

## **pandemic response catalyst conversations:** **Innovations in Diagnostics and Detection on the Road to Re-densification** **Fact Sheet**

### **Which types of tests are currently available?**

As of mid-August, available tests include:

- **Molecular / PCR:** A **diagnostic** test that detects nucleic acid from the virus, often done via a nasal swab. This is **highly accurate** because it is most sensitive in looking for a fragment of the virus.
  - *Status:* All top 10 global diagnostic companies have launched a COVID-19 test. As of August 20, the U.S. has issued Emergency Use Authorization for [141 diagnostic tests and to 35 testing labs](#). Many of these tests are also available and approved for [use outside the U.S.](#)
- **Rapid / Antigen:** A **diagnostic** test that detects antigens from the virus, often done via nasal or throat swab. This is **highly accurate** but less sensitive and may require a second test to confirm negative results.
  - *Status:* As of August 20, there are only [two rapid antigen tests](#) with Emergency Use Authorization in the U.S. At the global level, only [38 are commercialized](#) but have seen limited overall adoption.
- **Serological / Antibody:** A test to see contact with the virus and potentially developed **immune response**, often done via blood testing. This has **limited accuracy** because it is least sensitive and often shows discrepancies with results from molecular / PCR test results.
  - *Status:* All major serology players are offering tests in this space. As of August 20, the U.S. has issued Emergency Use Authorization to [39 serology tests](#), but the FDA also explicitly identified [80 tests no longer to be made available](#) to the public due to poor performance.

### **What is the current scientific understanding of test accuracy and adoptability?**

According to Yves Dubaquie, head of diagnostics solutions at MilliporeSigma, “The PCR tests will not go away as the confirmatory tests, but the point-of-care testing – being able to test in other settings, decentralized and being faster to test results – is going to be important.”

The scientific outlook is that **molecular / PCR tests will remain the standard**, as they are the most sensitive and improvements are being made to these tests, such as using a nose swab rather than nasopharyngeal or point-of-care tests with isothermal amplification.

Test	Benefits	Considerations
<b>Molecular / PCR</b>	<ul style="list-style-type: none"> <li>• Highest accuracy and sensitivity</li> <li>• Simple to build</li> </ul>	<ul style="list-style-type: none"> <li>• Nasal swab can be challenging to run</li> </ul>
<b>Rapid / Antigen</b>	<ul style="list-style-type: none"> <li>• High accuracy and sensitivity</li> <li>• Potential for faster time to results with lateral flow</li> </ul>	<ul style="list-style-type: none"> <li>• May require confirmation of negative results</li> <li>• Longer process to make reagents</li> <li>• Fewer available in today's market due to issues explained above</li> </ul>
<b>Serological / Antibody</b>	<ul style="list-style-type: none"> <li>• Easy to develop</li> <li>• Blood draw can be easier to manage than nasal swabs</li> </ul>	<ul style="list-style-type: none"> <li>• Low sensitivity and specificity</li> <li>• Discrepancies with molecular / PCR test results</li> <li>• Uncertainty about relationship between antibody presence and future immunity to virus</li> <li>• Clinical utility undefined</li> <li>• <a href="#">FDA issued guidance</a> not to use for individual diagnostic decisions (only for convalescent plasma donor screening or surveillance / epidemiology)</li> </ul>

\*Visit the [FDA's](#) or [CDC's](#) webpages on coronavirus testing for further information.

### What role can digitalization play in detection and contact tracing?

According to Jim Harper, co-founder and chief operating officer at Sonde Health, "If you can augment the potential exposure [deduced from contact tracing] with the correlation of growth in symptoms, fusing this kind of data gives you additional actionability when it comes to population health – even prioritizing what will be in our limited resources for contact tracing and individual follow up."

**Vocal biomarkers** picked up by digital devices can be leveraged as a means of health assessment to assist in contact tracing efforts with Covid-19.

- **Vocal biomarker analysis** involves a health monitoring audio analysis technology and uses subtle changes in a person's voice to screen for everything from depression to cardiovascular problems.
- The goal is to extract **clinically meaningful health information** from everyday voice interactions people have on a range of devices they already own. See the Pandemic Response Supermind Activation's [Diagnostics and Monitoring report chapter](#) for more detailed proposals and exploration of digital contact tracing.



## How can scientists track indications of viral spread through genomic content?

According to Mariana Matus, CEO and co-founder of Biobot Analytics, “What we’re observing is that people are adopting different data streams, like the clinical Q-PCR testing; when they have access to it, antibody testing; random testing surveys, wastewater testing data, and then looking at it altogether, side-by-side to paint a better picture of what’s happening.”

**Wastewater epidemiology** research can help track viral spread in large populations by gathering Covid-19-related data from sewage.

- A [June 2020 study](#) determines that both symptomatic and asymptomatic individuals shed SARS-CoV-2 in their stool, and the viral RNA is present in high loads for a prolonged time:
  - Median initial fecal RNA load was 7.68 log<sub>10</sub> copies/mL and remained **steadily high** for **>3 weeks**.
  - Fecal positivity remained **≥80 percent**.
  - The median RNA load in fecal samples was **significantly higher** than that for nasopharyngeal swab specimens over time.
- An [April 2020 study](#) found that most frequent shedding occurs in infected individuals immediately after contracting the virus:
  - Shedding begins **approximately seven days** before exhibiting symptoms.
- [Wastewater analysis reports](#) of communities with Covid-19 show a correlation between **increased virus concentration** in wastewater and an **increase in new cases** in the following days.

### For more information:

Scientists are collaborating to source solutions to Covid-19 challenges on the Pandemic Response CoLab, an open platform from MIT’s Center for Collective Intelligence and Community Biotechnology Initiative. MilliporeSigma is a founding member of the online community, which works to harness collective intelligence and better address public health crises. Join the conversation and view the contributions at [www.PandemicResponseCoLab.org](http://www.PandemicResponseCoLab.org).