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HEALTH | JOURNAL REPORTS: HEALTH CARE

Facts and Myths About Coronavirus Antibody Tests

How reliable are they? How can (and should) you get them? We answer the most important questions.



A drive-through test site in Bolinas, Calif. Coronavirus antibody tests based on a finger prick probably aren't as accurate as those run in sophisticated labs with highly trained employees.

PHOTO: JOHN G. MABANGLO/EPA-EFE/SHUTTERSTOCK

By Sumathi Reddy

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Everyone has their hopes pinned on antibody or serology tests—blood tests designed to detect who was previously infected with the new coronavirus and has developed antibodies to it. Businesses and governments hope the tests can help slowly open up the economy. Individuals hope the tests can tell them if they will be protected from getting Covid-19 again.

In an effort to get the tests out as quickly as possible, the Food and Drug Administration isn't requiring manufacturers to get approval from the agency. The result, experts say, is that many tests are of dubious quality and include false claims.

Even tests that are well-designed and validated aren't the panacea many think they are, as it is still not proved that the presence of antibodies results in immunity.

"There's probably more we don't know than we do know" about the tests, says Bala Hota, a professor of medicine in the division of infectious disease at Rush University Medical Center in Chicago.

For a closer look at all of these issues, we asked experts what we know—and don't know—about the tests.

The basics

Q: What is an antibody test? How is it different from a diagnostic test?

A: Diagnostic tests tell you whether you are infected with Covid-19. They are molecular tests that detect the presence of the genetic material from the virus, says David Walt, a professor of pathology at Harvard Medical School and Brigham and Women's Hospital in Boston. They typically use a nasopharyngeal swab that is pushed way back into the nose to get a sample of your mucus.

Antibody tests take a sample of your blood to test your immune response to the infection to see if your body has produced antibodies. They don't detect active infections but tell you if you were previously infected with the virus.

Q: What is an antibody?

A: Any antibody is a protein produced by the immune system, designed to bind to particular proteins on the virus. Once the antibodies bind with the virus proteins, they ideally trigger a process to neutralize the virus and remove it from the body.

Q: If I have antibodies to the virus that causes Covid-19, does that mean I'm protected from getting it again? If so, for how long?

A: We don't know. "Just because people have an antibody response to this virus does not mean that they are protected against being reinfected," says Dr. Walt.

Marc Jenkins, director of the Center for Immunology at the University of Minnesota Medical School, says the assumption is that the presence of antibodies provides some level of protection and could last a few years. The question is, how many antibodies do

you need? Different people make different amounts of antibodies based on their genetics and other factors, including how intense their viral infection was. It is possible that people with milder infections—or who are asymptomatic—may not develop as many antibodies and may have less protection from the next infection, he says.

“Most likely, people who have recovered from Covid-19 with antibodies in their bloodstream will be immune for months or one to two years,” says David Reich, president of Mount Sinai Hospital in New York. “But this is unknown currently, and we have to study that over time.”

Meanwhile, some experts say it’s possible that people with antibodies may not be immune. Gregory Storch, a professor of pediatrics at Washington University in St. Louis, says for most viruses, the presence of antibodies corresponds to immunity, but there are exceptions, such as HIV and hepatitis C. “People may have antibodies in their blood at the same time they are actively infected with those viruses,” he says. With respiratory syncytial virus (RSV), a common respiratory virus in babies, children can have an antibody response but still become infected a second time, he says.

Q: So, what is the value of antibody tests right now?

A: From a public-health perspective, experts say, the tests are crucial for determining the country’s and local communities’ rate of infection of the virus, and the true mortality rate. On an individual level, the tests can determine whether a person had an infection of the virus that causes Covid-19.

Gauging quality

Q: Where can I get an antibody test?

A: The priority right now is to develop tests to be used by hospitals on health-care workers and patients, and as part of clinical trials. So, experts say it will be a few months or possibly longer before average consumers will be able to access credible tests. Over-the-counter tests, like pregnancy tests, are under development and will likely exist some day.

But tests that require a finger prick or drop of blood on a strip of paper probably won’t be as accurate as those run in sophisticated laboratories with highly trained employees. “In many cases, they just won’t be as sensitive,” says Dr. Walt. “A low concentration of antibodies may come up as negative.”

Q: How reliable are antibody tests?

A: There was a huge concern about the quality of the first group of antibody tests that hit the market about a month ago, says Amy Karger, an assistant professor in laboratory medicine and pathology at the University of Minnesota Medical School. “We were inundated with a flood of emails and calls from questionable companies that we had never heard of trying to sell these tests,” she says. “Companies were pivoting to shipping testing kits from overseas that hadn’t been independently evaluated.”

