CLIAwaived™ Inc.
The Point-of-Care Marketplace

LUCIRA™

COVID-19 & FLU TEST

Is it Covid or Flu?

Know for sure. Know now.

Lucira is the only *all-in-one molecular* COVID-19 & flu test that delivers **PCR-quality accuracy** in 30 minutes or less

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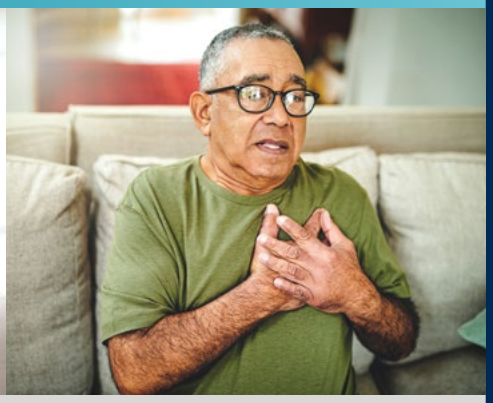
It's Not *"Just the Flu"*

Lower respiratory infections are the world's most deadly communicable disease and rank as the **4th leading cause of death**.

https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death



Children + Flu

Influenza can **kill 100 or more children** in the US per year in a bad flu season.

https://www.cdc.gov/flu/weekly/index.htm

Diabetes + Flu

3X more likely to be **hospitalized**

4X more likely to be **admitted to the ICU**

https://diabetesjournals.org/care/article/33/7/1491/39391/Diabetes-and-the-Severity-of-Pandemic-Influenza-A
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7780362/

Cardiac Issues + Flu

10X more likely to have a ***first*** **heart attack**

8X more likely to have a ***first*** **stroke**

https://www.nejm.org/doi/full/10.1056/nejmoa1702090
https://erj.ersjournals.com/content/51/3/1701794.short

Both COVID-19 and influenza can cause significant inflammation, leaving people more susceptible to other infections or pathogens.

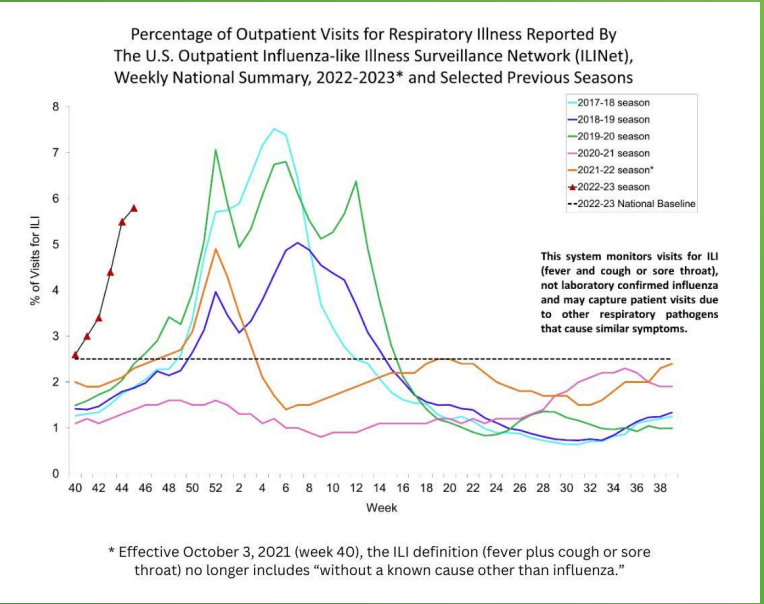
Prepare for a Difficult Flu Season

How bad could it be?

"Not since the 2009 H1N1 swine flu pandemic has there been such a high burden of flu, a metric the CDC uses to estimate a season's severity based on laboratory-confirmed cases, doctor visits, hospitalizations and deaths."

Lack of exposure to the flu virus during the COVID-19 pandemic has resulted in **lowered immunity** in the population, and **reduced masking** and **decreased social distancing** could increase transmission.

https://www.washingtonpost.com/health/2022/10/28/flu-season-2022-cdc/



* Effective October 3, 2021 (week 40), the ILI definition (fever plus cough or sore throat) no longer includes "without a known cause other than influenza."

Is it Covid? Flu? Both?

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

Is it COVID or Flu?	Rapid Antigen	PCR	Lucira
Get an **ACCURATE** answer		🔴	🟢
Get the answer **NOW**	*		🟢
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 prescribing appropriate treatment beyond effective window.

