LUCIRA™

COVID-19 & Flu Test

Nucleic Acid Amplification Test (NAAT)

LUCIRA™ HEALTH

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Lucira™ COVID-19 & Flu Test
Instructions for Use

For *in vitro* Diagnostic Use Only

For Use with Self-collected Nasal Swab Specimens in individuals aged 14 and older or Nasal Swab Specimens collected by an adult in individuals ≥2 years

Intended Use

The Lucira COVID-19 & Flu Test is a single use real-time RT-LAMP test kit intended for self testing at home for the simultaneous rapid qualitative detection and differentiation of RNA from SARS-CoV-2, Influenza A and Influenza B virus from self-collected nasal swab samples in individuals 14 years and older (self- collected) or individuals ≥2 years (collected by an adult) with symptoms of respiratory viral infection consistent with COVID-19, Influenza A and/or Influenza B. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

This test is also intended for use at the Point of Care (POC) for individuals with symptoms of respiratory viral infection consistent with COVID-19, Influenza A and/or Influenza B with specimens collected by trained personnel. The Lucira COVID-19 & Flu 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 SARS-CoV-2, Influenza A or Influenza B RNA is generally detectable in nasal swab samples during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2, Influenza A or Influenza B RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Persons who test positive with the Lucira COVID-19 & Flu Test should seek follow up care with their physician, or healthcare provider, as additional testing and public health reporting may be necessary.

Negative results do not preclude infection from SARS-CoV-2, Influenza A, and/or Influenza B and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Summary and Explanation of the Test

The Lucira COVID-19 & Flu Test is a rapid, instrument-free, single-use molecular diagnostic test for the qualitative detection of SARS-CoV-2, Influenza A, and Influenza B RNA from nasal swab samples in individuals with known or suspected COVID-19 or flu. The test contains all the components required to perform testing.

Principles of the Procedures

The Lucira COVID-19 & Flu Test utilizes RT-LAMP technology to detect RNA of SARS-CoV-2, Influenza A, and Influenza B. This technology can create a signal from a few copies of RNA in less than 30 minutes. The RT-LAMP amplification reaction occurs in two phases, a non-cyclic phase followed by a cyclic phase. During the non-cyclic phase, reverse transcriptase, with RNase H activity, converts the RNA target into cDNA. A DNA polymerase with strand displacement activity then amplifies the cDNA. A successful amplification reaction creates a pH change and subsequently a color change of the halochromic agents within the reaction mixture.

The Sample Vial contains an elution buffer that allows the swab contents to be eluted and lysed at room temperature, releasing viral and human RNA for downstream detection. Upon engagement of the Sample Vial and Test Unit, this eluant enters a fluidic module contained within the Test Unit that has several individual reaction chambers. The eluant resolubilizes lyophilized reagents contained within these chambers, which are needed to perform the RT-LAMP reaction. An internal electronic heating element detects this chamber filling and automatically turns on, initiating amplification within the reaction chambers. The reactions are confined within the fluidic unit and no other part of the Test Unit has contact with the sample during amplification.

The Test Unit contains two chambers that target SARS-CoV-2 RNA, two chambers that target Flu A, two chambers that target Flu B, and one chamber for a control (TIC). For SARS-CoV-2, the test targets the N gene and the Orf7b/8 gene. For Influenza A, the test targets one region of Segment 5, two non-overlapping regions of Segment 7, and one region of Segment 8. For Influenza B, the test targets one region of Segment 5 and one region of Segment 8.

The color change of the reaction mixture is detected in real time using optical and electronic elements contained within the Test Unit. An on-board microprocessor analyzes the color change data to detect the presence of amplification, and hence the target RNA, in each chamber. A diagnostic algorithm, included in the device firmware, is then used to determine patient infectivity status and the results are shown via LED indicators. Results for the test are displayed as either positive, negative, or invalid. A positive result may show in as few as 11 minutes; a negative or invalid result will display in 30 minutes. The result display persists for a minimum of 8 hours and a maximum of 12 hours after the test has finished running.

PRECAUTIONS - GENERAL

- For *in vitro* diagnostic use.
- This home test has been authorized by Health Canada under an Interim Order Authorization.
- This home test has been authorized only for the testing of nasal swabs for detection of nucleic acid from SARS-CoV-2, Influenza A, and Influenza B, not for any other viruses or pathogens.
- Leave test components sealed in foil pouch until just before use.
- Proper sample collection and sample handling are essential for correct results.
- Do not touch swab tip when handling swab sample.
- Do not use any components with visible damage.
- Use the product only as specified, without modification, or the protection supplied by the product can be compromised.
- Do not use components after their expiration date.
- Choose a level location to do this test where you can let the test sit undisturbed (out of reach of pets, pests, or children) for 30 minutes.
- The device may be hot to touch after the test is done.
- Do not place the test near devices or appliances that may cause interference while the test is running.
- All kit components are single use items. Do not use with multiple specimens.
- Dispose of components and patient samples according to all local regulations.
- At low frequency, clinical samples contain inhibitors that may generate invalid results.
- Performance characteristics of this test have been established with specimen types listed in the Intended Use section only. The performance with other specimen types or samples has not been validated.

SECTION A - Reagents and Materials

Lucira™ COVID-19 & Flu Test contents:

- Package Insert
- Nasal Swab: one sterile flocked nasal swab in a peel-pouch;
- Sample Vial: a single-use, disposable vial containing an elution buffer to release and lyse virions from a nasal swab sample;
- Test Unit: a single-use, disposable unit with lyophilized reagents for multiplexed amplification and electronic readout for detection of SARS-CoV-2, Flu A, and Flu B RNA;
- Batteries: two AA batteries for the Test Unit; and
- Plastic disposal bag to dispose of the test after use.

NOTE: For optimal performance, use the swabs provided in the test. Other swabs are not suitable for use with this test.

STORAGE AND HANDLING

- Tests must always be stored at temperature between 15-30°C / 59-86°F.
- Tests must be stored at ambient humidity 10%-80%.
- IP21: The Test Unit has an enclosure protection rating of IP21. This means the Test Unit has protection from the insertion of a finger or solid objects greater than 1/2" (12.5mm) in diameter. This also means the Test Unit has protection against vertically falling drops of water or condensation.
- Do not reuse test components.
- Do not remove the Test Unit from the foil pouch until immediately before use.

Section B – Directions for running the Lucira COVID-19 & Flu Test

- **Choose a location to do this test where it can sit UNDISTURBED for 30 minutes.**
- **Please read all instructions carefully before you begin.**
- **Do not insert batteries into test unit until ready to perform test.**
- **Keep test box to create a personal verified digital record of your test result.**
- Make sure your test kit contains: 2 AA batteries, test unit (pouch 1), sample vial (pouch 2), swab (labeled 3), and plastic disposal bag.
- Wash and dry hands.

