LUCIRA® by Pfizer

Expand testing capabilities

with LUCIRA® by Pfizer COVID-19 & Flu Test

Emergency Use Authorized

Pfizer

May 2024 PP-LIA-USA-0267

Intended For Payor Audience Only

Picture for illustrative purposes only.
Please see Package Insert instructions for proper handling and usage.

Emergency Use Authorization

The LUCIRA® by Pfizer COVID-19 & Flu Test 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. 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.

Indication For Use

The LUCIRA® by Pfizer COVID-19 & Flu Test is authorized for the simultaneous 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. Emergency use of this test is limited to authorized laboratories. 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. This 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.

Please see all authorized device labeling at
LUCIRAbyPfizer.com/hcp/labeling.

LUCIRA® by Pfizer COVID-19 & Flu Test:

PCR-quality accuracy* at the point of care for COVID-19, Flu A, and Flu B[1]

List Price
$ 83.90
Based on orders of 24

Offer molecular testing and PCR-quality accuracy* for ages 2 and up

The LUCIRA® by Pfizer COVID-19 & Flu Test, a device that uses RT-LAMP amplification technology, provides a level of accuracy comparable to highly sensitive lab-based PCR tests.

Expand with untethered convenience

You can take this cordless device to various point of care settings, expanding to areas you haven't considered before.

Onboard seamlessly

No capital investment (ie, central lab or supplies), extensive training, or ongoing calibration required.

Test for 3 viruses with a single swab

The LUCIRA® by Pfizer COVID-19 & Flu Test can detect and differentiate **COVID-19**, **Flu A**, and **Flu B** to help inform your clinical care plan, including treatment if appropriate.

Get results in 30 minutes

A positive result may show in as few as **11 minutes**, while a negative or invalid result will display in **30 minutes**.†

Swab, stir, and detect

Test in 3 steps with an easy-to-read display.

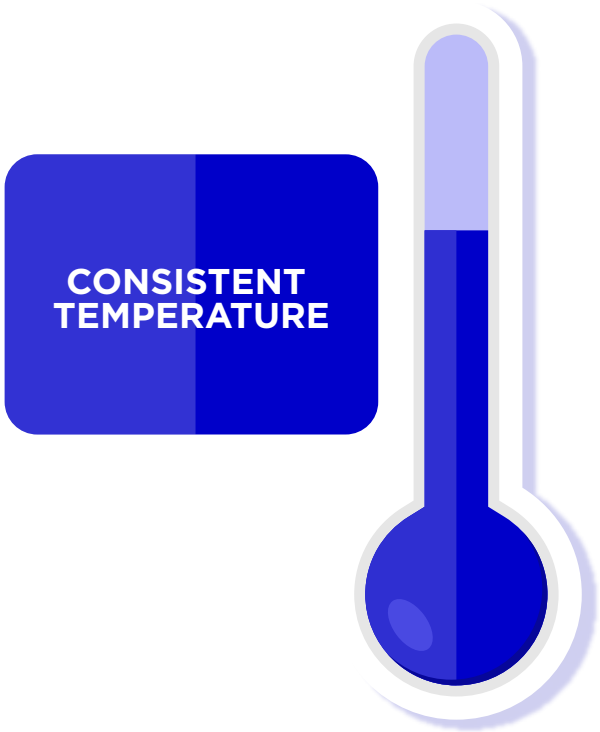
*The LUCIRA® by Pfizer COVID-19 & Flu Test provides a level of accuracy comparable to highly sensitive lab-based polymerase chain reaction (PCR) tests. Negative results do not preclude SARS-CoV-2, influenza A, and/or influenza B infection and should not be used as the sole basis for patient management decision.
†Full results appear in 30 minutes. Negative results should be confirmed with further testing, if clinically indicated.

Reference: 1. LUCIRA® by Pfizer for COVID-19 & Flu Test. Instructions for use. Pfizer Inc; 2023.

LUCIRA® by Pfizer COVID-19 & Flu Test leverages advanced nucleic acid amplification technology, similar to RT-PCR[1]

