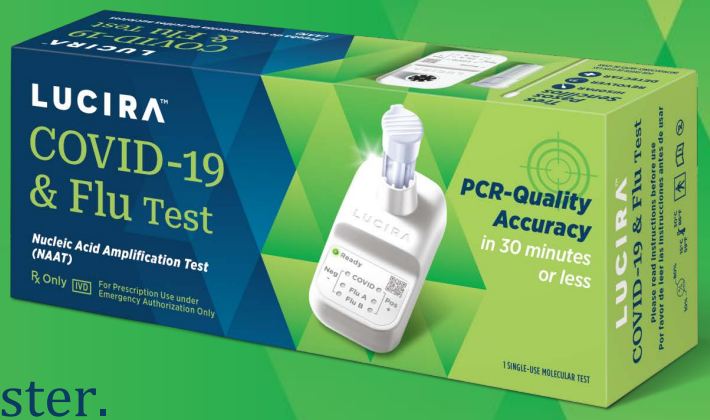
LUCIRA™

The **Only** All-in-One Molecular COVID-19 & Flu Test that delivers **PCR-Quality Accuracy**



Get your patients to better. Faster.

PERFORMANCE

PCR-quality compared to high-cōmplexity lab PCR tests

SPEED

Positive results in as little as 11 minutes; negative results confirmed in 30 minutes

IMPLEMENTATION

No calibration, controls, or training required

DESIGN

No instrument, reader, plug, or connectivity

Lucira COVID-19 & Flu Test performed comparably in head-to-head clinical trial and surrogate studies compared to highly sensitive lab-based PCR

Lucira COVID-19 & Flu Surrogate Sample Testing Study Results	Positive Percent Agreement (PPA)	Negative Percent Agreement (NPA)
COVID-19	98.2% (108/110)	100.0% (296/296)
Influenza A	100.0% (59/59)	99.7% (347/348)
Influenza B	97.6% (40/41)	99.5% (363/365)

PPA = Positive Percentage Agreement NPA = Negative Percentage Agreement

Competitors: Roche cobas SARS-CoV-2 Test and Quidel Lyra Influenza A+B Assays

Lucira COVID-19 & Flu Prospective Clinical Study Results	Positive Percent Agreement (PPA)	Negative Percent Agreement (NPA)
COVID-19 *(Study 1)*	94.1% (48/51)	98.0% (49/50)
COVID-19 *(Study 2)*	100.0% (2/2)	100.0% (235/235)
Influenza A	91.4% (32/35)	99.8% (422/423)
Influenza B	N/A* (0/0)	100.0% (240/240)

* Minimal Influenza B in circulation during the clinical trial period

Instructions For Use (IFU) INST032 Rev. A Lucira Health, Inc. 1412 62nd Street, Emeryville, CA 94608 United States

Co-circulating COVID-19 & Flu require a fast, accurate, differential test to treat effectively

Is it COVID or Flu?	Rapid antigen	PCR	Lucira
Get the answers NOW	*		●
Get an ACCURATE answer		●	●
Get the answer ANYWHERE	●		●

* 15-minute run-time, however, **unlikely** to detect COVID-19 until day 3+ of symptoms

Empiric treatment or sequential testing may delay treatment beyond the effective window

Applicable Covid-19 & Flu Test Related CPT Codes

Code	Descriptor	CMS Allowable
87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique.	$51.31 (Q4-2022)
87636	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	$142.63 (Q4-2022)

Where is the swab collected?

During E/M-in person visit	Office or Group Practice Testing Site	Independent Testing Site
N/A *(included in E/M)*	99211 99000** *(if code requirements are met)*	99211 99001** *(If code requirements are met)*

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.

CLIAwaived™ Inc. The Point-of-Care Marketplace

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