDx SARS-CoV-2 & Flu A/B test strips.

No impact on test performance or high dose hook effect was observed in any of the test channels on the LumiraDx SARS-CoV-2 & Flu A/B test up to the concentrations detailed in the table below:

Virus tested for Hook Effect	Concentration ($TCID_{50}$/mL)
SARS-CoV-2	7.55×10^5
Influenza A H1N1	2.08×10^5
Influenza A H3N2	6.33×10^5
Influenza B	8.49×10^4

Point of care use

Point of care use was assessed previously for the LumiraDx SARS-CoV-2 Ag test. 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.

In addition, a contrived testing study was completed with untrained intended use operators at point of care testing sites to demonstrate usability using contrived specimens at <2 x LOD of the SARS-CoV-2 & Flu A/B Test. The study protocol included 2 point of care sites and 6 untrained intended use operators who tested samples positive for SARS-CoV-2, or Flu A or Flu B, near to the LOD, plus negative specimens in a blinded manner.

References:

1. World Health Organisation **who.int**
2. Centers for Disease Control and Prevention **cdc.gov**
3. Taubenberger JK, Morens DM. The pathology of influenza virus infections. *Annu Rev Pathol.* 2008;3:499-522. doi:10.1146/annurev.pathmechdis.3.121806.154316

Symbols glossary

Symbol	Meaning
	Temperature limitation
	Manufacturer
IVD	*In Vitro* Diagnostic Medical Device
REF	Catalogue Number
LOT	Batch code/Lot Number
	Use-by Date – indicates the date after which the unopened IVD/Quality Control Material cannot be used
	Refer to Instructions for Use
	Do Not Re-use
	For near patient testing
UK CA	UK conformity assessed under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002
	Importer
CE	"CE Mark ". This product fulfils the requirements of the European Directive 98/79/EC on *in vitro* diagnostic medical devices.
	Indicates the presence of the Radio Frequency Identification (RFID) reader/ tag.
	Total number of IVD tests that can be performed with the IVD medical device.
UDI	Indicates a carrier that contains unique device identifier information.
EC REP	Indicates the authorized representative in the European Community/ European Union.
STERILE EO	Indicates a *medical device* that has been sterilized using ethylene oxide
	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

LumiraDx customer services:
For product inquiries and technical support please contact LumiraDx Customer Services by email: **customerservices@lumiradx.com** or **Lumiradx.com**

For return policy

If there is a problem with the **LumiraDx SARS-CoV-2 & Flu A/B 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@lumiradx.com**

Limited warranty

LumiraDx SARS-CoV-2 & Flu A/B 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 & Flu A/B 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:

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

Test Strips:

LumiraDx UK Ltd
Dumyat Business Park
Alloa FK10 2PB, UK

Company number: 09206123

CE UKCA

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

Swabs:

Puritan Medical Products
31 School St.
P.O. Box 149
Guilford,
ME 04443-0149

CE 02076

EC REP Emergo Europe B.V., Prinsessegracht 20, The Hague, 2514 AP, The Netherlands

Zhejiang Gongdong Medical Technology Co., Ltd.
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