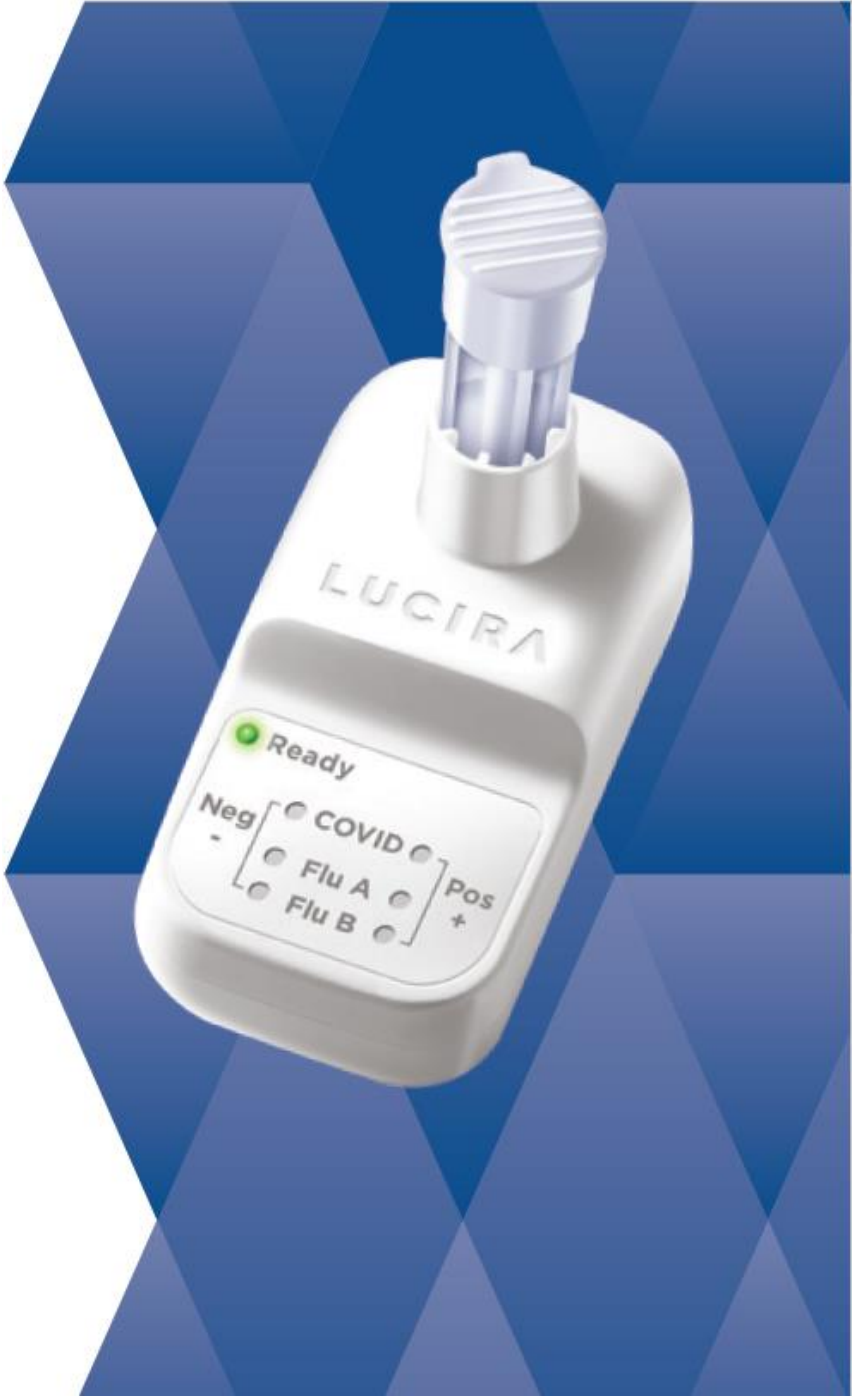
LUCIRA®

by Pfizer

COVID-19 & Flu Test

Nucleic Acid Amplification Test (NAAT)



Pfizer

Table of Contents

Lucira® by Pfizer COVID-19 & Flu Test

Instructions for Use

For Use under Emergency Use Authorization (EUA) only
For *in vitro* Diagnostic Use
Rx Only

Intended Use

The Lucira by Pfizer COVID-19 & Flu Test is a single-use (disposable) RT-LAMP test kit intended for the simultaneous rapid *in vitro* qualitative detection and differentiation of SARS-CoV-2, Influenza A, and Influenza B viral RNA in anterior nasal swab specimens collected from individuals (2 years of age or older) who are suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and Influenza can be similar.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived complexity tests. The Lucira by Pfizer COVID-19 & Flu Test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the simultaneous detection and differentiation of SARS-CoV-2, Influenza A, and Influenza B viral RNA in clinical specimens and is not intended to detect Influenza C virus. SARS-CoV-2, Influenza A, and Influenza B viral RNA is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2, Influenza A, and/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 pathogens not detected by the test. The agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Negative results for SARS-CoV-2 and Influenza B are presumptive and should be confirmed with an alternative molecular FDA-cleared or authorized assay, if necessary for patient management. Negative results do not preclude SARS-CoV-2, Influenza A, and/or Influenza B infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information.