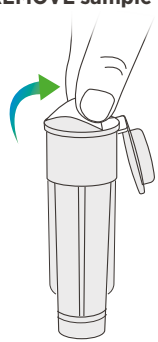
1. Set Up Your Test

- When ready to begin test, open test unit pouch 1.

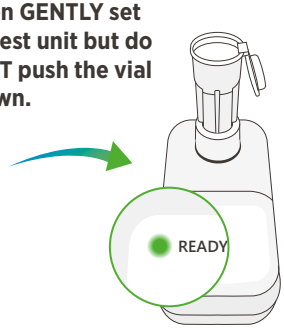
Open battery door and insert batteries. Check that **Ready light** is on.

- Open sample vial pouch 2.

REMOVE sample vial seal



then GENTLY set in test unit but do NOT push the vial down.



Do not open swab until ready to use.

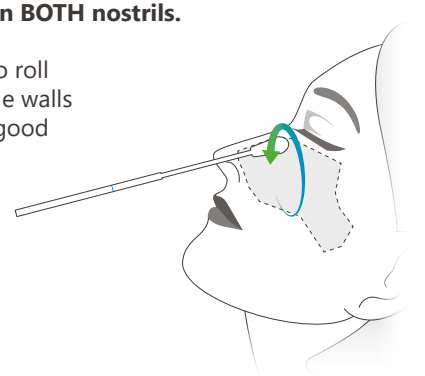
2. Swab Both Nostrils

For this test to work properly, it is important you swab BOTH nostrils.

- Remove swab and hold with handle end. Do not set swab down.
- Tilt head back and **gently insert swab tip until it is fully inside your/patient nostril** and you meet resistance.
- Once swab tip is fully inside nostril, **roll the swab 5 times around the inside walls of your nostril. The swab should be touching the walls of the nostril as you rotate.**
- **Repeat swab step in other nostril.**

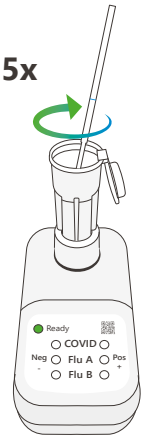
Rotate 5x in BOTH nostrils.

Make sure to roll around inside walls to collect a good sample.



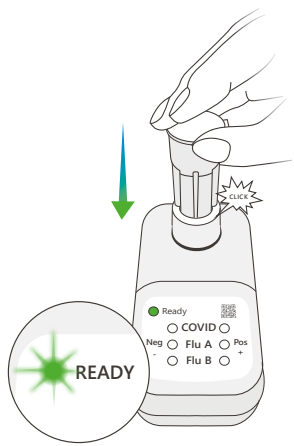
Adults must swab children ages 2-13.

3. Stir Swab and Run Test



- Insert swab into the sample vial until it **touches the bottom.**
- Mix sample by **stirring around the sample vial 15 times.**
- Discard swab.

- Snap cap closed and press vial down into test unit until it clicks.
- Ready light will start **blinking** when test is running.



If Ready light is not blinking within 5 seconds, use palm of your hand to press down more firmly to start test.

Do not move test unit once the test has started running.

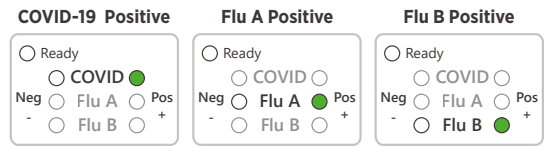
Wait 30 minutes.

4. Read and Report Result

- Ready light will continue blinking while the test is running.
- Positive results may display before the test is done running.
- Ready light will turn off and all results for COVID-19, Flu A, and Flu B will display in 30 minutes when test is done.

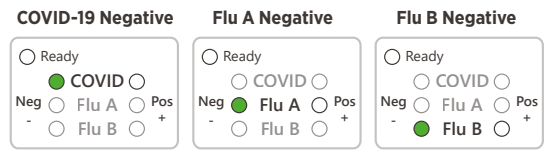
POSITIVE Results

Positive results light up on the right



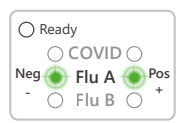
NEGATIVE Results

Negative results light up on the left



INVALID Results

Positive and Negative lights flash if result is Invalid



Invalid results may occur for one, two or all three viruses. Positive or negative results for other viruses are still valid if one or two viruses are invalid.

Share your results with your healthcare provider. If you receive any invalid results, retest with a new test, consult with your healthcare provider or contact Lucira at 1-888-LUCIRA-4 (582-4724). Contact Lucira if your result is invalid after retesting.

LUCI PASS is a verified digital record of this test result.
To get your personal LUCI PASS, after taking this test:
1) Use your smartphone camera app to scan the QR code on the top of the test unit OR on the sticker
2) Tap the notification that appears on the screen to go to **lucipass.com**
3) Follow the easy step-by-step instructions

⊕ If the test is POSITIVE

It is very likely you have COVID-19 (if you tested positive for COVID-19) or flu (if you tested positive for Flu A or Flu B) and it is important to be under the care of a healthcare provider. It is likely you will be asked to isolate yourself at home to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive). Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.

⊖ If you test NEGATIVE

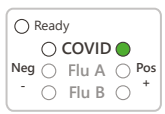
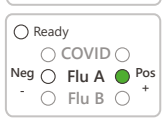
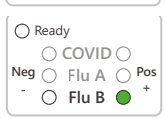
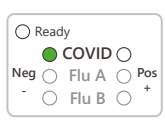
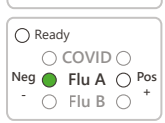
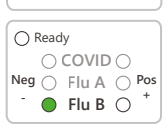
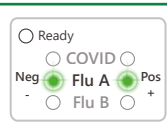
A negative result means the virus that causes COVID-19 (if you test negative for COVID-19) or flu (if you test negative for Flu A & Flu B) was not found in your sample. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19 or flu. This means you could possibly still have COVID-19 or flu even though the test is negative. If this is the case, your healthcare provider will consider the test result with all other aspects of your history such as symptoms and possible exposures to decide how to care for you. It is important you work with your healthcare provider to help you understand the next steps you should take.

5. Dispose of Test

After test is completed, remove the batteries, place the test unit in plastic disposal bag, and dispose of all materials in accordance with local regulations.

Section C - Test Unit Display Result

When the test is complete, the results are clearly displayed on the Test Unit.

