LUCIRA® by Pfizer

Covid-19 & Flu
Home Test

Nucleic Acid Amplification Test (NAAT)

For Individuals with signs and symptoms of Respiratory Tract Infection including COVID-19

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Lucira® by Pfizer COVID-19 & Flu Home Test

Instructions for Use

For Use under Emergency Use Authorization (EUA) only
For *in vitro* Diagnostic Use
For Use with Self-collected Nasal Swab Specimens in individuals aged 14 years or older For Use with Adult-collected Nasal Swab Specimens in individuals aged 2 years or older For Over-the-Counter (OTC) Use

Intended Use

The Lucira by Pfizer COVID-19 & Flu Home Test is a single use (disposable) home test kit intended for simultaneous rapid in vitro qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B viral nucleic acid. This test is authorized for non-prescription home use with anterior nasal swab samples from individuals 14 years or older (self-collected) or individuals 2 years or older (collected by an adult) with signs and symptoms consistent with a respiratory tract infection, including COVID-19. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

The Lucira by Pfizer COVID-19 & Flu Home Test is intended for use in the differential diagnosis of SARS-CoV-2, influenza A, and influenza B in clinical specimens and is not intended to detect influenza C. SARS-CoV-2, influenza A, and influenza B viral nucleic acid is generally detectable in anterior nasal swab samples during the acute phase of infection.

Positive results indicate the presence of viral nucleic acid, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other pathogens not detected by the test. The agent detected may not be the definitive cause of disease. Individuals who test positive with the Lucira by Pfizer COVID-19 & Flu Home Test should self-isolate and seek follow up care with their physician or healthcare provider as additional testing may be necessary.

Negative results for SARS-CoV-2 and influenza B are presumptive, meaning that they should be confirmed, if necessary for patient management, with an authorized or cleared molecular test performed in a CLIA-certified laboratory that meets requirements to perform high or moderate complexity tests.

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 other management decisions, including infection control decisions. Negative results should be considered in the context of current prevalence of infection, an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with respiratory infection. Individuals who test negative and continue to experience symptoms of fever, cough and/or shortness of breath may still have a respiratory infection and should seek follow up care with their healthcare provider.

Individuals should report all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The Lucira by Pfizer COVID-19 & Flu Home Test is authorized for non-prescription self-use by individuals aged 14 years or older and/or, as applicable, for an adult lay user testing another person aged 2 years or older in a non-laboratory setting. The Lucira by Pfizer COVID-19 & Flu Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Summary and Explanation of the Test

The Lucira by Pfizer COVID-19 & Flu Home 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 by Pfizer COVID-19 & Flu Home 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 two non-overlapping regions in the N gene and 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.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use
- For use under FDA Emergency Use Authorization (EUA) only.
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA.
- This product has been authorized only for the detection and differentiation of nucleic acid from SARS-CoV-2, Influenza A, and Influenza B, not for any other viruses or pathogens; and,
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- 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 closer than 30 cm (12 inches) to devices or appliances, such as antenna cables and external antennas, that may cause interference while the test is running.
- All kit components are single use items. Do not use with multiple specimens.
- Do not try to disassemble the Test Unit.
- The elution buffer may contain irritants. Do not ingest the contents of the tube. If the contents of the tube are splashed in your eyes, flush your eyes with water. If the contents splash onto your skin, wash with soap and water. If irritation persists, notify a health care provider.
- After use remove the batteries, place the test unit in plastic disposal bag and dispose all test kit materials in trash. Do not allow the test unit to come into contact or be disposed of with bleach, as harmful gases could be emitted as a result.
- 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.
- Only use the components provided. Do not use swabs from the other tests.

SECTION A - Reagents and Materials

Lucira® by Pfizer COVID-19 & Flu Home 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" (12.5 mm) 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 by Pfizer COVID-19 & Flu Home 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 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.

Note: **Keep** vial away from children. Avoid contact with eyes and skin. If contact occurs, rinse with water. If irritation persists, seek medical attention.

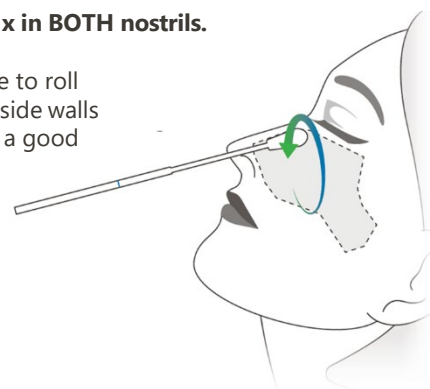
2. Swab Both Nostrils

For this test to work properly, it is important to 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 nostril and you meet resistance.
  - For adults - insert less than one inch.
  - For younger children - insert less than 1/2 inch
- 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.