COVID-19 and flu have many of the same symptoms. **Testing** is required to confirm a diagnosis and treat the illness. The Lucira test can also detect if someone has Covid and flu at the same time.

https://www.cdc.gov/flu/symptoms/flu-vs-covid19.htm

Know for sure.

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 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

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)

Competitors: Roche cobas SARS-CoV-2 Test and Quidel

Know now.

The Lucira COVID-19 & Flu Test detects positives in as little as **11 minutes** and confirms results in 30 minutes.

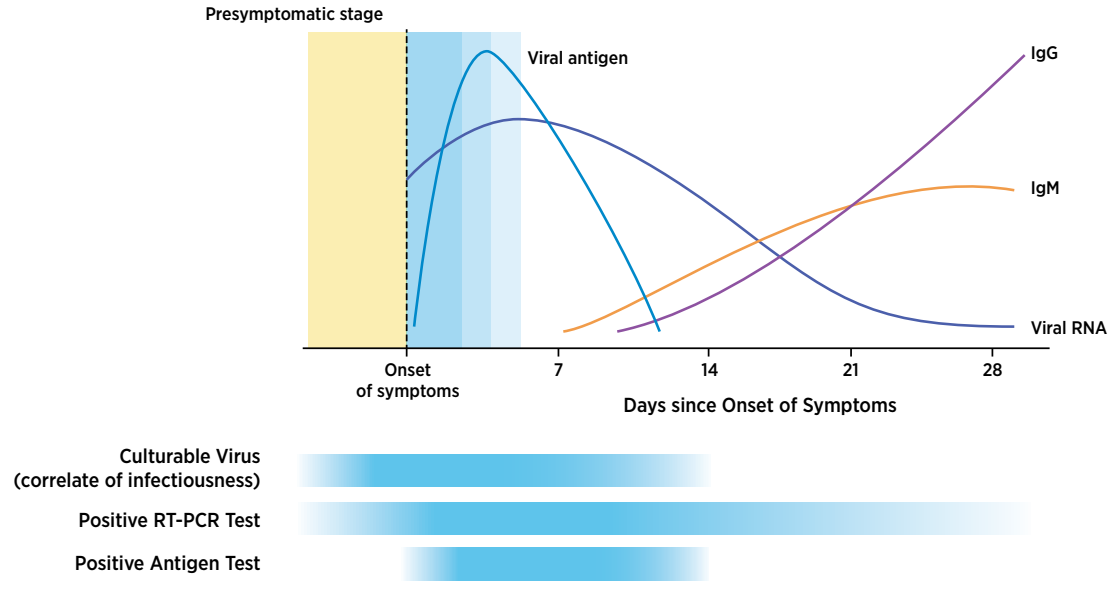
Treatment of Covid & flu must begin **2-5 days from symptom onset.** Antigen tests can take too long to detect, PCR test results can arrive too late.

With Lucira, you do not have to wait days for results, increasing the risk of viral transmission and possibly **missing the window of effective treatment.**