Display	Interpretation of Results and Follow-up Actions
	COVID-19 Positive SARS-CoV-2 Viral RNA detected
	Flu A Positive Flu A Viral RNA detected
	Flu B Positive Flu B Viral RNA detected
	COVID-19 Negative SARS-CoV-2 Viral RNA not detected
	Flu A Negative Flu A Viral RNA not detected
	Flu B Negative Flu B Viral RNA not detected
	Positive and Negative lights flashing Test should be repeated

Section D - Quality Control Testing for Point of Care Settings

The Lucira COVID-19 & Flu Test is a single-use test and does not require external run controls (ERCs).

PERFORMANCE CHARACTERISTICS

1) Limit of Detection (LoD) - Analytical Sensitivity

The limit of detection was determined for 5 human derived viral isolates individually (referred to as anchor strains):

1. Influenza A H3N2: A/HongKong/4801/2014
2. Influenza A H1N1pdm09: A/Michigan/45/2015
3. Influenza B, Yamagata Lineage: B/Phuket/3073/2013
4. Influenza B, Victoria Lineage: B/Colorado/6/2017
5. SARS-CoV-2: Heat Inactivated 2019-nCoV/USA-WA1/2020

Each virus was serially diluted into Natural Nasal Swab Matrix (NNSM), pipetted onto a fresh, unused nasal swab, and run on two device lots. NNSM was prepared by pooling negative patient specimens in viral transport media, previously tested negative for SARS-CoV-2, Influenza A, and Influenza B. The preliminary LoD for the device was determined by testing at least three (3) target concentrations at 2-fold dilutions on each lot of devices. For each lot, each concentration was tested in replicates of seven (7) devices by three (3) unique operators, for a total of 21 replicates per concentration. Additionally, each operator ran two (2) Non-Template Controls (NTC) as negative controls immediately after each target concentration. The LoD for each lot was separately determined as the lowest concentration that yielded greater than 95% positive results. At least one of the concentrations run had < 95% of the devices be positive for each virus. The preliminary LoD for the device was defined as the highest LoD of the two lots.

The LoD was confirmed by testing 20 replicates at the preliminary LoD concentration on a single lot for each target. Two (2) additional operators, who were not involved in determining the preliminary LoD, will perform the confirmation testing by running ten (10) devices from one lot with each virus diluted in NNSM and spiked on swabs at the determined preliminary LoD concentration. Each virus had ≥ 19/20 replicates are positive, confirming the LoD for each virus. Detailed results are shown in Table 1 through 5 and summarized in Table 6 below.

Table 1. LoD Determination Results – SARS-CoV-2

Genome equivalents / mL VTM*	Genome equivalents / swab	Positive/Total Valid			Percent Positive		
SARS-CoV-2: Heat Inactivated 2019-nCoV/USA-WA1/2020		Preliminary Lot 1	Preliminary Lot 2	**Confirmatory**	Preliminary Lot 1	Preliminary Lot 2	**Confirmatory**
727	2180	21/21	21/21	--	100%	100%	--
363	**1090**	**21/21**	**20/21**	**20/20**	**100%**	**95%**	**100%**
181	544	21/21	19/21	--	100%	90%	--
91	272	15/21	14/21	--	71%	67%	--

* Since most tests utilize viral transfer media (VTM) as a matrix to elute the swab, the concentrations of genome equivalents per swab were also converted to corresponding concentrations of genome equivalents per mL of VTM (assuming 100% elution of a swab into 3 mL of VTM). For example, the concentration of 1260 genome equivalents (GE) per swab corresponds to 420 copies per mL of VTM.

Table 2. LoD Determination Results – Influenza A H1N1pdm09

Genome equivalents /mL VTM*	Genome equivalents /swab	Positive/Total Valid			Percent Positive		
Influenza A H1N1pdm09: A/Michigan/45/2015		Preliminary Lot 1	Preliminary Lot 2	**Confirmatory**	Preliminary Lot 1	Preliminary Lot 2	**Confirmatory**
2500	7500	21/21	21/21	--	100.00%	100.00%	--
1250	**3750**	**21/21**	**21/21**	**20/20**	**100.00%**	**100.00%**	**100%**
627	1880	19/21	19/21	--	90%	90%	--
313	938	13/21	15/21	--	62%	71%	--

Table 3. LoD Determination Results – Influenza A H3N2

Genome equivalents /mL VTM*	Genome equivalents /swab	Positive/Total Valid			Percent Positive		
Influenza A H3N2 A/HongKong/4801/2014		Preliminary Lot 1	Preliminary Lot 2	**Confirmatory**	Preliminary Lot 1	Preliminary Lot 2	**Confirmatory**
1680	5040	21/21	21/21	--	100%	100%	--
840	2520	21/21	21/21	--	100%	100%	--
420	**1260**	**21/21**	**20/21**	**19/20**	**100%**	**95%**	**95%**
210	630	18/21	18/21	--	86%	86%	--

Table 4. LoD Determination Results – Influenza B, Victoria Lineage

Genome equivalents /mL VTM*	Genome equivalents /swab	Positive/Total Valid			Percent Positive		
Influenza B, Victoria Lineage: B/Colorado/6/2017		Preliminary Lot 1	Preliminary Lot 2	**Confirmatory**	Preliminary Lot 1	Preliminary Lot 2	**Confirmatory**
5767	17300	21/21	21/21	--	100%	100%	--
2890	8670	21/21	21/21	--	100%	100%	--
1443	**4330**	**20/21**	21/21	**20/20**	**95%**	100%	**100%**
723	2170	13/21	**20/21**	--	62%	**95%**	--

Table 5. LoD Determination Results – Influenza B, Yamagata Lineage

Genome equivalents /mL VTM*	Genome equivalents /swab	Positive/Total Valid			Percent Positive		
Influenza B, Yamagata Lineage: B/Phuket/3073/2013		Preliminary Lot 1	Preliminary Lot 2	**Confirmatory**	Preliminary Lot 1	Preliminary Lot 2	**Confirmatory**
1690	**5070**	**20/21**	21/21	20/20	**95%**	100%	100%
847	2540	14/21	**20/21**	--	67%	**95%**	--
423	1270	15/21	18/21	--	71%	86%	--
211	634	13/21	16/21	--	62%	76%	--

Table 6. LoD Summary

Assay and Subtype or Lineage	Target	Limit of Detection (GE/swab)	Limit of Detection (GE / mL VTM equivalents)
COVID-19	2019-nCoV/USA-WA1/2020	1090	363
Flu A, H1N1pdm09	A/Michigan/45/2015	3750	1250
Flu A, H3N2	A/Hong Kong/4801/2014	1260	420
Flu B, Victoria Lineage	B/Colorado/6/2017	4330	1440
Flu B, Yamagata Lineage	B/Phuket/3073/2013	5070	1690

Co-spike LoD Equivalency Study

To demonstrate that a co-spike of 3 viral targets does not impact the limit of detection, a confirmatory LoD study at the established LoD of 1X LoD was performed. All three targets were diluted in NNSM to a concentration of 3X LoD and then pooled together to form a co-spike at 1X LoD in NNSM. The NNSM containing all three targets at 1X LoD was then pipetted onto a fresh, unused nasal swab and ran per the instructions for use. The results demonstrated that ≥ 95% of replicates were positive at 1X LoD, indicating that the LoD is confirmed in a triple co-spike and a co-spike of all three targets is acceptable to use for additional studies. The results are summarized below.