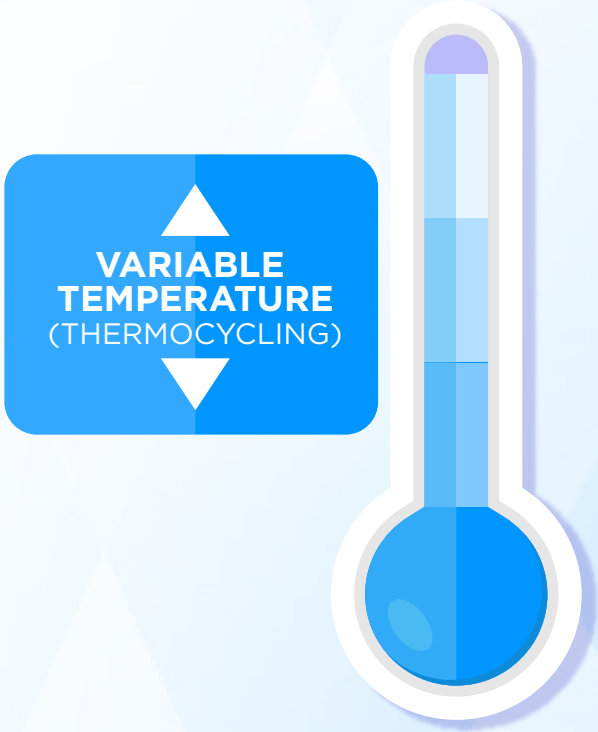
RT-LAMP[1]

RT-LAMP detects target viral RNA, creates cDNA via reverse transcription, and then amplifies the resulting cDNA. LUCIRA® by Pfizer COVID-19 & Flu Test performs nucleic acid amplification at **one consistent temperature**.



RT-PCR[2,3]

RT-PCR assays identify target viral RNA, convert it into cDNA through reverse transcription, and then amplify the cDNA by cycling **through various temperatures**.



The LUCIRA® by Pfizer COVID-19 & Flu Test provides a level of accuracy* comparable to highly sensitive lab-based PCR tests[1]

General attributes of test types do not imply specific product claims or specific product comparative claims.

*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.[1]

cDNA, complementary DNA; RNA, ribonucleic acid; RT-LAMP, reverse-transcription loop-mediated isothermal amplification; RT-PCR, reverse transcription polymerase chain reaction.

Reference: 1. LUCIRA® by Pfizer for COVID-19 & Flu Test. Instructions for use. Pfizer Inc; 2023.

LUCIRA® by Pfizer COVID-19 & Flu Test performance comparable to highly sensitive lab-based PCR tests in a head-to-head clinical trial and a surrogate study[1]

The **Surrogate Sample Testing Study** compared LUCIRA® by Pfizer COVID-19 & Flu Test performance to that of FDA-cleared or -authorized comparator methods.

Samples were collected in viral transport medium 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 Instructions for Use (IFU).

Surrogate Sample Testing Study Results

	Positive Percent Agreement	Negative Percent Agreement
COVID-19 *(Total=406)*	**97.3%** *(n=107/110; 95% CI: 92.3%-99.1%)*	**99.7%** *(n=295/296; 95% CI: 98.1%-99.9%)*
Influenza A *(Total=408)*	**98.4%** *(n=60/61; 95% CI: 91.3%-99.7%)*	**100%** *(n=347/347; 95% CI: 98.9%-100%)*
Influenza B *(Total=407)*	**95.3%** *(n=41/43; 95% CI: 84.5%-98.7%)*	**99.7%** *(n=363/364; 95% CI: 98.5%-100%)*

The surrogate study found

>95%

positive agreement for COVID-19, influenza A, and influenza B, and **close to 100%** negative agreement for all viruses

Reference: 1. LUCIRA® by Pfizer for COVID-19 & Flu Test. Instructions for use. Pfizer Inc; 2023.

LUCIRA® by Pfizer COVID-19 & Flu Test performance comparable to highly sensitive lab-based PCR tests in a head-to-head clinical trial and a surrogate study[1]

The **Prospective Sample Study** evaluated clinical performance of the LUCIRA® by Pfizer COVID-19 & Flu Test at 7 U.S. study sites during the 2022-2023 flu season. 1161 anterior nasal swab samples were evaluated after collection from subjects with signs and symptoms consistent with respiratory infection.

LUCIRA® by Pfizer COVID-19 & Flu Test performance was evaluated using samples collected by participants. Comparator assay test (FDA EUA SARS-CoV-2 molecular assay and FDA-cleared influenza A and B molecular assay) samples were collected by a healthcare professional as indicated in the IFUs.

Prospective Study Results

	Positive Percent Agreement	Negative Percent Agreement
COVID-19 *(Total=952)*	**88.3%** *(n=83/94; 95% CI: 80.2%-93.3%)*	**100%** *(n=858/858; 95% CI: 99.6%-100%)*
Influenza A *(Total=1066)*	**90.1%** *(n=109/121; 95% CI: 83.5%-94.2%)*	**99.3%** *(n=938/945; 95% CI: 98.5%-99.6%)*
Influenza B *(Total=1065)*	**N/A*** *(n=0/0)*	**99.9%** *(n=1064/1065; 95% CI: 99.5%-100%)*

The prospective study found

>88%

positive agreement for COVID-19 and influenza A and **close to 100%** negative agreement for COVID-19, influenza A, and influenza B

*No positive samples for influenza B were collected during the study due to low levels of influenza B in circulation at the time.