The Lucira by Pfizer COVID-19 & Flu Test is intended for use by operators who have received specific training in the use of the Lucira by Pfizer COVID-19 & Flu Test. The Lucira by Pfizer COVID-19 & Flu 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 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 anterior 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 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 use under FDA Emergency Use Authorization (EUA) only.
- For in vitro diagnostic use.
- For prescription use only.
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- 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 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.
- Do not try to disassemble the Lucira by Pfizer COVID-19 & Flu Test device.
- 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.
- Dispose of components and patient samples according to all local regulations. 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 other tests.
- It is important to clean the workspace to remove any environmental contamination. Prior to testing, wipe the testing area with a sanitizing wipe (such as SaniCloth cleaning wipes) or 10% bleach solution.
- Treat all biological specimens, including used Lucira by Pfizer COVID-19 & Flu Test devices, as if capable of transmitting infectious agents. Follow universal precautions when handling patient samples. All patient samples should be treated as potentially infectious.
- Use of gloves is recommended when handling patient samples. If gloves are not available, wash and thoroughly dry your hands to prevent any sample contamination.
- External run controls (ERCs) are not required to use this test but are available for purchase from suppliers. See Section D below.

SECTION A - Reagents and Materials

Lucira® by Pfizer 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” (12.5 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 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.

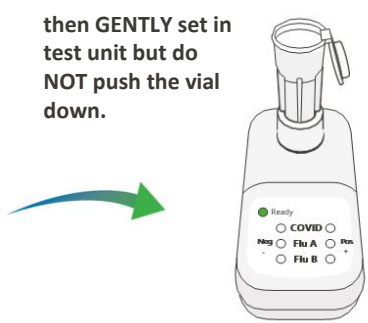
- Wash and dry hands.

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.

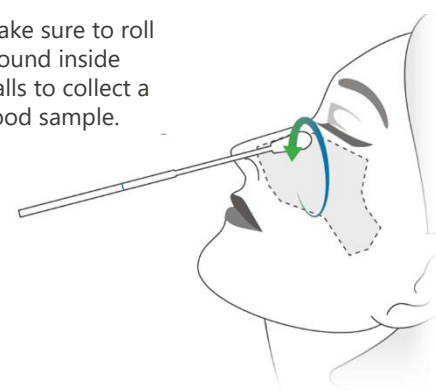
2. Swab Both Nostrils

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 the individual's nostril** and you meet resistance.
- Once swab tip is fully inside nostril, **roll the swab 5 times around the inside walls of the 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.



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.

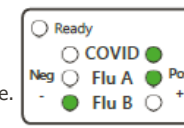
- Do not move test unit once the test has started running.

Wait 30 minutes.

4. Read Result

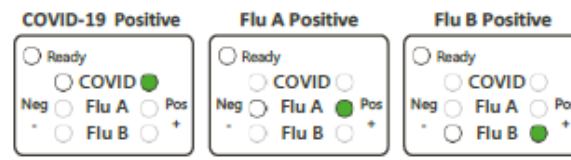
- Ready light will continue blinking while the test is running.
- Positive results may display before the test is done running.
- Results may be positive for more than one virus.
- Ready light will turn off and all results for COVID-19, Flu A, and Flu B will display in 30 minutes when test is done.

Example Result: Positive for COVID-19 and Flu A; Negative for Flu B.
Do not report results until the Ready light has stopped blinking, indicating the test is complete.
See Section C for all possible results.



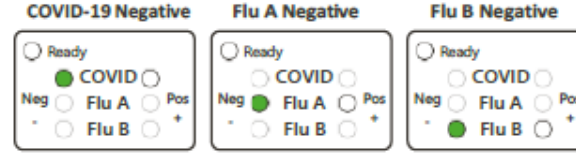
⊕ POSITIVE Results

Positive results light up on the right



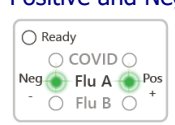
⊖ NEGATIVE Results

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.

If you receive any invalid results, retest with a new test or contact Pfizer at 1-888-LUCIRA-4 (582-4724). Contact Pfizer if result is invalid upon retesting.

LUCI PASS is a verified digital record of this test result. After taking this test, the individual can make a LUCI PASS for personal use if you invite them to:
1)Use their smartphone camera app to scan the QR code on the top of the test unit OR on the box 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 the test individual has 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).

