


# Coronavirus: How to tell if your misery was really COVID-19

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Was your recent fever, cough and unremitting phlegm just another routine illness, or was it COVID-19?

Stanford University hopes to offer an answer, as it races to expand manufacturing of its new coronavirus antibody test for use by the public within two months.

“Ultimately, we aspire to provide serological testing to as many people in Northern California as we can,” said Dr. Thomas Montine, professor and chair of pathology at the Stanford School of Medicine.

The serological test detects protective antibodies to the virus in a person’s blood stream, rather than the virus itself. This reveals whether you’ve been previously infected – and therefore may be immune to future infection.

Stanford is now able to test 500 samples per day. Its experts are identifying who will receive the test first, with health care workers and other hospital staffers getting priority.

What’s limiting more widespread use, said Montine, is the availability of the special robots used to run the test. There aren’t enough.

“We’re looking for more of them, but they’re not easy to buy right now,” he said.

Commercial serological tests are now being developed around the world, but their quality is uncertain and variable, said Montine.

“We thought this was an urgent medical need, and the usual supply chains were unreliable, so we decided to build our own.”

There’s pent-up demand for antibody testing — in part because there is so little testing for the actual virus.

Because the COVID-19 virus may cause few or no symptoms, many people don’t know they’ve been infected. Measuring antibody levels in those who have not been severely ill will help to determine how common mild infections are in the general population.

And if antibodies are protective, which remains unproven, it means some people could care for relatives without fear of re-infection, return to jobs earlier, or safely exit quarantine once their symptoms have abated.

"If the testing were to show that I did have COVID-19, I would be relieved to know that I would not be likely to get it again," said Ron Simi of Orinda, who was very sick yet denied a test – three times.

For two weeks in late March and early April, the 69-year-old fought a high fever, body aches and cough. His throat was so sore he couldn't swallow. At night, he'd be jerked awake by thick and choking mucus in his throat. He sought virus testing at Kaiser on April 2, 7 and 11th, but didn't meet the criteria.

"The antibodies test can free me," said Tom Kruse, 75 years old and now quarantined in Eugene, OR. "Some family with a business can re-open as soon as they have a crew with antibodies."

If the test reveals that she hasn't had the disease, Berkeley's Mary Tilson said it would help her to construct a smart behavior plan when the state's strict shelter-in-place order is slowly eased.

But if she tests positive, and there's proof that antibodies provide immunity, "knowing I'd had it would be a superpower," she said. "Going outdoors would be fun instead of a death threat."

"Knowledge is power," said Tilson.

The Stanford effort was led by Dr. Scott Boyd, associate professor of pathology and a leading expert in antibody research. His team worked around the clock for two weeks on test development, validating it using negative and positive patient samples. It is already being offered to Stanford Health Care workers.

It differs from an externally developed test that Stanford researchers recently used in a "prevalence study" to identify the scope of the virus in Santa Clara County.

Such blood tests find two antibodies in the blood — molecules called IgM and IgG — that are made by the immune system in response to a viral attack. The test detects their unique signature.

The slow rollout of the test may feel like an eternity in what's been dubbed "COVID time," when every day of restrictive sheltering hurts families, communities and the nation's economy.

But there's the robot problem. In addition, the Stanford team has focused on ensuring they can manufacture large quantities of the reagents needed for the test.

"We've built sufficient inventory (of reagents) to support the test for at least six months," Montine said.

It is being manufactured at three locations, including the Clinical Virology Lab in Palo Alto, which provides a full range of diagnostic services for the detection and monitoring of all viral illnesses at Stanford University Hospital and the Lucile Packard Children's Hospital.

There are important limitations to this method. Antibodies offer evidence, but they're only fingerprints left behind by the culprit. A person whose blood contains coronavirus antibodies could still be sick, or could feel well but still be contagious. It can take up to two weeks for a person's immune system to develop antibodies to coronavirus, so even if their blood isn't showing it, they could currently be fighting the infection.

More definitive is the test that detects the virus's RNA — a more expensive and time-consuming process that is currently used in testing around the country. But because they're fast and more affordable, blood tests will be an important tool moving forward.

Stanford experts are applying to the U.S. Food and Drug Administration for an "Emergency Use Authorization," which speeds up the process of approval.

Only one test, produced by the Research Triangle Park, N.C., company Cellex, is already approved and being rolled out for use in select groups. Two others are awaiting FDA approval. One is from Aytu Biosciences/Orient Gene Biotech; the other is ScanWell Health/INNOVITA.

Six other tests have been approved in the U.S., but they are only for research or surveillance purposes. Other tests are still in development.

Five antibody tests have been approved for use in China. In addition, one is approved in Singapore and one in Korea.

"I pray we will learn that many have had it," said Oregon's Kruse.

"If that is the case," he said, "we can really get going."

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## Three types of antibody tests

### Rapid diagnostic test (RDT)

- **Time to results:** 10-30 minutes
- **What it tells us:** Whether antibodies are present
- **What it cannot tell us:** The concentration of antibodies or if the antibodies are able to protect against future infection.

### Enzyme linked immunosorbent assay (ELISA)

- **Time to results:** 1-5 hours

- **What it tells us:** The concentration of antibodies that are present
- **What it cannot tell us:** If the antibodies are able to protect against future infection.

### Neutralization assay

- **Time to results:** 3-5 days
- **What it tells us:** The presence of antibodies that can inhibit the virus in a cell culture system, indicating protection.
- **What it cannot tell us:** It may miss antibodies to viral proteins that are not involved in replication.

Source: U.S. Food and Drug Administration