Reference: 1. LUCIRA® by Pfizer for COVID-19 & Flu Test. Instructions for use. Pfizer Inc; 2023.

Requesting reimbursement is simple

Use CPT Code 87636QW for combined COVID-19, Flu A, and Flu B molecular tests like LUCIRA® by Pfizer COVID-19 & Flu Test[1-3]

COVID-19 + Flu A/B combined molecular tests

CPT Code[1]
87636

CPT Description

Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique

Modifiers[2]
QW*

Modifier Description

QW modifier must be used when billing for tests performed in facilities with a CLIA certificate of waiver.

*The **QW** modifier must be added to **87636** to denote that the LUCIRA® by Pfizer COVID-19 & Flu Test diagnostic test is being conducted in your office setting and not in a traditional lab setting. Please ensure that when billing for LUCIRA® by Pfizer COVID-19 & Flu Test, the code **87636QW** is used.[2,3]

CLIA, Clinical Laboratory Improvement Amendments of 1988; CPT, Current Procedural Terminology.

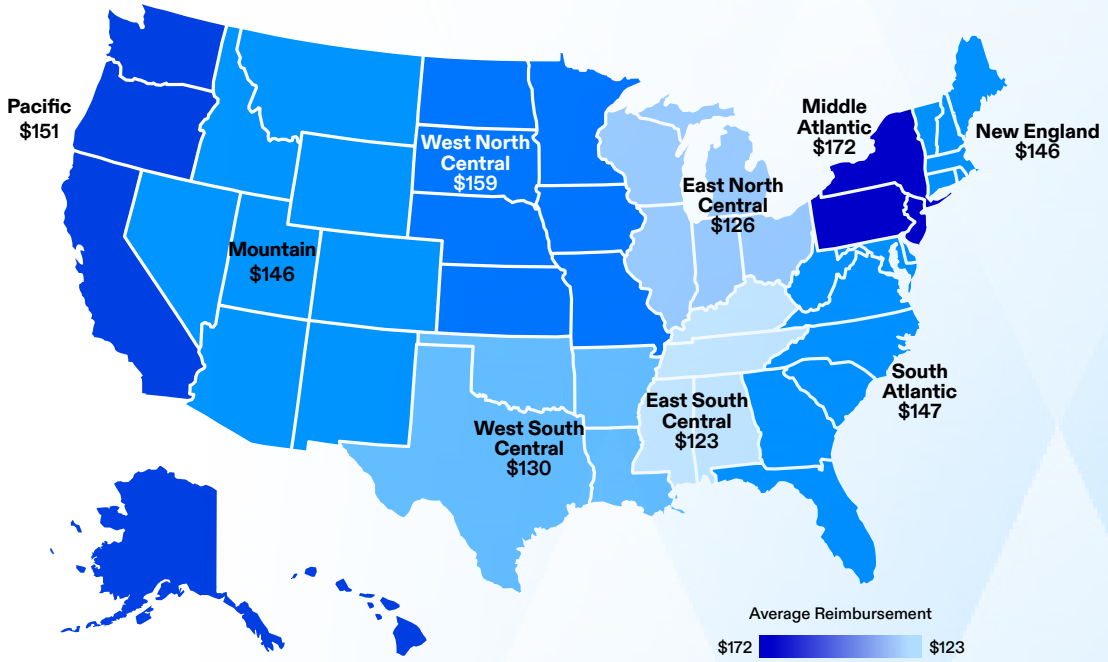
References: 1. American Medical Association (AMA). Accessed April 16, 2024. https://www.ama-assn.org/press-center/press-releases/new-cpt-codes-multi-virus-tests-detect-covid-19-and-flu **2.** Centers for Medicare and Medicaid Services (CMS). Accessed April 16, 2024. https://www.cms.gov/files/document/mm12269.pdf **3.** LUCIRA® by Pfizer. Accessed April 16, 2024. https://www.lucirabypfizer.com/hcp/using-the-test

Reimbursement for LUCIRA® by Pfizer COVID-19 & Flu Test

2024 CMS Rate[1]

$142.63

Mean commercial reimbursement[2] for the most common molecular complex at the point of care (CPT 87636QW) ranges from **$123 to $172**



CPT, Current Procedural Terminology; CMS, Centers for Medicare & Medicaid Services.

References: 1. Centers for Medicare & Medicaid Services (CMS). Accessed April 29, 2024. https://www.cms.gov/files/document/mac-covid-19-test-pricing.pdf **2.** Analysis of Milliman's Consolidated Health Sources Database (Jan-Aug 2023).