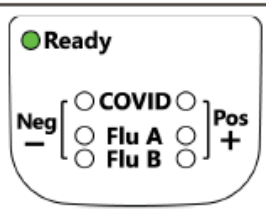
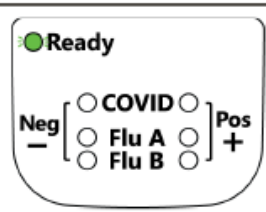
If the test is NEGATIVE

Negative test results for COVID-19 and flu B are presumptive and should be confirmed using an alternate molecular diagnostic test, if clinically indicated. A negative result means the virus that causes COVID-19 (if the test result is negative for COVID-19) or flu (if the test result is 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 the tested individual could possibly still have COVID-19 or flu even though the test is negative. If this is the case, the test result with all other aspects of the individual's history such as symptoms and possible exposures should be used to decide care.

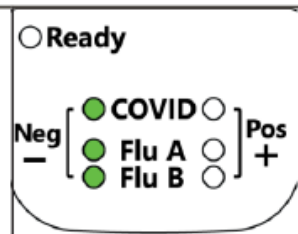
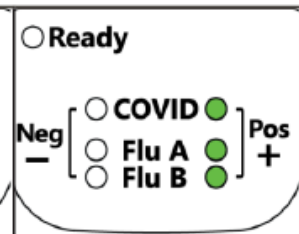
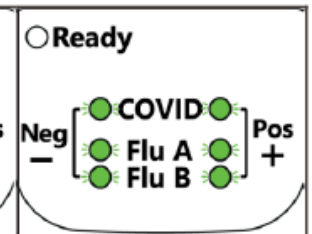
5. Dispose of Test

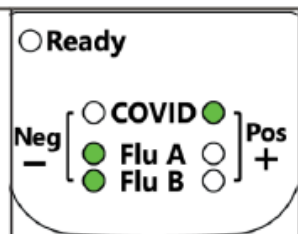
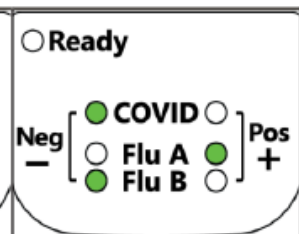
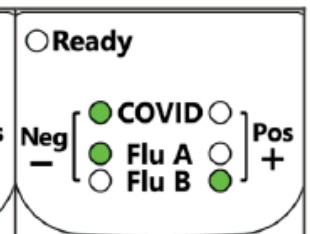
After test is completed, remove the batteries, place the test unit in plastic disposal bag, and dispose of all materials in accordance with local regulations. Do not allow the test unit to come into contact or be disposed of with bleach, as harmful gases could be emitted as a result.

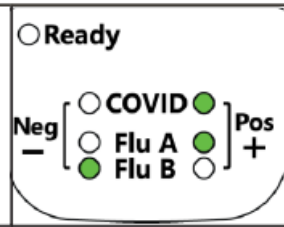
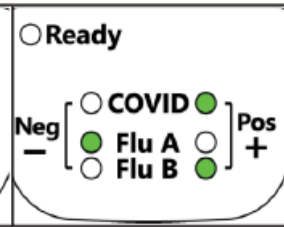
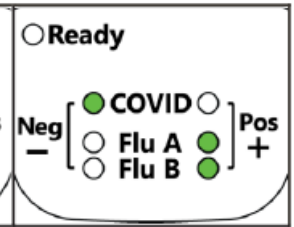
Section C - Test Unit Result Display

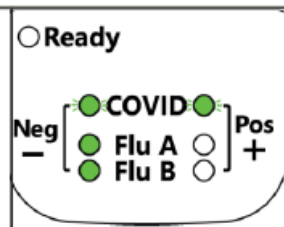
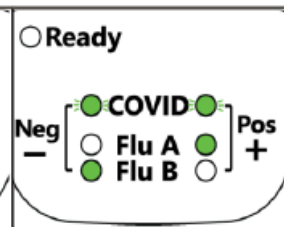
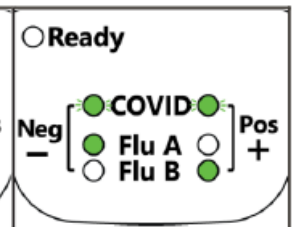
	
Test is ready to be run	Test is running

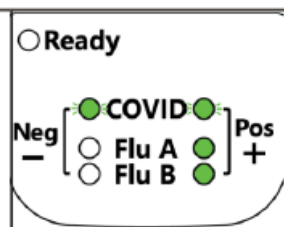
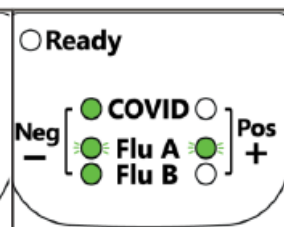
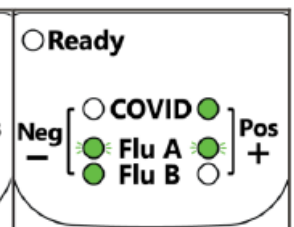
 Blinking/flashing

