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Roche Coronavirus Antibody Test Wins FDA Approval for Emergency Use

The Swiss health-care giant says its test has proven 100% accurate at detecting Covid-19 antibodies in the blood

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Antibody tests are performed on a blood sample, and are seen by many governments as key to better understanding the spread of mild and asymptomatic cases of Covid-19.

The Food and Drug Administration has cleared for emergency use an antibody test from diagnostics giant Roche Holding AG RHHBY 2.40% , the company said Sunday, a move that could add significant capacity to efforts to determine the wider spread of Covid-19.

Roche's test, which identifies antibodies made by the body to fight off the new coronavirus, is designed to tell people whether they have been infected in the past. For many diseases, antibodies remain in the blood for weeks, months or even years after infection. Antibody tests are performed on a blood sample and are different from the swab tests used to diagnose a current infection.

Antibody tests are seen by many governments around the world as key to better understanding the spread of mild and asymptomatic cases of Covid-19, although so far most commercially available tests—around 10 have so far received emergency clearance from the FDA—aren't deemed accurate enough.

Roche says its test has proven 100% accurate at detecting Covid-19 antibodies in the blood, and 99.8% accurate at ruling out the presence of those antibodies. In other words, only two in every 1,000 samples lacking the antibodies would produce a "false positive" result.

Thomas Schinecker, who leads Roche's diagnostics business, said in an interview that the company was able to run its test on around 6,000 blood samples, a figure he said was significantly higher than smaller rivals. He said the test reliably detects antibodies when the blood sample is drawn at least 14 days after infection.

Governments around the world hope reliable antibody testing could help gauge how much of the population remains susceptible to the virus, in order to guide decisions about easing lockdowns. Some have even considered issuing "immunity passports" to people who have antibodies that could allow them to, for example, return to work earlier.

In most infectious diseases, the antibodies produced after a first infection act quickly to neutralize any subsequent infection, protecting the person from falling ill again. But even a reliable antibody test may not be a foolproof way of measuring immunity against Covid-19. Because the virus is so new, scientists still don't know how long antibodies remain in the blood. What's more, it is unclear whether it is possible to fall ill from Covid-19 a second time, despite the presence of antibodies.

The Swiss health-care giant's heft means it can ramp up the provision of its antibody test quickly. The test kits are designed to run on the company's automated machines, which are already installed in more than 100 laboratories across the U.S. They will be made available immediately.

Roche says it will be able to churn out test kits, made in Germany, in the high double-digit millions per month by June. The company aims to double that capacity by the end of the year, said Mr. Schinecker.

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