Table 7. Co-spike LoD Confirmation

Cospike	Target 1	Target 2	Target 3	Flu A POS/ Total Valid	Flu B POS/	COVID-19 POS / Total Valid
Co-spike 1	A/Michigan/45/2015	B/Colorado/6/2017	SARS-CoV-2	20/20	20/20	20/20
Co-spike 2	A/Hong Kong/4801/2014	B/Phuket/3073/2013	SARS-CoV-2	20/20	20/20	20/20

2) Inclusivity (Analytical Reactivity)

a) Wet Testing

The inclusivity of the Lucira assays was evaluated with 20 Influenza A strains (10 H1N1 pdm09 and 10 H3N2), 10 Influenza B strains 5 Yamagata and 5 Victoria lineages), and 3 SARS-CoV-2 strains representing temporal, geographic, and genetic diversity within the currently circulating subtypes and lineages. At least 2 strains from the last 5 years were selected for Influenza A H1N1pmo09, Influenza A H3N2 and Influenza B. All Influenza strains were quantified by an in-house, validated qPCR assay to standardized concentration units. SARS-CoV-2 strains were quantified by ddPCR by the manufacturer. All strains were individually tested at 3X LoD in 3 replicates to demonstrate inclusivity. The results are shown in Tables 8 through 10 below.

Table 8. COVID-19 Assay Results with Tested SARS-CoV-2 Strains

Target		Test Concentration (cp/swab)	COVID-19 POS / Total Valid	% Positive
SARS-CoV-2 isolate USA/CA_CDC_5574/2020	Alpha Variant	3275	3 / 3	100%
SARS-CoV-2 isolate USA/MD-HP01542/2021	Beta Variant	3275	3 / 3	100%
SARS-CoV-2 isolate hCoV-19/USA/MD-HP05285/2021	Delta Variant	3275	3 / 3	100%
SARS-CoV-2 strain 2019-nCoV/USA-WA1/2020	Anchor CoV	3275	3 / 3	100%

Table 9. Flu A Assay Results with Tested Influenza-A Strains

Target	Subtype	Test Concentration (cp/swab)	Flu A POS / Total Valid	%Positive
A/Indiana/02/2020	H1N1pdm09	11250	3 / 3	100%
A/Hawaii/66/2019	H1N1pdm09	11250	3 / 3	100%
A/Victoria/2570/2019	H1N1pdm09	11250	3 / 3	100%
A/Wisconsin/588/2019	H1N1pdm09	11250	3 / 3	100%
A/Michigan/45/2015	H1N1pdm09	11250	3 / 3	100%
A/Bangladesh/3002/2015	H1N1pdm09	11250	3 / 3	100%
A/Dominican/Republic/7293/2013	H1N1pdm09	11250	3 / 3	100%
A/Iowa/53/2015	H1N1pdm09	11250	3 / 3	100%
A/Christchurch/16/2010	H1N1pdm09	11250	3 / 3	100%
A/California/7/2009	H1N1pdm09	11250	3 / 3	100%
A/New York/21/2020	H3N2	3785	3 / 3	100%
A/Tasmania/503/2020	H3N2	3785	3 / 3	100%
A/Hong Kong/2671/2019	H3N2	3785	3 / 3	100%
A/Hong Kong/45/2019	H3N2	3785	3 / 3	100%
A/Singapore/INFIMH-16-0019/2016	H3N2	3785	3 / 3	100%
A/Hong Kong/4801/2014	H3N2	3785	3 / 3	100%
A/Switzerland/9715293/2013	H3N2	3785	3 / 3	100%
A/Brisbane/10/2007	H3N2	3785	3 / 3	100%
A/Texas/50/2012	H3N2	3785	3 / 3	100%
A/Perth/16/2009	H3N2	3785	3 / 3	100%

Table 10. Flu B Assay Results with Tested Influenza B Strains

Target	Lineage	Test Concentration (cp/swab)	Flu B POS / Total Valid	%Positive
B/Washington/02/2019	Victoria	13000	3 / 3	100%
B/Colorado/6/2017	Victoria	13000	3 / 3	100%
B/Florida/78/2015	Victoria	13000	3 / 3	100%
B/Texas/02/2013	Victoria	13000	3 / 3	100%
B/Michigan/09/2011	Victoria	13000	3 / 3	100%
B/Texas/81/2016	Yamagata	15200	3 / 3	100%
B/Phuket/3073/2013	Yamagata	15200	3 / 3	100%
B/Montana/05/2012	Yamagata	15200	3 / 3	100%
B/Massachusetts/02/2012	Yamagata	15200	3 / 3	100%
B/Wisconsin/1/2010	Yamagata	15200	3 / 3	100%

b) *In silico*

i) SARS-CoV-2 Predicted Reactivity

Inclusivity of the Lucira SARS-CoV-2 Assay was demonstrated by in-silico reactivity of the assay against publicly available SARS-CoV-2 strains using the assay's primers. SARS-CoV-2 sequences were downloaded from the Global Initiative on Sharing All Influenza Data (GISAID, https://www.gisaid.org) database from December 1 2020 through April 15, 2022. Sequences were trimmed from whole genomes to 2.4-3.6kb windows covering the target regions and analyzed to predict reactivity using established rules to either primer sets of the assay. Between December 1, 2020 and April 15, 2022, 803,027 sequences were analyzed and 99.98% were found to be reactive.

Lucira performs monthly surveillance of emerging SARS-CoV-2 strains by periodically evaluating in silico reactivity against sequence databases to ensure that emerging strains of SARS-CoV-2 are reactive to the Lucira COVID-19 & Flu Test. As of April 15, 2022, all of the sequences from variants of concern as identified by CDC and World Health Organization (WHO) were found to be reactive to at least one primer set of the assay. The analysis includes:

(1) Omicron (also known as B.1.1.529, BA.1, BA.1.1, BA.2, BA.2.9.1, BA.2.11, BA.2.13, BA.2.12.1, BA.3, BA.4, BA.5 and XE) first detected in multiple countries
(2) Delta (also known as B.1.617.2, all sublineages) first detected in India
(3) Alpha (also known as B.1.1.7, all sublineages) first detected in the United Kingdom
(4) Beta (also known as B.1.351, all sublineages) first detected in South Africa
(5) Gamma (also known as P.1, all sublineages) first detected in Japan/Brazil
(6) Lambda (also known as C.37, all sublineages) first detected in Peru
(7) Mu (also known as B.1.621, all sublineages) first detected in Colombia.