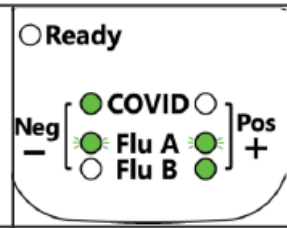
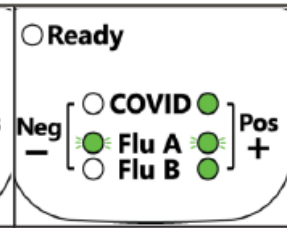
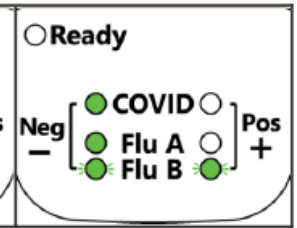
			
COVID-19	Negative	Positive	Invalid
Flu A	Negative	Positive	Invalid
Flu B	Negative	Positive	Invalid

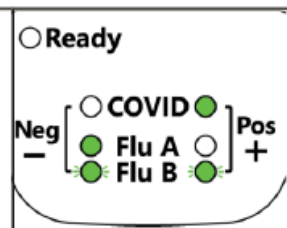
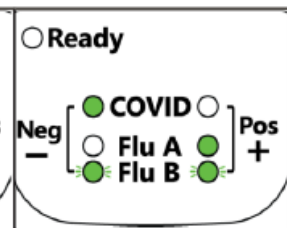
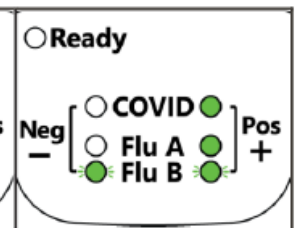
			
COVID-19	Positive	Negative	Negative
Flu A	Negative	Positive	Negative
Flu B	Negative	Negative	Positive

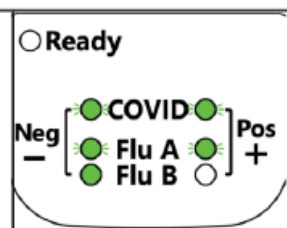
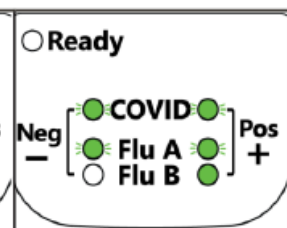
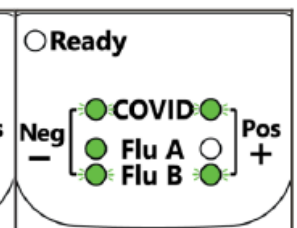
			
COVID-19	Positive	Positive	Negative
Flu A	Positive	Negative	Positive
Flu B	Negative	Positive	Positive

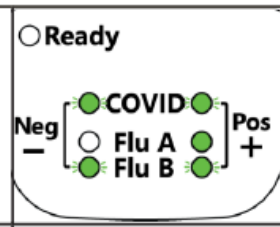
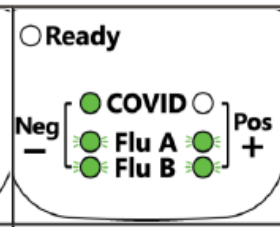
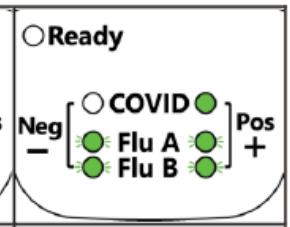
			
COVID-19	Invalid	Invalid	Invalid
Flu A	Negative	Positive	Negative
Flu B	Negative	Negative	Positive

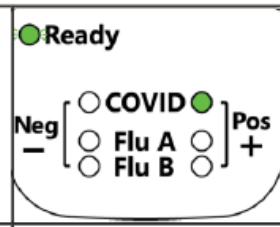
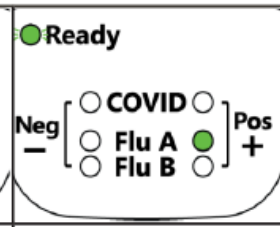
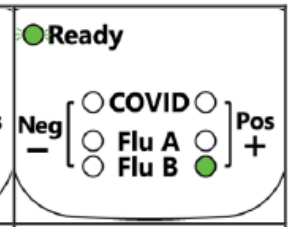
			
COVID-19	Invalid	Negative	Positive
Flu A	Positive	Invalid	Invalid
Flu B	Positive	Negative	Negative