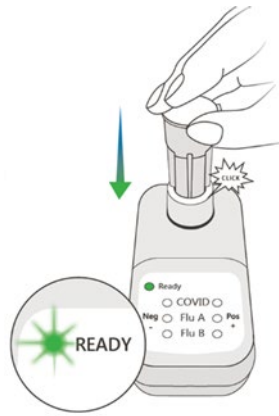


Adults must swab children ages 2 years or older.

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.

- Immediately 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.

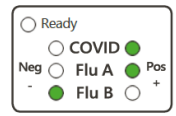
Wait 30 minutes.

4. Read Result

- Ready light will continue blinking while the test is running.
- Positive results may display before the test is done running; however, you must wait until the Ready light has stopped blinking to interpret all test results.
- Results may be positive for more than one virus.
- 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.

Example Result: Positive for COVID-19 and Flu A; Negative for Flu B.

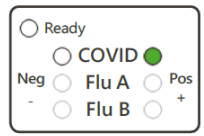
See Section C for all possible results.



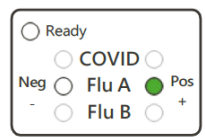
POSITIVE Results

Positive results light up on the right

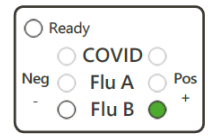
COVID-19 Positive



Flu A Positive



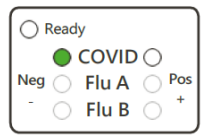
Flu B Positive



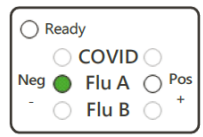
NEGATIVE Results

Negative results light up on the left

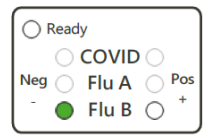
COVID-19 Negative



Flu A Negative



Flu B Negative



INVALID Results

Positive and Negative lights flash/blink if result is Invalid

Invalid results may occur for one, two or all three viruses. If an invalid result is observed for any of the viruses the entire test is considered invalid. Retest with a new test and use the retest as final.

If you receive any invalid results, retest or contact Pfizer at 1-888-LUCIRA-4 (582-4724) to obtain a free replacement test.

Lucira Connect is a website that helps you:

- Create a shareable digital record of your test result
- Use your smartphone camera to scan the QR code on the top of the test unit or on the sticker on the back of the box to begin at luciraconnect.com

If the test is POSITIVE

It is very likely you have COVID-19 (if the test result is positive for COVID-19) or flu (if the test result is 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 the test is 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.

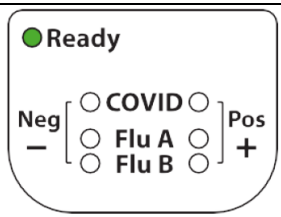
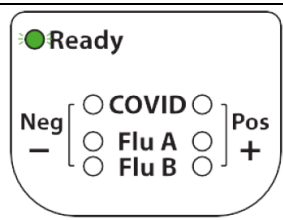
If the test is INVALID

An invalid result means something with the test did not work properly. If the test result is invalid, the positive and negative lights on the device will be blinking/flashing. If your test shows an invalid result, retest or contact Pfizer at 1-888-LUCIRA-4 (582-4724) to obtain a free replacement test.

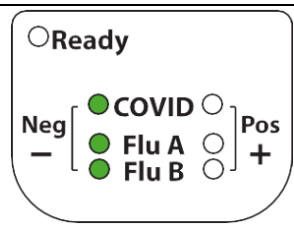
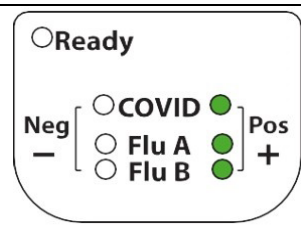
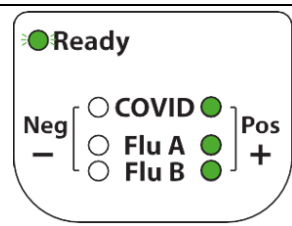
5. Dispose of Test

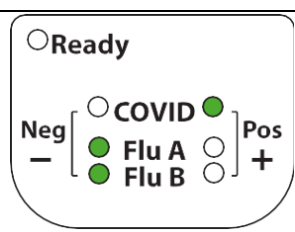
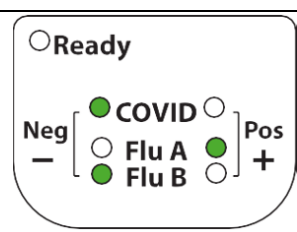
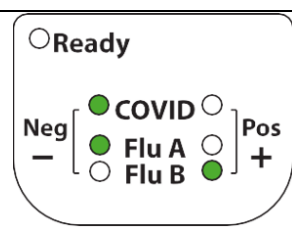
After use remove the batteries, place the test unit in plastic disposal bag and dispose all test kit materials in trash. Do not allow the test unit to come into contact or be disposed of with bleach, as harmful gases could be emitted as a result.