A Technical Brief related to Lucira's most current analysis is available on Lucira's website.

ii) Influenza Predicted Reactivity

Sequences were downloaded for each targeted segment for each dataset: A/H3N2, A/pH1N1, B/Victoria, and B/Yamagata. Primer binding with both primer sets was predicted based on established rules. All are reactive to over 95% of sequences in the last 5 years (2016-2021).

3) Cross-Reactivity (Analytical Specificity)

a) Wet Testing

The specificity of the assay was evaluated in cross-reactivity testing using 26 commensal organisms, including 11 bacteria/fungi, and 15 viruses. For each organism, 35 µL of undiluted organism was spiked onto a nasal swab with 35 µL of NNSM. The swab was then eluted and run on the Lucira test. All spike concentrations were at a concentration of 1E+066 CFU/mL or higher for bacteria and 1E+05 TCID50/mL or higher for viruses. As shown below in Table 11, the cross-reactivity testing confirmed that none of the organisms were cross reactive with the Lucira COVID-19 & Flu Test at the concentrations tested.

Table 11. Cross-Reactivity Results

Microbial Target	Test Concentration	COVID-19 (# POS / # Tested)	Flu A (# POS / # Tested)	Flu B (# POS / # Tested)	Cross Reactive
Adenovirus C1	3.09E+08 TCID50/mL	0/3	0/3	0/3	No
Human Metapneumovirus (hMPV)	4.17E+05 TCID50/mL	0/3	0/3	0/3	No
Chlamydia pneumonaie	1.25E+07 IFU/mL	0/3	0/3	0/3	No
Parainfluenza virus 1	1.26E+06 TCID50/mL	0/3	0/3	0/3	No
Parainfluenza virus 2	1.60E+06 TCID50/mL	0/3	0/3	0/3	No
Legionella pneumophila	1.91E+10 CFU/mL	0/3	0/3	0/3	No
Parainfluenza virus 3	8.51E+07 TCID50/mL	0/3	0/3	0/3	No
Parainfluenza virus 4	1.15E+07 TCID50/mL	0/3	0/3	0/3	No
Haemophilus influenzae	6.97E+08 CFU/mL	0/3	0/3	0/3	No
Enterovirus 68	1.51E+06 TCID50/mL	0/3	0/3	0/3	No
Respiratory Syncytial Virus -A	1.17E+05 TCID50/mL	0/3	0/3	0/3	No
Streptococcus pneumoniae	1.34E+09 CFU/mL	0/3	0/3	0/3	No
Respiratory Syncytial Virus -B	4.57E+06 TCID50/mL	0/3	0/3	0/3	No
Rhinovirus 1A	2.20E+07 PFU/mL	0/3	0/3	0/3	No
Streptococcus pyogenes	2.39E+09 CFU/mL	0/3	0/3	0/3	No
Bordetella pertussis	1.96E+10 CFU/mL	0/3	0/3	0/3	No
Mycoplasma pneumoniae	2.70E+08 CCU/mL	0/3	0/3	0/3	No
Candida albicans	4.76E+08 CFU/mL	0/3	0/3	0/3	No
Pseudomonas aeruginosa	6.90E+08 CFU/vial	0/3	0/3	0/3	No
Staphylococcus epidermis	1.40E+08 CFU/vial	0/3	0/3	0/3	No
Streptococcus salivarius	1.20E+08 CFU/vial	0/3	0/3	0/3	No
Human Coronavirus 229E	1.41E+06 TCID50/mL	0/3	0/3	0/3	No
Human Coronavirus OC43	1.70E+05 TCID50/mL	0/3	0/3	0/3	No
Human Coronavirus NL63	1.17E+05 TCID50/mL	0/3	0/3	0/3	No
SARS-COV-1	1.00E+08 PFU/mL	0/3	0/3	0/3	No
MERS-coronavirus	8.90E+05 TCID50/mL	0/3	0/3	0/3	No

Cross-reactivity of Influenza A, Influenza B, and SARS-CoV-2 at high concentrations was evaluated. As shown below, the cross-reactivity testing confirmed that viruses were not cross-reactive at the concentrations tested.

Table 12. Cross Reactive Analysis for Flu A, Flu B, and SARS-CoV-2 Spiked at High Concentrations

Microbial Target	Stock Concentration	COVID-19 (POS/#Tested)	FLU A (#POS/#Tested)	Flu B (POS/#Tested)	Cross Reactive
Influenza A/ Hk	9.60E+08 CEID50/mL	0/3	3/3	0/3	No
Influenza A/ Mi	1.00E+09 CEID50/mL	0/3	3/3	0/3	No
Influenza B/ Co	1.60E+08 CEID50/mL	0/3	0/3	3/3	No
Influenza B/ Ph	1.10E+09 CEID50/mL	0/3	0/3	3/3	No
SARS-COV-2	6.45E+06 TCID50/mL	3/3	0/3	0/3	No

b) In Silico

In silico analysis was conducted to verify the assay does not cross-react with other high prevalence disease agents and normal or pathogenic flora that are reasonably likely to be encountered in a clinical specimen. Whole genome sequences were downloaded from NCBI. Results are summarized below in Table 13.

BLAST alignments were found for only two of the species tested: SARS-CoV-1 and *Haemophilus influenzae.* Since neither of these species had complete primer sets predicted to bind, they are not predicted to have cross reactivity with either primer set. SARS-CoV-1 has > 80% homology on individual primers for SARS-CoV-2 and *Candida albicans* and *Staphylococcus salivarius* have > 80% homology on individual primers for Influenza A and were tested and found not to have microbial interference, as shown in Table 15.