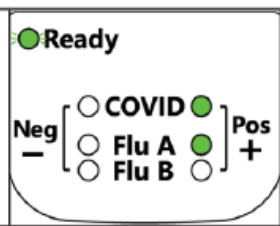
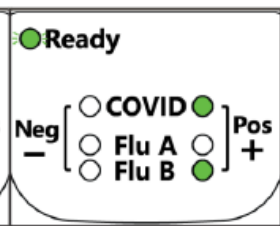
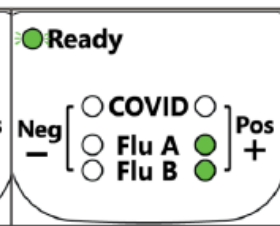
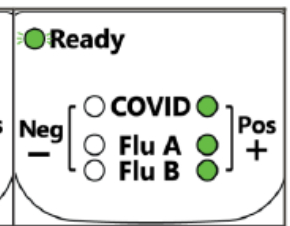
			
COVID-19	Negative	Positive	Negative
Flu A	Invalid	Invalid	Negative
Flu B	Positive	Positive	Invalid

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

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

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

			
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	Positive	Not available yet	Positive
Flu A	Positive	Not available yet	Positive	Positive
Flu B	Not available yet	Positive	Positive	Positive

Section D - Quality Control Testing for Point of Care Settings

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

In certain point of care or CLIA Waiver laboratory settings, ERCs may be tested, regularly or when new test kits are received, in order to train new operators, or to conform with local regulations, accrediting groups, or the lab's standard Quality Control procedures. Pfizer recommends the use of commercially available positive and negative external run controls from Microbiologics (Catalog No. 8246). Instructions to use these controls with the Lucira by Pfizer COVID-19 & Flu Test kit are provided below:

1. Always test negative control before positive control to avoid any template contamination.
2. Tear open pouch at notch. Remove swab from pouch.
3. Run Swab on the Lucira by Pfizer COVID-19 & Flu Test per standard Package Insert.

If the correct control results are not obtained, repeat the control tests. Results from the repeated assay(s) must be acceptable to proceed. If acceptable results are not obtained, do not perform patient tests or report patient results and contact your distributor for Technical Support before testing new patient specimens.

Keep External Run Control Swabs stored per manufacturer instructions until control testing is performed. Do not use beyond manufacturer labeled expiry date. Each swab can be used 1 time.

Section E - Conditions of Authorization for the Laboratory

The Lucira by Pfizer COVID-19 & Flu Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas.

However, to assist clinical laboratories using the Lucira by Pfizer COVID-19 & Flu Test, the relevant Conditions of Authorization are listed below:

- Authorized laboratories[1] using the Lucira by Pfizer COVID-19 & Flu Test must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using Lucira by Pfizer COVID-19 & Flu Test must use Lucira by Pfizer COVID-19 & Flu Test as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use Lucira by Pfizer COVID-19 & Flu Test are not permitted.
- Authorized laboratories that receive the Lucira by Pfizer COVID-19 & Flu Test must notify the relevant public health authorities of their intent to run the Lucira by Pfizer COVID-19 & Flu Test prior to initiating testing.
- Authorized laboratories using the Lucira by Pfizer COVID-19 & Flu Test must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must collect information on the performance of the Lucira by Pfizer COVID-19 & Flu Test and report to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (1-888-582-4724) any suspected occurrence of false-positive or false-negative results and significant deviations from the established performance characteristics of the Lucira by Pfizer COVID-19 & Flu Test of which they become aware.
- All operators using the Lucira by Pfizer COVID-19 & Flu Test must be appropriately trained in performing and interpreting the results of the Lucira by Pfizer COVID-19 & Flu Test, use appropriate personal protective equipment when handling this kit, and use the Lucira by Pfizer COVID-19 & Flu Test in accordance with the authorized labeling.
- Pfizer, authorized distributors, and authorized laboratories using the Lucira by Pfizer COVID-19 & Flu Test must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

[1]The letter of authorization refers to, “laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived complexity tests. The Lucira by Pfizer COVID-19 & Flu Test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation” as “authorized laboratories.”

Section F - Quality Systems Evaluation

The Quality Systems of the Lucira by Pfizer COVID-19 & Flu 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 $\geq$ 19/20 positive replicates, confirming the LoD for each virus.

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 (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 $\geq$ 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 presence of all three target analytes in a specimen did not adversely affect the analytical sensitivity of the Lucira by Pfizer COVID-19 & Flu Test.

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 1 through 3 below.

Table 1. 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	3275	3 / 3	100%
SARS-CoV-2 isolate 015421/2021	3275	3 / 3	100%
SARS-CoV-2 isolate hCoV-19/USA/MD-HP05285/2021	3275	3 / 3	100%
SARS-CoV-2 strain 2019-nCoV/USA-WA1/2020	3275	3 / 3	100%

Table 2. 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 3. 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 October 15, 2022. 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, 2021 and October 15, 2022, 999,891 sequences were analyzed and 99.97% were found to be reactive.