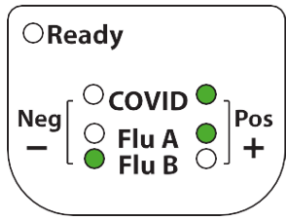
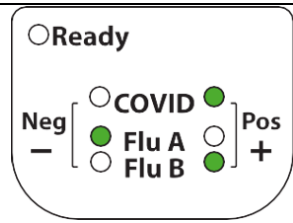
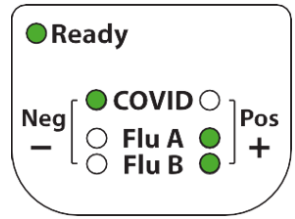
Section C - Test Unit Result Display

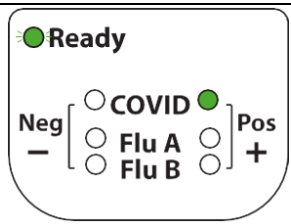
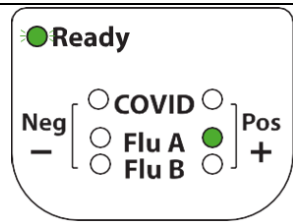
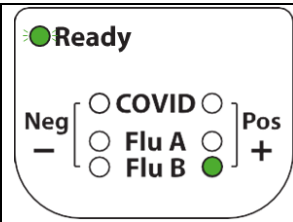
	
Test is ready to be run	Test is running

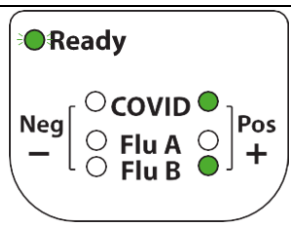
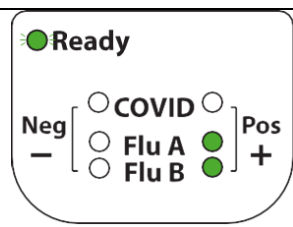
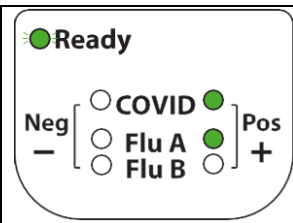
 Blinking/flashing

			
COVID-19	Negative	Positive	Positive
Flu A	Negative	Positive	Positive
Flu B	Negative	Positive	Positive

			
COVID-19	Positive	Negative	Negative
Flu A	Negative	Positive	Negative
Flu B	Negative	Negative	Positive

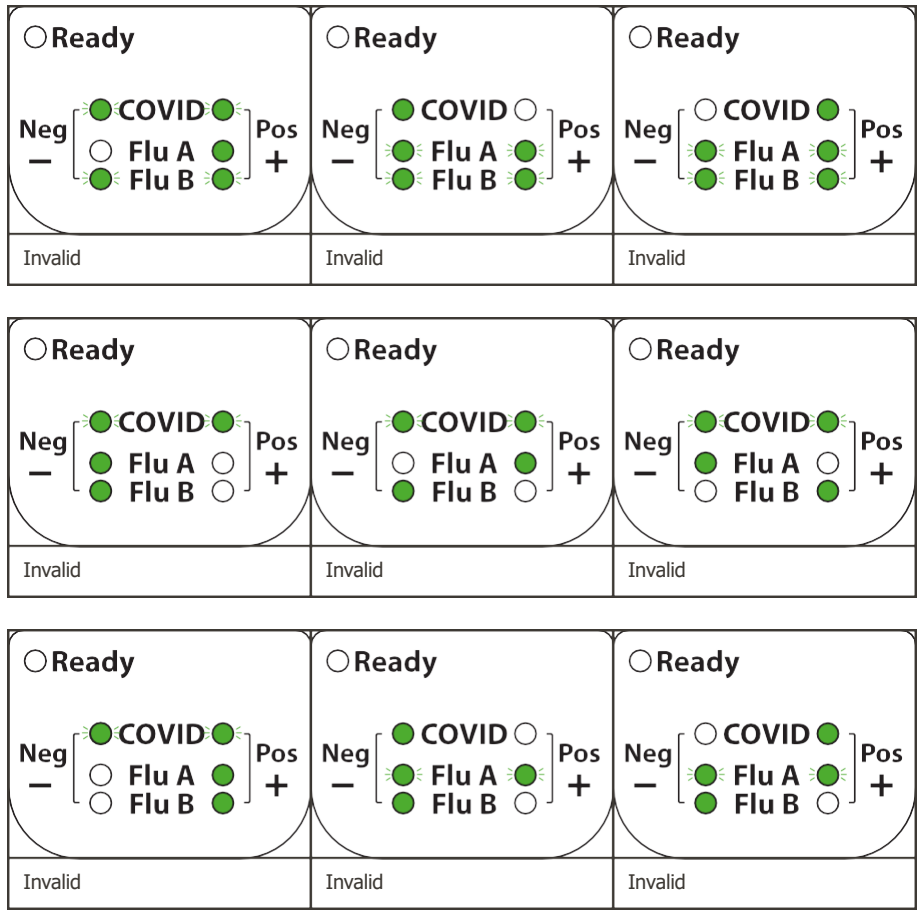
			
COVID-19	Positive	Positive	Negative
Flu A	Positive	Negative	Positive
Flu B	Negative	Positive	Positive