Table 13. Cross-Reactivity BLAST Results

Species	SARS-CoV-2		Influenza A				Influenza B	
	Set 1	Set 2	Set 1	Set 2	Set 3	Set 4	Set 1	Set 2
SARS-CoV-1	B1c (100%), F1c (100%)	F2 (100%), F3 (84%)	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
MERS-CoV	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Human coronavirus 229E	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Human coronavirus OC43	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Human coronavirus HKU1	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Human coronavirus NL63	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Adenovirus (e.g. C1 Ad. 71)	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Human Metapneumovirus (hMPV)	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Parainfluenza virus 1-4	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Influenza A	N.A.F.	N.A.F.	-	-	-	-	N.A.F.	N.A.F.
Influenza B	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	-	-
Enterovirus (e.g. EV68)	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Respiratory syncytial virus	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Rhinovirus	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Chlamydia pneumoniae	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Haemophilus influenzae	N.A.F.	F1c (65%)	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Legionella pneumophila	N.A.F.	N.A.F.	N.A.F.	F1c (71%)	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Mycobacterium tuberculosis	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Streptococcus pneumoniae	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Streptococcus pyogenes	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Bordetella pertussis	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Mycoplasma pneumoniae	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Pneumocystis jirovecii (PJP)	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Candida albicans	N.A.F.	N.A.F.	N.A.F.	LB (86%)	F3 (77%)	N.A.F.	N.A.F.	N.A.F.
Pseudomonas aeruginosa	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Staphylococcus epidermis	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Staphylococcus salivarius	N.A.F.	N.A.F.	N.A.F.	F2 (81%)	N.A.F.	N.A.F.	N.A.F.	N.A.F.
Passes Acceptance Criteria	PASS	PASS	PASS	PASS	PASS	PASS	PASS	PASS

4) Microbial Interference Studies

a) Competitive Inhibition

Competitive microbial interference was tested for SARS-CoV-2, Influenza A, and Influenza B. Each anchor strain was evaluated with 3 sample replicates spiked on a swab at low (3x LoD) concentration and a high level (≥1E+05 copies / mL) of the anchor strains of the other targets pooled to represent the worst-case scenario. No interference was seen as shown below.

Table 14. Competitive Inhibition Testing Results

Test Configuration	Viral Target at 3X LoD Concentration	Other Viral Targets at High Concentration	COVID-19 Assay Results	Flu A Assay Results	Flu B Assay Results	Competitive Inhibition Present (Y/N)
Co-spike I	A/HK	B/Ph, SARS-CoV	3/3 positive	3/3 positive	3/3 positive	No
Co-spike II	B/Ph	A/HK, SARS-CoV	3/3 positive	3/3 positive	3/3 positive	No
Co-spike III	SARS-CoV-2	A/HK, B/Ph	3/3 positive	3/3 positive	3/3 positive	No

b) Microbial Interference

Each microorganism selected for cross-reactivity was also tested for microbial interference. Testing was performed with contrived samples prepared with SARS-CoV-2 (2019-nCoV/USA-WA1/2020), Influenza A (A/Hong Kong/4801/2014), and Influenza B (B/Phuket/3073/2013) viral targets at final concentration of 3xLOD in a co-spike tested individually with each microorganism at a challenging high (stock) concentration. Each microorganism was tested in three replicates. No microbial interference was detected, as shown below.

Table 15. Microbial Interference Testing Results

Microbe	Concentration	COVID-19 Assay Results (POS/Valid)	Flu A Assay Results (POS/Valid)	Flu B Assay Results (POS/Valid)	Interference Observed (Yes/No)
Parainfluenza virus 1	1.26E+06 TCID50/mL	3/3	3/3	3/3	No
Parainfluenza virus 2	1.6E+06 TCID50/mL	3/3	3/3	3/3	No
Parainfluenza virus 3	8.51E+07 TCID50/mL	3/3	3/3	3/3	No
Parainfluenza virus 4	1.15E+07 TCID50/mL	3/3	3/3	3/3	No
Adenovirus C1	3.09E8 TCID50/mL	3/3	3/3	3/3	No
Enterovirus 68	1.51E+06 TCID50/mL	3/3	3/3	3/3	No
Respiratory Syncytial Virus -A	1.17E+05 TCID50/mL	3/3	3/3	3/3	No
Respiratory Syncytial Virus -B	4.57E+06 TCID50/mL	3/3	3/3	3/3	No
Human Metapneumovirus (hMPV)	4.17E+05 TCID50/mL	3/3	3/3	3/3	No
Human Coronavirus 229E	1.41E+06 TCID50/mL	3/3	3/3	3/3	No
Human Coronavirus OC43	1.70E+05 TCID50/mL	3/3	3/3	3/3	No
Human Coronavirus NL63	1.17E+05 TCID50/mL	3/3	3/3	3/3	No
Rhinovirus 1A	2.2E+07 PFU/mL	3/3	3/3	3/3	No
MERS-coronavirus	8.90E+05 TCID50/mL	3/3	3/3	3/3	No
SARS-COV-1	1.00E+08 PFU/mL	3/3	3/3	3/3	No
Candida albicans	4.76E+08 CFU/mL	3/3	3/3	3/3	No
Chlamydia pneumonaie	1.25E+07 IFU/mL	3/3	3/3	3/3	No
Haemophilus influenzae	6.97E+08 CFU/mL	3/3	3/3	3/3	No
Legionella pneumophila	1.91E+10 CFU/mL	3/3	3/3	3/3	No
Streptococcus pneumoniae	1.34E+09 CFU/mL	3/3	3/3	3/3	No
Streptococcus pyogenes	2.39E+09 CFU/mL	3/3	3/3	3/3	No
Bordetella pertussis	1.96E+10 CFU/mL	3/3	3/3	3/3	No
Mycoplasma pneumoniae	2.70E+08 CFU/mL	3/3	3/3	3/3	No
Pseudomonas aeruginosa	6.90E+08 CFU/mL	3/3	3/3	3/3	No
Streptococcus salivarius	1.20E+08 CFU/mL	3/3	3/3	3/3	No
Staphylococcus epidermis	1.40E+08 CFU/mL	3/3	3/3	3/3	No

5) Endogenous/Exogenous Interference Substances Studies`

Endogenous interference studies were conducted to assess potential interference effects on the Lucira assay from substances that may naturally be present in respiratory specimens or artificially introduced onto the nasal swab. 35 µL of the potentially interfering substances listed in the table below was spiked onto the swab at the listed concentrations and evaluated with and without virus spikes:

1. An Influenza A (H3N2) virus, Influenza B (Yamagata Lineage) virus, and SARS-CoV-2 virus, all at 3X LoD, were co-spiked to assess Influenza A, Influenza B and SARS-CoV-2 positive performance.
2. NTC devices to evaluate performance in the absence of template.

Substances that yielded 0/3 positive in valid NTC tests and 3/3 positive in valid POS tests were recorded as non-interfering. Invalid tests were repeated until 3 valid devices were obtained. As shown in below, none of the substances tested showed interference effects with the Lucira assay.