The NEW ENGLAND JOURNAL of MEDICINE

Rapid Diagnostic Testing for SARS-CoV-2

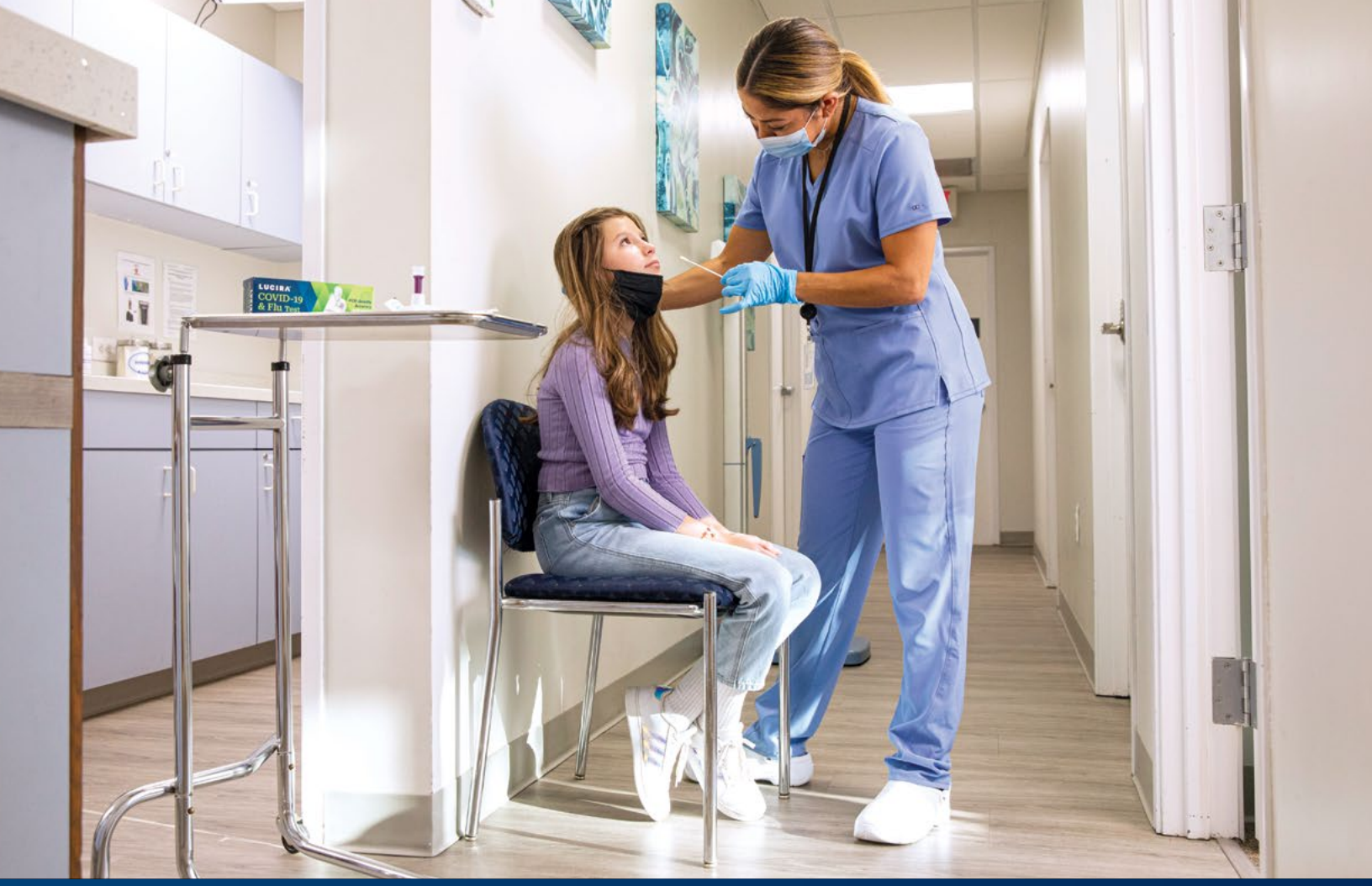
Pathophysiology and Timeline of Viremia, Antigenemia, and Immune Response during Acute SARS-CoV-2 Infection



Treatment must start within first few days of symptom onset

PCR tests can take too long to receive results

Rapid antigen tests can take too long to begin detecting



MOLECULAR TESTS ARE PROVEN TO BE

More Sensitive and Specific than Antigen Tests

Robust NIH-sponsored head-to-head study of at-home antigen tests and lab-based PCR assays PUBLICATION PENDING

Sensitivity	Symptomatic	Asymptomatic	Asymptomatic excluding singleton PCR+*
Starting day of PCR+ (D0)			
1 test, D0	59.6%	9.3%	11.7%
2 tests, D0 + D2	96.2%	39.3%	50.7%
3 tests, D0 + D2 + D4	93.6%	56.4%	74.6%
Aggregate of D0-6			
1 test	82.5%	34.2%	38.5%
2 tests, 48 hours	93.4%	55.6%	62.9%
3 tests, 96 hours	94.8%	68.8%	79.2%

* Singleton PCR+ is a single positive PCR test preceded and followed by negative PCR tests

Title: *Performance of Screening for SARS-CoV-1 2 using Rapid Antigen Tests to Detect Incidence of Symptomatic and Asymptomatic SARS-CoV-2 Infection: findings from the Test Us at Home prospective cohort study*[1]

Status: *Pre-print*, Funding: NIH, Timing: October 2021 to February 2022, N=7,361

RAPID ANTIGEN TEST SENSITIVITY:

- Single test symptomatic 60-83%; asymptomatic 9-34%
- 2 tests 48 hours apart symptomatic 92%
- 3 tests 96 hours apart asymptomatic 75-80%.