			
COVID-19	Positive	Not available yet	Not available yet
Flu A	Not available yet	Positive	Not available yet
Flu B	Not available yet	Not available yet	Positive

			
COVID-19	Positive	Not available yet	Positive
Flu A	Not available yet	Positive	Positive
Flu B	Positive	Positive	Not available yet

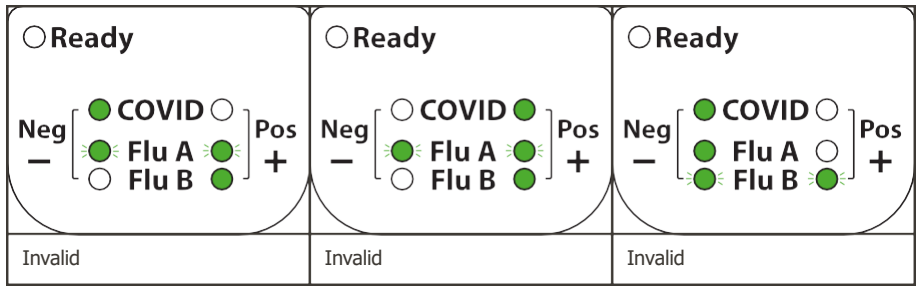
Covid-19, Flu A, Flu B — Invalid Results

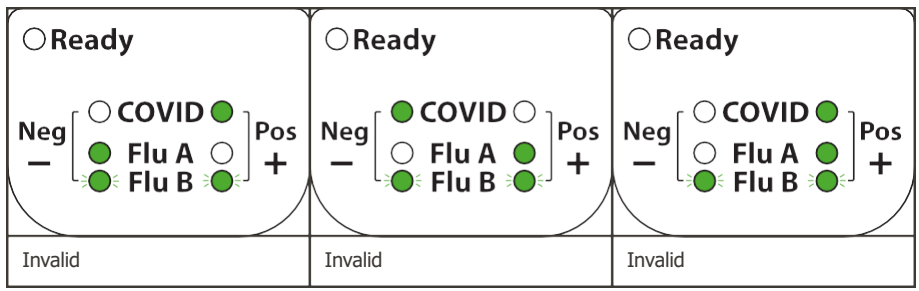
If any individual assay gives an invalid result, all results for that Test Unit should be considered invalid and testing should be repeated with a new Lucira by Pfizer COVID-19 & Flu Home Test.

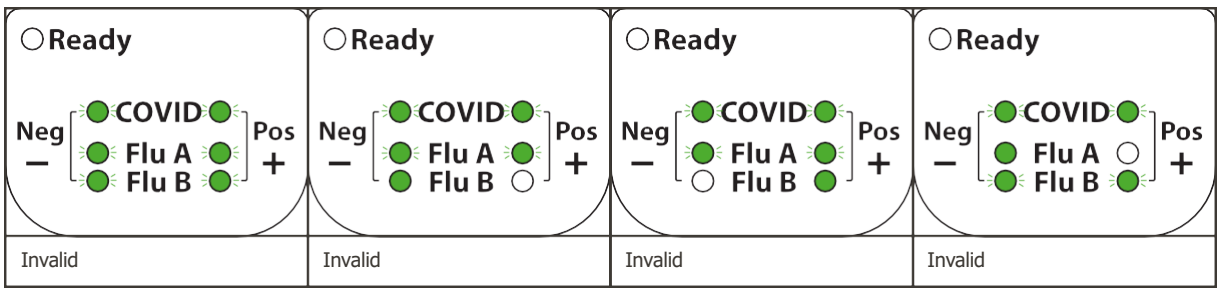


Covid-19, Flu A, Flu B — Invalid Results

If any individual assay gives an invalid result, all results for that Test Unit should be considered invalid and testing should be repeated with a new Lucira by Pfizer COVID-19 & Flu Home Test.







Section D – Quality Control Testing for Point of Care Settings

External run controls (ERCs) are not required to use this test kit.

Section E – Quality Systems Evaluation

The Quality Systems of the Lucira by Pfizer COVID-19 & Flu Home Test were independently evaluated. The evaluation has provided evidence to establish that the quality systems and manufacturing capability are likely to achieve the performance noted in this labeling.