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A lot of the rapid tests that could be done with finger pricks were unreliable, she says.

Now the FDA has made it clear that antibody tests that aren’t approved under the emergency use authorization, or EUA, need to be independently evaluated by a certified clinical laboratory to show

they work before they are used, says Dr. Karger.

Still, experts say the tests will be highly variable. “It’s kind of the Wild West out there in terms of tests,” says Dr. Jenkins.

Antibody testing is somewhat tricky, says Dr. Storch, as there are many variables. “I am very concerned that antibody tests are being released without having undergone adequate regulatory scrutiny, and it will be difficult for consumers and even physicians to distinguish which tests are reliable,” he says.

For now, Dr. Hota advises patients against using these tests to determine whether they are immune or not until there is some standardization of the tests. “Because there’s so much variation between the tests out there, it’s hard to know if a test is a false positive because of another coronavirus,” he says.

Q: How can I tell if an antibody test is reliable?

A: Dr. Karger says to make sure the test is coming from a reputable lab or diagnostics company. Chances are, if it is a lab name or company you recognize, it is more likely to be reputable.

Approval by the FDA under the EUA is another good indicator, she says. (There are currently only a handful of such approved tests.)

Rapid tests offered from a physician's office are probably not reliable this early, she says. "The main clinical labs should be involved," she says. "If it sounds too good to be true, it probably is."

Q: Do antibody tests have high false positive or false negative rates?

A: Depending on the test, they can. Test makers try to balance specificity with sensitivity. A highly specific test will exclude false positives but might be less sensitive and miss some positives. If a test is very sensitive, it may pick up a signal in people not really infected.

Experts are especially concerned about the possibility of false-positive results as that could result in a false sense of security. "That could influence behavior improperly," says Dr. Jenkins. "You would hate to think you're walking around with antibodies and you're not."

Dr. Reich warns, "There's this fiction out there that people think we're going to have this massive immune workforce that's able to go back to work. It's more likely that we'll just have to rethink the way the workforce is designed for the next year or year and a half until there is widespread vaccination."

Another tricky point, Dr. Storch says, is that the tests may measure antibodies produced for other coronaviruses, which don't reflect infection with Covid-19. There are several other very common coronaviruses that are seasonal and cause the common cold.

"Often the immune system will make antibodies that cover a number of viruses in the same family," he says.

Producing antibodies

Q: How long after infection does the body start producing antibodies? When do they peak? How long do we have them?

A: Dr. Jenkins says studies have shown the body starts producing antibodies about a week after infection, and nearly everyone has antibodies in their blood 10 days after symptoms start. "Those levels stay high in those people's blood for as long as we've looked at them," which is about a month so far, says Dr. Jenkins. It is unknown how long the antibodies will remain, but one study found that for another deadly coronavirus, severe acute respiratory syndrome, or SARS, the antibodies faded after a couple of years, he says.

Dr. Reich says that antibodies are present 14 days after diagnosis but are much stronger 21 days after, according to testing from the National Covid-19 Convalescent Plasma Project, which collects blood from people who have recovered from the virus to donate to those still infected. Antibodies typically peak four to six weeks after symptoms start, he says.

Dr. Hota says an unpublished study from China shows that when you take blood from Covid-19 patients, about 70% of the time antibodies that neutralize the virus are found. “We don’t understand why 30% had negative tests,” says Dr. Hota.

That study also showed that Covid-19 patients who had the most robust immune response were older.

Q: Are there different types of antibodies?

A: Yes. In a typical immune response, the first class of antibodies produced is called IgM, or immunoglobulin M. Next, the body produces IgG, which is better able to recognize and target the specific virus. The body also produces IgA, which is usually found in higher amounts on mucus-membrane surfaces.

Dr. Storch says IgM is transient and typically isn’t detectable after a few months. IgG is detectable for much longer and is probably the most useful to measure.

The tests under development vary in which class they are testing for, and some may test for more than one. Some tests just give a “yes” or “no” for the presence of antibodies. Others may classify antibody responses as low, medium or high. And some more-refined tests may give a level of antibodies, referred to as a titer.

Dr. Jenkins says eventually it will be important to know the level of antibodies as studies give some indication of what level is needed for protective immunity.

Q: I am young and healthy. Should I just expose myself to the virus if I can so that I can eventually get an antibody test and resume my normal life?

A: Experts recommend against doing this. You never know what kind of reaction you may have, and even young and healthy people have ended up hospitalized and have even died. The goal is to take pressure off the health-care system, so exposing yourself intentionally—and exposing those around you—is foolish, they say.

Exposing yourself is “an unwarranted risk given that we still don’t know much about this infection,” Dr. Jenkins says.

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