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.
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://www.ncbi.nlm.nih.gov/pmc/articles/PMC789262/

Cardiac Issues + Flu
10X more likely to have a first heart attack
8X more likely to have a first stroke


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.

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.

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 accuracy is comparable to high-sensitivity lab PCR tests.

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

**Lucira Technology**

Know for sure.

Laboratory quality in the palm of your hand

**DESIGN FAIL-SAFES TRIGGER INVALIDS TO HELP MITIGATE FALSE RESULTS**

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

<table>
<thead>
<tr>
<th>Lucira COVID-19 &amp; Flu Prospective Clinical Study Results</th>
<th>Positive Percent Agreement (PPA)</th>
<th>Negative Percent Agreement (NPA)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COVID-19</strong>&lt;br&gt;(Study 1)</td>
<td>94.1% (48/51)</td>
<td>98.0% (49/50)</td>
</tr>
<tr>
<td><strong>COVID-19</strong>&lt;br&gt;(Study 2)</td>
<td>100.0% (2/2)</td>
<td>100.0% (236/236)</td>
</tr>
<tr>
<td><strong>Influenza A</strong></td>
<td>91.4% (32/35)</td>
<td>99.8% (422/423)</td>
</tr>
<tr>
<td><strong>Influenza B</strong></td>
<td>N/A* (0/0)</td>
<td>100.0% (240/240)</td>
</tr>
</tbody>
</table>

* Minimal Influenza B in circulation during the clinical trial period

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>COVID-19</strong></td>
<td>98.2% (108/110)</td>
<td>100.0% (266/266)</td>
</tr>
<tr>
<td><strong>Influenza A</strong></td>
<td>100.0% (59/59)</td>
<td>99.7% (347/348)</td>
</tr>
<tr>
<td><strong>Influenza B</strong></td>
<td>97.6% (40/41)</td>
<td>99.5% (363/365)</td>
</tr>
</tbody>
</table>

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.

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

![Graph showing the timeline of viremia, antigenemia, and immune response during SARS-CoV-2 infection.](image-url)
The Lucira COVID-19 & Flu Test detects positives in as little as 11 minutes and confirms negatives in 30 minutes. No waiting days for results and possibly missing the window of effective treatment.

Persons infected with SARS-CoV-2 are infectious days before antigen tests can detect the virus.

Effective treatment must begin within 5 days of symptom onset, which may be difficult if PCR test results are delayed.

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

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

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

Title: Performance of Screening for SARS-CoV-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

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

Reference:

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...

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

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
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 accuracy is comparable to high-sensitivity lab PCR tests.

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Lucira Technology 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**

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**Scan to Learn More**

IT’S WHAT’S INSIDE THAT MATTERS
Applicable Covid-19 & Flu Test Related CPT Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Descriptive</th>
<th>CMS Allowable</th>
</tr>
</thead>
<tbody>
<tr>
<td>87635</td>
<td>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.</td>
<td>$51.31 (Q4-2022)</td>
</tr>
<tr>
<td>87636</td>
<td>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</td>
<td>$142.63 (Q4-2022)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Part B-1500 Form</th>
<th>Details</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>CS</td>
<td>Yes</td>
<td>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</td>
<td><a href="https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf">https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf</a></td>
</tr>
<tr>
<td>CR</td>
<td>Yes</td>
<td>Defined as &quot;Catastrophe/disaster-related&quot; • 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</td>
<td><a href="https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf">https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf</a></td>
</tr>
</tbody>
</table>
Get your patients to better. Faster.