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 to produce < 95% positive results for the virus. The preliminary LoD for the device was defined as the higher 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, performed the confirmation testing by each running ten (10) devices from one lot at the determined preliminary LoD concentration. Each virus produced ≥ 19/20 positive replicates, 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	4200
Flu B, Victoria Lineage	B/Colorado/6/2017	4330	1440
Flu B, Yamagata Lineage	B/Phuket/3073/2013	5070	1690

The LoD for SARS-CoV-2, Influenza A H3N2: A/HongKong/4801/2014, Influenza A H1N1pdm09: A/ Michigan/45/2015, Influenza B, Yamagata Lineage: B/Phuket/3073/2013 and Influenza B, Victoria Lineage: B/ Colorado/6/2017 were determined to be 1090, 1260, 3750, 5070 and 4330 Genome equivalent/swab (GE/swab), respectively. Additional studies confirmed the LoD as determined by preliminary results.

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 (Co-spike 1: Influenza A/Michigan/45/2015, Influenza B/ Colorado/6/2017 and SARS-CoV-2 and Co-spike 2: Influenza A/Hong Kong/4801/2014, Influenza B/ Phuket/3073/2013 and SARS-CoV-2) 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 tested per the instructions for use. The results demonstrated that ≥ 95% (for each of the three targets) 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 presence of all three target analytes in a specimen did not adversely affect the analytical sensitivity of the Lucira by Pfizer COVID-19 & Flu Home Test.

Table 7. Co-spike LoD Confirmation

Co-spike	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	38/40	39/40	40/40
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 assays was evaluated with 20 Influenza A strains (10 H1N1pdm09 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 supplier. 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 5574/2020	Alpha Variant	3275	3 / 3	100%
SARS-CoV-2 isolate 015421/2021	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 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 monthly from December 1, 2020 through January 15, 2023. As of April 15, 2021, all SARS-Cov-2 sequences uploaded to GISAID each month are downloaded and up to 50,000 sequences are sampled. Prior to the April 15, 2021 datapoint, all sequences uploaded that month were included in the analysis. For each sample, sequences were imported into Geneious and trimmed to remove ambiguous bases, filtering by length post-trim to ensure coverage of target regions. Geneious was then used to predict primer binding, and binding results were analyzed to apply reactivity rules. Reactivity for a set was defined as having at most one mismatch on a primer, and no mismatches within 5 nucleotides of the leading edge for each primer. A single nucleotide mismatch in one of the primers for LAMP assays is not expected to impact the limit of detection, unless it is in the leading end of the primer as previously demonstrated by work on MERS-CoV (PMID 25103205). Between December 1, 2020 and January 15, 2023, 1,068,203 sequences were analyzed and 99.97% were found to be reactive.

Table 11. SARS-CoV-2 Reactivity Results by Month

Sequence Dates	N	No. Passing Sequences	Percent Passing
Dec 1 – Dec 31, 2020	34,775	34,761	99.96%
Jan 1 – Jan 31, 2021	25,824	25,808	99.94%
Feb 1 – Feb 28, 2021	42,888	42,885	99.99%
Mar 1 – March 31, 2021	72,943	72,936	99.99%
Mar 15 – Apr 15, 2021	49,611	49,597	99.97%
Apr 15 – May 15, 2021	48,435	48,424	99.98%
May 15 – Jun 15, 2021	49,365	49,341	99.95%
Jun 15 – Jul 15, 2021	48,252	48,241	99.98%
Jul 15 – Aug 15, 2021	48,650	48,646	99.99%
Aug 15 – Sep 15, 2021	48,547	48,545	100.00%
Sep 15 – Oct 15, 2021	49,886	49,870	99.97%
Oct 15 – Nov 15, 2021	48,804	48,797	99.99%
Nov 15 – Dec 15, 2021	47,592	47,583	99.98%
Dec 15, 2021 – Jan 15, 2022	48,105	48,099	99.99%
Jan 15 – Feb 15, 2022	47,011	46,999	99.97%
Feb 15 – Mar 15, 2022	45,907	45,900	99.98%
Mar 15 – Apr 15, 2022	46,605	46,595	99.98%
Apr 15 – May 15, 2022	45,870	45,844	99.94%
May 15 – Jun 15, 2022	44,542	44,497	99.90%
Jun 15 – Jul 15, 2022	46,113	46,099	99.97%
Jul 15 – Aug 15, 2022	23,857	23,845	99.95%
Aug 15 – Sep 15, 2022	25,003	24,997	99.98%
Sep 15 – Oct 15, 2022	11,306	11,301	99.96%
Oct 15 – Dec 15, 2022	41,491	41,478	99.97%
Dec 15, 2022 – Jan 15, 2023	26,821	26,814	99.97%
All time points (Dec 1, 2020 to Jan 15, 2023)	1,068,203	1,067,902	99.97%

ii) SARS-CoV-2 Reactivity Results by Variant

For SARS-CoV-2, reactivity was also predicted for each Greek-letter variant monitored by WHO or CDC. Up to 10,000 sequences are sampled each month for each Greek-letter variant. Reactivity predictions based on established rules were tabulated by variant for the sample of SARS-CoV-2 sequences uploaded to GISAID between December 15, 2022, and January 15, 2023. The Lucira by Pfizer COVID-19 & Flu Home Test is predicted to be reactive to all variants identified. Specifically, within this dataset, 8776/8779 (99.97%) Omicron sequences were predicted to be reactive to the assay demonstrating that the Lucira by Pfizer COVID-19 & Flu Home Test is reactive to the Omicron variant.