Table 4. 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%
All time points (Dec 1, 2021 to Oct 15, 2022)	999,891	999,610	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 September 15, 2022, and October 15, 2022. The Lucira by Pfizer COVID-19 & Flu Test is predicted to be reactive to all variants identified. Specifically, within this dataset, 7,329 of 7,336 (99.90%, CI: 99.80-99.96%) Omicron sequences were predicted to be reactive to the assay demonstrating that the Lucira by Pfizer COVID-19 & Flu Test is reactive to the Omicron variant.

Table 5. SARS-CoV-2 Reactivity Results by Variant

Variant	No. Sequences Downloaded (post filter)	No. Sequences Reactive In Silico (Percent)
Alpha	463	463 (100.00%)
Beta	11	11 (100.00%)
Delta	1,235	1,235 (100.00%)
Epsilon	18	18 (100.00%)
Eta	197	197 (100.00%)
Gamma	14	14 (100.00%)
Iota	4	4 (100.00%)
Lambda	1	1 (100.00%)
Mu	25	25 (100.00%)
Omicron	7,336	7,329 (99.90%)
Zeta	2	2 (100.00%)
Total	9,306	9,299 (99.92%)

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 – September 2022) and the last 3 years (December 2019 – September 2022). All are also reactive to over 95% of sequences in the last 5 years (2017-2022).

Table 6. Predicted Reactivity per Influenza Target

	A/H3N2		A/pH1N1		B/Victoria		B/Yamagata	
Years	**Reactive**	**N**	**Reactive**	**N**	**Reactive**	**N**	**Reactive**	**N**
2016-2017	99.5%	5,754	98.7%	1,123	99.5%	1,447	99.6%	1562
2017-2018	99.1%	4,097	96.8%	3,456	89.1%*	829	99.8%	3335
2018-2019	98.4%	5,268	98.3%	4,746	93.9%	2,409	99.7%	675
2019-2020	97.4%	1,157	99.7%	2,976	97.8%	3,627	98.2%	112
2020-2021	98.1%	270	98.5%	194	99.2%	1,007	N/A	N/A
2021-2022	98.1%	11,760	96.4%	1,057	99.6%	259	N/A	N/A
2019-2022 Last 3 years	98.0%	13,187	98.8%	4,227	98.2%	4,893	98.2%	112
2017-2022 Last 5 years	98.3%	22,552	98.1%	12,429	96.0%	8,131	99.7%	4,122

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

*Wet testing confirmed assay performance with B/Colorado/6/2017 as reported in Table 3.

3) Cross-Reactivity (Analytical Specificity)

a) Wet Testing

The specificity of the assay was evaluated in cross-reactivity testing using 26 potential pathogens or 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 by Pfizer COVID-19 & Flu 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 Test at the concentrations tested.

Table 7. 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 pneumoniae	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 epidermidis	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 8. 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 11.

Table 9. 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 10. 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

Based on the cross-reactivity testing and *in silico* sequence alignment above, any organism that had ≥ 80% homology to any primer binding region in the assays was evaluated for competitive inhibition testing. SARS-CoV-1 was identified as the only microorganism with potential to interfere with the performance of the assay for SARS-CoV-2. *Candida albicans* and *Streptococcus salivarius* were identified as the only potential microorganisms with potential to interfere with the performance of the assay for Influenza A. No microorganisms were identified with potential to interfere with the assay for Influenza B.

To evaluate potential interference for these identified potential interfering organisms, swabs were co-spiked with the microorganism in question and the target microorganism at 3X LoD. The results showed that no microbial interference was detected.

Table 11. Competitive Inhibition Results

Anchor Strain spiked at 3X LoD	Potential interfering Microbe spiked at high concentration	Concentration of potential interfering microbe	COVID-19 Assay Results (# Pos/ # Tested)	Flu A Assay Results (# Pos/ # Tested)	Flu B Assay Results (# Pos/ # Tested)
A/Hong Kong/4801/2014	*Candida albicans*	4.76E+08 CFU/mL	0/3	3/3	0/3
	Streptococcus salivarius	1.20E+08 CFU/mL	0/3	3/3	0/3
SARS-Cov-2 (2019-nCoV/USA-WA1/2020)	SARS-CoV-1	1.00E+08 PFU/mL	3/3	0/3	0/3

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 (H3N2) virus, Influenza B (Yamagata Lineage) 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 12. 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 device 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:

- 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 13. Surrogate 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							
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) Clinical Study

Clinical performance of the Lucira by Pfizer COVID-19 & Flu 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.