Practical Interpretation

If 150 people are screened with a single rapid antigen test and 15 of them are in their first week of a COVID infection...

Based on this study...

5 will have symptoms early in their infection / 10 will not have symptoms

1 of 5 symptomatic will test negative

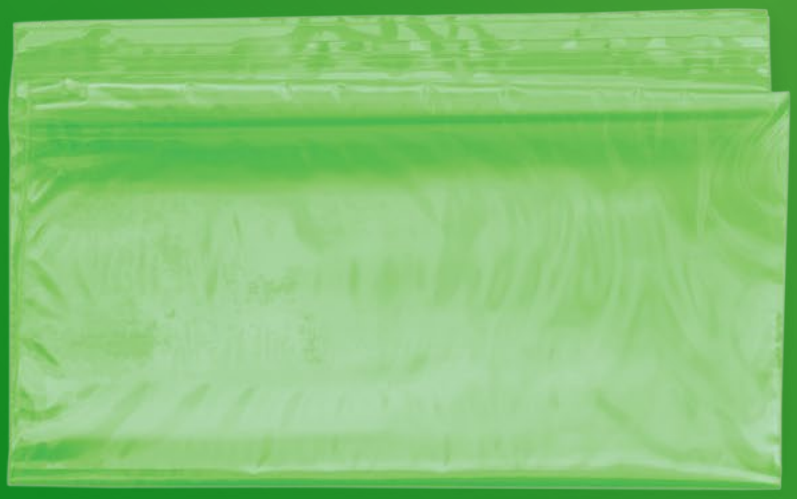
6 of 10 asymptomatic will test negative

7 of 15 infected people will be cleared by a screening protocol using 1 rapid antigen test

Reference:
1. Apurv, S. et al. (2022) Performance of Screening for SARS-CoV-1 2 using Rapid Antigen Tests to Detect Incidence of Symptomatic and Asymptomatic SARS-CoV-2 Infection: findings from the Test Us at Home prospective cohort study. MedRxiv. https://doi.org/10.1101/2022.08.05.22278466

All-in-One Design

This equipment-free platform requires no capital investment, calibration, or training. Each single use test can be run independently, allowing for unlimited simultaneous testing. Everything needed to run the Lucira COVID-19 & Flu Test comes in one box. Batteries included.



Lucira Technology

Laboratory quality in the palm of your hand

The Lucira test uses **RT-LAMP** which amplifies viral genetic material while the test is running. The amplification that occurs in PCR and the Lucira test allows molecular tests to detect a positive sample with greater sensitivity than antigen tests. As a result, ***Lucira's detection limit is comparable to high-sensitivity lab PCR tests.***

DESIGN FAIL-SAFES TRIGGER INVALIDS TO HELP MITIGATE FALSE RESULTS

- Lysis and positive control
- Signal intensity monitoring
- Temperature control monitoring
- Fluid fill-time monitoring
- Battery-life measurement
- Delayed start (humidity risk)
- Other device malfunctions

IT'S WHAT'S INSIDE THAT MATTERS

SCAN TO WATCH VIDEO

LUCIRA™

Covid-19 Molecular Test
Covid-19 & Flu Molecular Test

2022 Part B Provider Reimbursement Guide

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)

Part B Modifiers Used during the Covid-19 Public Health Emergency (PHE)

Modifier	Part B-1500 Form	Details	References
CS	Yes	Waives cost-sharing during the PHE • Should only be used for a medical visit that results in an order for or administration of a COVID-19 lab test • Should be applied to each applicable line on the claim that would result in patient responsibility	https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf
CR	Yes	Defined as "Catastrophe/disaster-related" • Should be used for Part B billing, both institutional and non-institutional (i.e., claims submitted using the ASC X12 837 professional claim format or paper Form CMS-1500 or, for pharmacies, in the NCPDP format) • This requirement does not apply for purposes of compliance with waivers (blanket or individual) of sanctions under the physician self-referral law	https://www.cms.gov/-files/document/summary-covid-19-emergency-declaration-waivers.pdf https://www.cms.gov/-files/document/se20011.pdf
95	Yes	Defined as "Synchronous Telemedicine Service Rendered via Real-Time Interactive Audio and Video Telecommunications System"	https://www.cms.gov/-files/document/se20016.pdf