Table 12. SARS-CoV-2 Reactivity Results by Variant

Variant	No. Sequences Downloaded (post-filter)	No. Sequences Reactive In-Silico (Percent)
Alpha	1854	1854 (100.00%)
Beta	44	44 (100.00%)
Delta	5800	5799 (99.98%)
Gamma	1098	1098 (100.00%)
Omicron	8779	8776 (99.997%)
Epsilon	51	51 (100.00%)
Eta	18	18 (100.00%)
Kappa	11	11 (100.00%)
Mu	1	1 (100.00%)
Zeta	238	238 (100.00%)
Total	17,894	17,890 (99.998%)

iii) Influenza Predicted Reactivity

Sequences were downloaded for each targeted segment for each subtype: A/H3N2, A/pH1N1, B/Victoria, and B/Yamagata. Sequences were imported to Geneious and trimmed to remove ambiguities, and then filtered by length to include only whole segment sequences. Primer binding with both primer sets was predicted using Geneious and results were analyzed using R to apply reactivity rules. Reactivity was defined as having at least one primer set with at most one SNP on each primer, and no SNPs within 5 nucleotides of the leading edge for each primer. All four subtypes had over 95% of sequences reactive for both the last year (December 2021 – January 2023) and the last 3 years (December 2019 – January 2023). All are also reactive to over 95% of sequences in the last 5 years (2017-2023).

Table 13. Predicted Reactivity per Influenza Target

Years	A/H3N2		A/pH1N1		B/Victoria		B/Yamagata	
	Reactive	N	Reactive	N	Reactive	N	Reactive	N
Dec 2016-Dec 2017	99.5%	5,754	98.7%	1,123	99.5%	1,447	99.6%	1,562
Dec 2017-Dec 2018	99.1%	4,097	96.8%	3,456	89.1%*	829	99.8%	3,335
Dec 2018-Dec 2019	98.4%	5,268	98.3%	4,746	93.9%	2,409	99.7%	675
Dec 2019-Dec 2020	97.4%	1,157	99.7%	2,976	97.8%	3,627	98.2%	112
Dec 2020-Dec 2021	98.1%	270	98.5%	194	99.2%	1,007	N/A	N/A
Dec 2021-Jan 2023	97.7%	15,062	95.5%	2,271	99.6%	531	N/A	N/A
Dec 2019-Jan 2023 [Last 3 years]	97.7%	16,489	98.0%	5,441	98.3%	5,165	98.2%	112
Dec 2017 – Jan 2023 [Last 5 years]	98.1%	25,854	97.8%	13,643	96.1%	8,403	99.7%	4,122

Years: Defined as Dec 1st of start year to Nov 30th of the end year. 2022 data covers through December 15, 2022.

*Wet testing confirmed assay performance with B/Colorado/6/2017 as reported in Table 10.

3) Cross-Reactivity (Analytical Specificity)

a) Wet Testing

The specificity of the assay was evaluated in cross-reactivity testing using 29 potential pathogens or commensal organisms. 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. As shown below, the cross-reactivity testing confirmed that none of the organisms were cross-reactive with the Lucira by Pfizer COVID-19 & Flu Home Test at the concentrations tested.

Table 14. Cross-Reactivity Results

Microbial Target	Test Concentration	COVID-19 (# POS / # Tested)	Flu A (# POS / # Tested)	Flu B (# POS / # Tested)	Cross-Reactive
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
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
Adenovirus C1	3.09E+08 TCID50/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
Respiratory Syncytial Virus -B	4.57E+06 TCID50/mL	0/3	0/3	0/3	No
Human Metapneumovirus (hMPV)	4.17E+05 TCID50/mL	0/3	0/3	0/3	No
Rhinovirus 1A	2.20E+07 PFU/mL	0/3	0/3	0/3	No
Candida albicans	4.76E+08 CFU/mL	0/3	0/3	0/3	No
Chlamydia pneumoniae	1.25E+07 IFU/mL	0/3	0/3	0/3	No
Haemophilus influenzae	6.97E+08 CFU/mL	0/3	0/3	0/3	No
Legionella pneumophila	1.91E+10 CFU/mL	0/3	0/3	0/3	No
Streptococcus pneumoniae	1.34E+09 CFU/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
Pseudomonas aeruginosa	6.90E+08 CFU/mL	0/3	0/3	0/3	No
Streptococcus salivarius	1.20E+08 CFU/mL	0/3	0/3	0/3	No
Staphylococcus epidermidis	1.40E+08 CFU/mL	0/3	0/3	0/3	No
Human Coronavirus 229E	5.62E+04 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
Human Coronavirus HKU1*	5.50E+04 Copies/uL	0/3	0/3	0/3	No
Pneumocystis jirovecii	1.00E+08 Nuclei/mL	0/3	0/3	0/3	No
SARS-COV-1	3.33E+07 PFU/mL	0/3	0/3	0/3	No
MERS-coronavirus	8.90E+05 TCID50/mL	0/3	0/3	0/3	No
Mycobacterium tuberculosis	1.15E+08 CFU/mL	0/3	0/3	0/3	No