Each patient sample was tested using the Lucira by Pfizer COVID-19 & Flu 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 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-six (1066) 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 Test demonstrated positive agreement of 88.3% and 90.1% 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 14. Prospective Study Results

Sample Category	Comparator				N	Success / Total N	PPA 95% Wilson CI		Success / Total N	NPA 95% Wilson CI	
	Positive Lucira		Negative Lucira								
	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)	109	12	7	938	1066	109	90.1%		938	99.3%	
						121	83.5%	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 Test and obtain the expected results.

Table 15. 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 16. 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

9) Electromagnetic Compatibility

The Device has been tested and found to be appropriate for use. 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 Pfizer 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 meters, 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 anterior 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.htmh
- 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.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens for Flu A. No clinical samples for Flu B have been tested as per the IFU.
- Detection of the endogenous internal control indicates that human nucleic acid is present and implies that human biological material was collected and successfully extracted and amplified. It does not necessarily indicate that the specimen is of appropriate quality to enable detection of SARS-CoV-2 or influenza A/B.
- Performance characteristics for influenza A were established when influenza A/H3 and A/H1 were the predominant influenza A viruses in circulation. When other Influenza A viruses are emerging, performance characteristics may vary.
- If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.
- The detection of viral sequences is dependent upon proper specimen collection, handling, transportation, storage and preparation (including extraction). Failure to observe proper procedures in any one of these steps can lead to incorrect results. There is a risk of false-negative values resulting from improperly collected, transported, or handled specimens.

TECHNICAL ASSISTANCE

Contact Pfizer at 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. The batteries should be removed from the test unit before disposal and handed in for recycling in accordance with local environment regulations for battery disposal.
	Test unit should be disposed of separately from household waste and recycled. You must dispose of the Lucira by Pfizer COVID-19 & Flu Test properly according to local laws and regulations. Once the batteries are removed, the test unit should be placed in the disposal bag and handed in for recycling in accordance with local environment regulations for disposal of electrical and electronic equipment.
	Type BF applied part.
℞ Only	For Prescription Use Only.

Pfizer Inc.
181 Oyster Point Blvd., South San Francisco, CA 94080
United States

CYAN | MAGENTA | YELLOW | BLACK | PMS 361

UNFOLD

LUCIRA™ by Pfizer

COVID-19 & Flu Test

Nucleic Acid Amplification Test (NAAT)

SWAB STIR DETECT

The Lucira by Pfizer COVID-19 & Flu Test is for FDA Emergency Use Authorization (EUA) only

For Prescription Use Only
For In Vitro Diagnostic (IVD) Use

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- 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.
- For more information on EUAs go here: **https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization**

For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

Detailed instructions for point of care use (IFU) may be obtained at no additional cost at:

www.lucirahealth.com/IFU

or by calling Pfizer at 1-888-LUCIRA-4 (582-4724)

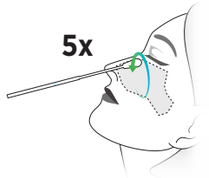
Package Insert (PI) INST037 Rev. B

Frequently Asked Questions

Please Read Instructions on Reverse

What tips will help me use the nasal swab correctly? How do I make sure I am getting a good sample?

It is important to roll the swab around the inside walls of both nostrils. You want the swab to be touching and rubbing around the inside walls as you rotate.



Rotating the swab 5 times around the inside walls of both nostrils is very important for the test to work properly.

What are the known and potential risks and benefits of this test?

Potential risks include:

- Possible discomfort during sample collection.
- Possible incorrect test results.

Potential benefits include:

- The results, along with other information, can help the healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 and flu to the family of the tested individual and others in your community.

What if the display shows an invalid test result?

This means something with the test did not work properly. If the test has any invalids, the Positive and Negative lights will be blinking when the test is done in 30 minutes. If the test shows an invalid result, please retest or contact Pfizer at 1-888-LUCIRA-4 (582-4724). Contact Pfizer if result is invalid upon retesting.

What is influenza A & B?

The two most common types of influenza are influenza A & B. This test tests for both of these types of flu. If the test is positive for either Influenza A (Flu A) or Influenza B (Flu B), the tested individual has the flu.

How accurate is this test?

The Lucira by Pfizer COVID-19 & Flu test was compared to an FDA-authorized known high sensitivity SARS-CoV-2 PCR test and an FDA-cleared known high sensitivity Influenza A and B PCR test. Please refer to the IFU at **www.lucirahealth.com/IFU** for complete data.

Can this test detect new SARS-CoV-2 variants and Flu strains?