Table 16. Endogenous/Exogenous Interference Results

Endogenous/ Exogenous Substance	Test Concentration	COVID-19 Assay in Presence of Substance	Flu A Assay in Presence of Substance	Flu B Assay in Presence of Substance	Interfering (Yes/No)
Afrin Original nasal spray	15% v/v	Pass	Pass	Pass	No
Cepacol	3 mg/mL	Pass	Pass	Pass	No
Choloroseptic Sore Throat Spray	5% v/v	Pass	Pass	Pass	No
Robitussin	5% v/v	Pass	Pass	Pass	No
Mucin, type I-S	2.5 mg/mL	Pass	Pass	Pass	No
Nicotine or Tobacco	0.03 mg/mL	Pass	Pass	Pass	No
Blood (human)	5% (v/v)	Pass	Pass	Pass	No
Relenza	5mg/mL	Pass	Pass	Pass	No
Tobrex	2.43mg/mL	Pass	Pass	Pass	No
Biotin	3.5 ug/mL	Pass	Pass	Pass	No
Zicam Allergy Relief	25% (v/v)	Pass	Pass	Pass	No
Flonase	25% (v/v)	Pass	Pass	Pass	No
Nasal Saline spray	25% (v/v)	Pass	Pass	Pass	No
NeoSynephrine Cold & Sinus Extra Strength	25% (v/v)	Pass	Pass	Pass	No
Nasacort	25% (v/v)	Pass	Pass	Pass	No
Mupirocin	12mg/mL	Pass	Pass	Pass	No
Tamiflu	6mg/mL	Pass	Pass	Pass	No
NeilMed Nasal Gel	1.25% (v/v)	Pass	Pass	Pass	No

6) Sample Stability Study

The Lucira Health assay is designed to be used immediately, at the point that the sample is collected. There is no ability to store the samples for later testing. In the worst case scenario, someone may wait up to 10 minutes to test the sample after collection. Therefore, Lucira tested sample stability immediately after spiking the swab and 10 minutes after spiking the swab with contrived samples at 3X LoD for the strains spiked both with and without virus:

1. An Influenza A (H3N2) virus, Influenza B (Yamagata Lineage) virus, and SARS-CoV-2 virus, all at 3X LoD were co-spiked to assess Influenza A, Influenza B and SARS-CoV-2 positive performance.
2. NTC devices to evaluate performance in the absence of template.

Table 17. Sample Stability Study

Sample Group	COVID-19 Results (#Positive /#Tested)	Flu A Results (#Positive /#Tested)	Flu B Results (#Positive /#Tested)
Positive Test samples with 10 minute delayed elution after spiking targets	3/3	3/3	3/3
Positive Control samples eluted promptly after spiking viral targets	3/3	3/3	3/3

7) Human Usability Study

Lucira conducted Human Usability testing among a total sample of 200 healthy, non-symptomatic users to evaluate the ability of various ages, ethnicities, and education levels to successfully run the Lucira COVID-19 & Flu Test and interpret test results. 100% (200/200) of users were able to run the test on their own. Participants were each shown six (6) simulated test results and correctly interpreted 99.7% (1194/1200) of results.

8) Clinical Performance

Lucira has conducted three (3) clinical studies to establish the performance characteristics and ease of use of the Lucira COVID-19 & Flu Test Kit:

a. Remnant Sample Testing Study
b. Prospective Study
c. Near the Cut-off Evaluation (NTCO)

a) Remnant Sample Testing Study

The Remnant Sample study compared Lucira COVID-19 & Flu device performance to two highly sensitive comparators. The Flu comparator was FDA approved and the COVID-19 comparator was Emergency Use Authorized. A total of 425 samples were evaluated.

Remnant samples were collected from the upper respiratory tract in patients with suspected influenza during the 2016-17 to 2021-22 influenza seasons or from suspected COVID-19 patients from 2020 to 2022.

Positive samples were remnant samples in either VTM or saline that were previously identified as positive by an FDA cleared or Emergency Use Authorized molecular assay. Positive samples were confirmed positive by a comparator used in this study prior to the study being executed to ensure an appropriate number of positive samples were run.

Negative samples were remnant samples in either VTM or saline that were previously identified as negative by an FDA cleared or Emergency Use Authorized molecular assay.

Comparator samples were prepared in the same manner as the samples used for candidate device testing with the Lucira COVID-19 & Flu Test. Samples were spiked onto a nasal swab, eluted in 3ml transport medium, aliquoted, shipped, and tested on the various comparator methods.

Lucira achieved the following performance:

- COVID-19: 98.2% positive percent agreement (108/111) and 100% negative percent agreement (296/296)
- Flu A: 100% positive percent agreement (59/59) and 99.7% negative percent agreement (347/348)
- Flu B: 97.6% positive percent agreement (40/41) and 99.5% negative percent agreement (363/365)

Table 18. Remnant Study Results

Sample Category	Comparator (PCR)				N	Success	PPA 95% Wilson CI		Success	NPA 95% Wilson CI	
	Positive		Negative			Total N			Total N		
	Lucira		Lucira								
	Pos	Neg	Pos	Neg							
Covid	108	2	0	296	406	108	98.2%		296	100.0%	
						110	93.6%	99.5%	296	98.7%	100.0%
Flu A	59	0	1	347	407	59	100.0%		347	99.7%	
						59	93.9%	100.0%	348	98.4%	99.9%
Flu B	40	1	2	363	406	40	97.6%		363	99.5%	
						41	87.4%	99.6%	365	98.0%	99.8%

b) Prospective Study

The Prospective study compared Lucira COVID-19 & Flu device performance to two highly sensitive comparators. The Flu comparator was FDA approved and the COVID-19 comparator was Emergency Use Authorized. A total of 252 subjects completed the study. Subjects aged 14 years or older self-collected a nasal swab. Subjects aged 2-13 years had a swab collected by a caregiver or guardian. One (1) additional nasal swab specimen was collected by the health care professional, prepared in Transport Medium, and sent for reference laboratory testing.

Lucira achieved the following performance:

- COVID-19: 100% positive percent agreement (2/2) and 100% negative percent agreement (235/235).
- Flu A: 90% positive percent agreement (9/10) and 99.6% negative percent agreement (229/230).
- Flu B: There were no observed Flu B samples. Lucira COVID-19 & Flu Device demonstrated 100% negative percent agreement (240/240).