* Human Corona HKU1 synthetic RNA was used due to unavailability of virus.

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

Microbial Target	Test 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 (2019-nCoV/USA-WA1/2020)	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.

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 for any target analyte. SARS-CoV-1 has > 80% homology on individual primers for SARS-CoV-2 and *Candida albicans* and *Streptococcus salivarius* have > 80% homology on individual primers for Influenza A and were tested and found not to have microbial interference, as shown in Table 18.

Table 16. 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 epidermidis	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 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

N.A.F. – No Alignment Found. Percentages indicate percent homology to primers with alignments.

4) Microbial Interference

a) Competitive Interference by Viral Panel Analytes

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 17. Competitive Microbial Interference 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 (2019-nCoV/ USA-WA1/2020)	A/HK, B/Ph	3/3 positive	3/3 positive	3/3 positive	No

b) Interference by Other Microorganisms

Microbial interference was evaluated using 29 potential pathogens or commensal organisms. For each organism, nasal swabs were spiked with 35 µL of each individual test microorganism and 35 µL of a co-spike of SARS-CoV-2, Influenza A (A/Hong Kong/4801/2014) and B (B/Phuket/3073/2013) viral targets diluted in NNSM at 3X LoD final concentration of each virus. The swab was then eluted and run on the Lucira test.

The results showed that no microbial interference was detected.

Table 18. Microbial Interference by Other Microorganisms Results

Microbial Target	Test Concentration	COVID-19 (# POS / # Tested)	Flu A (# POS / # Tested)	Flu B (# POS / # Tested)	Interference Observed
Parainfluenza virus 1	1.26E+06 TCID50/mL	3/3	3/3	3/3	No
Parainfluenza virus 2	1.60E+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	3.09E+08 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
Rhinovirus 1A	2.20E+07 PFU/mL	3/3	3/3	3/3	No
Candida albicans	4.76E+08 CFU/mL	3/3	3/3	3/3	No
Chlamydia pneumoniae	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 CCU/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 epidermidis	1.40E+08 CFU/mL	3/3	3/3	3/3	No
Human Coronavirus 229E	5.62E+04 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
Human Coronavirus HKU1*	5.50E+04 Copies/uL	3/3	3/3	3/3	No
Pneumocystis jirovecii	1.00E+08 Nuclei/mL	3/3	3/3	3/3	No
SARS-COV-1	3.33E+07 PFU/mL	3/3	3/3	3/3	No
MERS-coronavirus	8.90E+05 TCID50/mL	3/3	3/3	3/3	No
Mycobacterium tuberculosis	1.15E+08 CFU/mL	3/3	3/3	3/3	No

* Human Corona HKU1 synthetic RNA was used due to unavailability of virus.

5) Endogenous/Exogenous Interference Substances Studies

Endogenous interference studies were conducted to assess potential interference effects on the 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 (A/Hong Kong/4801/2014) virus, Influenza B (B/Phuket/3073/2013) virus, and SARS-CoV-2 (2019-nCoV/USA-WA1/2020) 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 results were obtained. As shown in below, none of the substances tested showed interference effects with the assay.

Table 19. 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
Chloraseptic 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	5 mg/mL	Pass	Pass	Pass	No
Tobrex	2.43mg/mL	Pass	Pass	Pass	No
Biotin	3.5 μg/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	12 mg/mL	Pass	Pass	Pass	No
Tamiflu	6 mg/mL	Pass	Pass	Pass	No
NeilMed Nasal Gel	1.25% (v/v)	Pass	Pass	Pass	No

6) Surrogate Sample Testing Study

The Surrogate Sample study compared Lucira by Pfizer COVID-19 & Flu Test performance to that of FDA cleared or authorized comparator methods using samples that were collected in Viral Transport Medium (VTM) and used to prepare contrived specimens for testing. A total of 425 samples were evaluated, and the comparator assays were performed as per the cleared or authorized IFU.