Pfizer performs routine surveillance of emerging SARS-CoV-2 and Influenza strains and will continue to monitor the situation with emerging variants. A technical brief that lists SARS-CoV-2 variants and flu strains to which the Lucira test is reactive is available at **lucirahealth.com**

LUCIRA™ by Pfizer

COVID-19 & Flu Test

Nucleic Acid Amplification Test (NAAT)

Test only works if you follow each step

Open for instructions

Intended Use

The Lucira by Pfizer COVID-19 & Flu Test is a single use (disposable) RT-LAMP test kit intended for the simultaneous rapid in vitro qualitative detection and differentiation of SARS-CoV-2, Influenza A, and Influenza B viral RNA in anterior nasal swab specimens collected from individuals (2 years of age or older) who are suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and Influenza can be similar.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived complexity tests. The Lucira by Pfizer COVID-19 & Flu Test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the simultaneous detection and differentiation of SARS-CoV-2, Influenza A, and Influenza B viral RNA in clinical specimens and is not intended to detect Influenza C virus. SARS-CoV-2, Influenza A, and Influenza B viral RNA is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2, Influenza A, and/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 pathogens not detected by the test. The agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Negative results for SARS-CoV-2, and Influenza B are presumptive and should be confirmed with an alternative molecular FDA-cleared or authorized assay, if necessary for patient management. Negative results do not preclude SARS-CoV-2, Influenza A, and/or Influenza B infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information.

The Lucira by Pfizer COVID-19 & Flu Test is intended for use by operators who have received specific training in the use of the Lucira by Pfizer COVID-19 & Flu Test. The Lucira by Pfizer COVID-19 & Flu Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Description

This Lucira by Pfizer COVID-19 & Flu Test contains everything needed to perform one (1) Lucira by Pfizer COVID-19 & Flu Test: Instructions, 2 AA Batteries, 1 test unit, 1 sample vial, 1 sterile nasal swab and 1 disposal bag. For this test to work properly, it is important to read the instructions and follow each step.

Instructions - Start Here

- **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 use for LUCI PASS.**
- 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

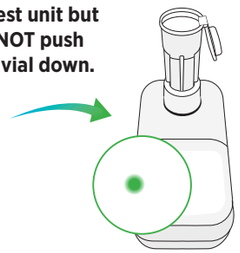
- When ready to begin test, open test unit pouch 1.

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.

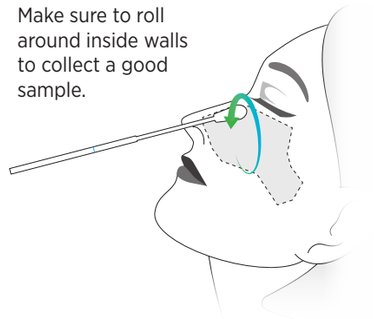
2 Swab Both Nostrils

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

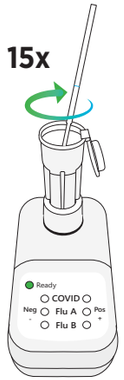
- Remove swab and hold with handle end. Do not set swab down.
- Tilt head back and **gently insert swab tip until it is fully inside the individual's nostril** and you meet resistance.
- Once swab tip is fully inside nostril, **roll the swab 5 times around the inside walls of the nostril. The swab should 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.



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.

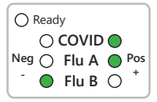
- Do not move test unit once the test has started running.

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.
- 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 & Flu A; Negative for Flu B. Do not report results until the Ready light has stopped blinking, indicating the test is complete.



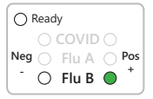
POSITIVE Results

Positive results light up on the right

COVID-19 Positive

Flu A Positive

Flu B Positive



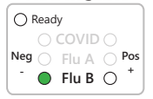
NEGATIVE Results

Negative results light up on the left

COVID-19 Negative

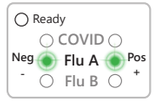
Flu A Negative

Flu B Negative



INVALID Results

Positive and Negative lights flash 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.

If you receive any invalid results, retest with a new test or contact Pfizer at 1-888-LUCIRA-4 (582-4724). Contact Pfizer if result is invalid upon retesting.

LUCI PASS is a verified digital record of this test result. After taking this test, the individual can make a LUCI PASS for personal use if you invite them to:
1) Use their smartphone camera app to scan the QR code on the top of the test unit OR on the box 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 the test individual has 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).

If the test is NEGATIVE

Negative test results for COVID-19, flu A and flu B are presumptive and should be confirmed using an alternative molecular diagnostic test, if clinically inidcated. A negative result means the virus that causes COVID-19 (if the test result is negative for COVID-19) or flu (if the test result is negative for flu A & flu B) was not found in the 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 the tested individual could possibly still have COVID-19 or flu even though the test is negative. If this is the case, the test result with all other aspects of the individual's history such as symptoms and possible exposures should be used to decide care.

5 Dispose of Test

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

External Run Controls (ERCs) are not required to use this test. ERCs may be tested, regularly or when new tests are received, in order to train new operators, or to conform with local regulations, accrediting groups, or the lab's standard Quality Control produces. Reference the complete IFU for more information.