Table 19. Prospective Study Results

Sample Category	Comparator (PCR)				N	Success	PPA 95% Wilson CI		Success	NPA 95% Wilson CI	
	Positive		Negative			Total N			Total N		
	Lucira		Lucira								
	Pos	Neg	Pos	Neg							
Covid	2	0	0	235	237*	2	100.0%		235	100.0%	
						2	34.2%	100.0%	235	98.4%	100.0%
Flu A	9	1	1	229	240*	9	90.0%		229	99.6%	
						10	59.6%	98.2%	230	97.6%	99.9%
Flu B	0	0	0	240	240*	0	NA		240	100.0%	
						0	NA	NA	240	98.4%	100.0%

*N<252 because comparator or candidate results were invalid/not available.

c) Near the Cut-off Evaluation (NTCO)

The Near The Cut-off (NTCO) evaluation study was performed to determine the effects of operator-to-operator variation. Contrived nasal swabs were run by untrained, intended users. The test included 40 well-characterized contrived nasal swab samples: 10 positive contrived samples at 2X LoD for SARS-CoV-2 virus in NNSM, 10 positive contrived samples at 2X LoD for Influenza A virus in NNSM, 10 positive contrived samples at 2X LoD for Influenza B virus in NNSM, and 10 negative contrived samples with NNSM only. This study design tested blinded, contrived swabs prepared by Lucira Health employees and run by ten untrained, intended users. All results in the study were valid and matched the expected results. Overall agreement with expected results was 100% for SARS-CoV-2, Influenza A, Influenza B Positive and Negative samples. The results demonstrate that untrained, intended users are able to use the Lucira COVID-19 & Flu Test and obtain the expected results.

Table 20. Summary of NTCO Results by Sample

Sample	Percent Agreement (95% CI)	(# Successes / # Tested)
SARS-CoV-2 Positive	100% (72.2%–100%)	10 / 10
Flu A Positive	100% (72.2%–100%)	10 / 10
Flu B Positive	100% (72.2%–100%)	10 / 10
Negative	100% (72.2%–100%)	10 / 10

Table 21. Summary of NTCO Results by Operator and Sample

Operator #	SARS-CoV-2 Spike (# Positive / # Tested)	Flu A Spike (# Positive / # Tested)	Flu B Spike (# Positive / # Tested)	Negative Spike (# Positive / # Tested)
1	3 / 3	3 / 3	4 / 4	0 / 4
2	4 / 4	4 / 4	3 / 3	0 / 3
3	3 / 3	3 / 3	3 / 3	0 / 3
Total	10 / 10	10 / 10	10 / 10	0 / 10

10) Electromagnetic Compatibility

The Device has been tested and found to be appropriate for use at home. In most cases, the Device should not interfere with other home electronic devices if used as instructed. The Device gives off a low level of radio frequency (RF) energy, but the low level of RF energy emitted by the Device is not likely to cause interference in nearby electronic equipment.

WARNING:

- The Device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect the Device.
- The use of accessories, transducers and cables other than those specified by Lucira Health may result in increased emissions or decreased immunity of the Device.
- The Device should not be adjacent to or stacked with other equipment, and if adjacent or stacked use is necessary, the Device should be observed to verify normal operation in the configuration in which it will be used.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Device; otherwise, degradation of the performance of this equipment could result.

Guidance and manufacturer's declaration - electromagnetic emissions

The Device is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity
The Device is intended for use in the electromagnetic environment specified below. The customer or the user of the Device should assure that it is used in such an environment.

Immunity test	Compliance test Level	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** **$d=1.2\sqrt{P}$** 80 MHz to 800 MHz **$d=2.3\sqrt{P}$** 800 MHz to 2.7 GHz

P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and **d** is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[A] should be less than the compliance level in each frequency range.[B]

Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[A] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the System is used exceeds the applicable RF compliance level above, the System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the System.

[B] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

IMMUNITY to proximity magnetic fields		
Test Frequency Hz	**Modulation**	**Level (A/m)**
30 kHz [a)]	CW	8
134.2 kHz	Pulse modulation [b)] 2.1kHz	65 [c)]
13.56 MHz	Pulse modulation [b)] 50kHz	7.5 [c)]

[a)] This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.
[b)] Carrier modulated using a 50% duty cycle square wave.
[c)] r.m.s., before modulation is applied.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT			
The EQUIPMENT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EQUIPMENT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EQUIPMENT as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz d = 1.2√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.7 GHz d = 2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
The calculation formula to determine the separation distance between this test and a mobile phone is given by d = 6/E√P where d is the minimum separation distance in metres, P is the maximum power in watts, and E is the immunity test level in V/m. For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

LIMITATIONS

- Performance was evaluated with swab specimens only, using the procedures provided in this instruction. Failure to follow these procedures may alter test performance.
- False negative results may occur if a specimen is improperly collected or handled.
- False negative results may occur if inadequate levels of viruses are present in the specimen.
- False negative results may occur if the virus mutates in the regions targeted by the test.
- The test is a qualitative test and does not provide the quantitative value of detected organism present.
- Cross-reactivity with respiratory tract organisms other than those tested in the Analytical Specificity Study may lead to erroneous results.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.
- Analyte targets (viral sequences) may persist in vivo, independent of virus viability. Detection of analyte target(s) does not imply that the corresponding virus(s) are infectious, nor are the causative agents for clinical symptoms.
- Positive and negative predictive values are dependent upon prevalence. False negative results are more likely during peak activity when disease prevalence is high and false positive results are more likely during periods of low activity.
- The performance of this device has not been asessed in a population vaccinated against COVID-19.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

TECHNICAL ASSISTANCE

Contact Lucira at cs@lucirahealth.com, or call 1-888-LUCIRA-4 (582-4724).

REFERENCES

1. Zhu N, Zhang D, Wang W, et al. A Novel Coronavirus from Patients with Pneumonia in China, 2019. N Engl J Med. 2020;382:727-33. PMID: 31978945.
2. https://www.who.int/emergencies/diseases/novel-coronavirus-2019
3. https://www.cdc.gov/coronavirus/2019-ncov/index.html

TABLE OF SYMBOLS

CE	Product is CE marked.
	Product is for single-use only. Do not re-use the same test kit.
	Consult the instructions for use.
IVD	Product is for *in vitro* Diagnostic Use.
Σ 1	Total number of IVD tests that can be performed with this IVD is 1.
	Caution is necessary when operating the device or control close to where the symbol is placed, or the situation needs operator awareness or operator action in order to avoid undesirable consequences.
15°C 59°F 30°C 86°F	Store and use product at temperature in the range of 15-30°C / 59-86°F.
	Product 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.
	Use-by date.
10% 80%	Store and use the product at relative humidity 10-80%.
STERILE EO	The swab is sterilized by ethylene oxide.

	Name and location of the product manufacturer.
REF	Product catalog number.
LOT	Product batch code.
75 kPa 106 kPa	Store and use the product at atmospheric pressure in the range of 75-106 kPa.
	Batteries within the test unit should be disposed of separately from household waste and recycled. Applies in the European Union only.
	Test unit should be disposed of separately from household waste and recycled. Applies in the European Union only.
	Type BF applied part.

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Covered by one or more of US Patents 10,146,909, 10,253,357 and other pending US and International Patents.