The following performance was achieved using the Lucira by Pfizer COVID-19 & Flu test authorized for use in a POC setting:

- SARS-CoV-2: 97.3% positive percent agreement (107/110) and 99.7% negative percent agreement (295/296)
- Flu A: 98.4% positive percent agreement (60/61) and 100% negative percent agreement (347/347)
- Flu B: 95.3% positive percent agreement (41/43) and 99.7% negative percent agreement (363/364)

Table 20. Surrogate Study Results

Sample Category	Comparator (PCR)					Success	PPA 95% Wilson CI		Success	NPA 95% Wilson CI	
	Positive		Negative								
	Lucira		Lucira		N	Total N			Total N		
	Pos	Neg	Pos	Neg							
SARS-CoV-2	107	3	1	295	406	107	97.3%		295	99.7%	
						110	92.3%	99.1%	296	98.1%	99.9%
Flu A	60	1	0	347	408	60	98.4%		347	100%	
						61	91.3%	99.7%	347	98.9%	100%
Flu B	41	2	1	363	407	41	95.3%		363	99.7%	
						43	84.5%	98.7%	364	98.5%	100%

7) Usability and User Comprehension Study

Human Usability testing was conducted 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 by Pfizer COVID-19 & Flu Home 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 Study

Clinical performance of the Lucira by Pfizer COVID-19 & Flu Home Test was evaluated at seven (7) study sites. Prospective anterior nasal samples were collected from subjects with signs and symptoms consistent with respiratory infection in the US during the 2022-2023 flu season. Sample collection and testing was performed in a simulated-home environment per the Lucira by Pfizer COVID-19 & Flu Home Test instructions.

Each patient sample was tested using the Lucira by Pfizer COVID-19 & Flu Home Test and a PCR method as the comparator assay (FDA emergency use authorized SARS-CoV-2 molecular assay and FDA cleared Influenza A&B molecular assay). The comparator samples were collected by the HCP as indicated in the comparator assay IFU. The Lucira by Pfizer COVID-19 & Flu Home Test was compared against results from the comparator assays.

For prospective specimens, a total of one thousand one hundred sixty-five (1165) subjects were enrolled in the study. One (1) participant withdrew prior to specimen collection and three (3) subjects were excluded due to previous participation. A total of one thousand one hundred sixty-one (1161) samples were evaluated in the performance analysis.

Of the total participants, nine hundred fifty-two (952) participants were evaluated for SARS-CoV-2 results (two hundred-nine (209) samples were assessed ineligible, 195 of which did not have comparator results), one thousand sixty-five (1065) samples were evaluated for Influenza A results (ninety-six (96) samples were assessed as ineligible, 82 of which did not have comparator results) and one thousand sixty-five (1065) samples were evaluated for Influenza B results (ninety-six (96) samples were assessed as ineligible, 82 of which did not have comparator result). Compared to the comparator assay, the Lucira by Pfizer COVID-19 & Flu Home Test demonstrated positive agreement of 88.3% and 90.0% for SARS-CoV-2 and Influenza A, respectively; and negative agreement of 100.0%, 99.3% and 99.9% for SARS-CoV-2, Influenza A, and Influenza B, respectively. No samples positive for Influenza B were collected during the study.

Table 21. Prospective Study Results

Sample Category	Comparator				N	Success	PPA 95% Wilson CI		Success	NPA 95% Wilson CI	
	Positive Lucira		Negative Lucira			Total N			Total N		
	Pos	Neg	Pos	Neg							
Covid (Total)	83	11	0	858	952	83	88.3%		858	100.0%	
						94	80.2%	93.3%	858	99.6%	100.0%
Flu A (Total)	108	12	7	938	1065	108	90.0%		938	99.3%	
						120	83.3%	94.2%	945	98.5%	99.6%
Flu B (Total)	0	0	1	1064	1065	0	NA		1064	99.9%	
						0	NA	NA	1065	99.5%	100.0%

8) 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 Pfizer (Lucira) 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 by Pfizer COVID-19 & Flu Home Test and obtain the expected results.

Table 22. 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 23. 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

LIMITATIONS

- Performance was evaluated with nasal 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 the test has not been established in individuals who received nasal administered Influenza vaccine. Individuals who received nasal administered Influenza A vaccine may have positive Influenza A test results for up to three days after vaccination. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr57e717a1.htm
- 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 of SARS-CoV-2 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.
- There is a higher chance of false-negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
- Performance characteristics for Influenza A were established with clinical specimens collected during the 2022 influenza season when H3N2 was the predominant influenza A virus subtype in circulation. When other influenza A viruses are emerging, performance characteristics may vary.
- Influenza B performance was assessed by testing surrogate samples only; it was not assessed by testing natural influenza B positive clinical samples.

TECHNICAL ASSISTANCE

Contact Pfizer at 1-888-LUCIRA-4 (582-4724).

REFERENCES

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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.
2	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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