



NEWS

Covid-19: Antibody test that claims to be 99% accurate is certified by EU

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The BMJ

An antibody blood test for covid-19, which the manufacturer Abbott claims is 99% accurate, has been certified for use by the European Union.

The test—which has received its CE mark, meaning that it complies with EU safety rules—detects the antibody IgG to identify whether a person has had covid-19.

Abbott said that the test had “demonstrated specificity and sensitivity of greater than 99% 14 days or more after symptoms started.” It has begun shipping thousands of tests to public health organisations throughout the UK for validation.

The World Health Organization has repeatedly warned that there is “no evidence that people who have recovered from covid-19 and have antibodies are protected from a second infection”; however, these tests can be used to show who has had the virus.¹

The test identifies the IgG antibody, which appears in the late stages of infection and remains for some time after the person has recovered. However, Abbott said that it was looking to expand its range to tests to include the detection of the IgM antibody, which is the first antibody to appear during the infection.

UK laboratories

Asked how the test was evaluated, a spokesperson for Abbott told *The BMJ*, “Abbott performed a study to determine the clinical performance of the SARS-CoV-2 IgG assay and generated the following data: 100% sensitivity (95% confidence

interval of 95.07% to 100%) for 73 positive samples ≥ 14 days post symptom onset (excluding immunocompromised patient) and $>99.6\%$ specificity (95% confidence interval of 99.05% to 99.90%) for 1070 negative samples.”

The company says that the test can be run on its ARCHITECT i1000SR and i2000SR machines. The UK has more than 250 of these in laboratories, and they can run 100–200 tests an hour.

Mike Clayton, managing director of northern Europe diagnostics at Abbott, said, “We are proud to be able to provide our antibody tests immediately as they will help understand who has had the virus, leading to greater confidence as we get back to living life. We are collaborating with the NHS, public health bodies, and private laboratories across the UK to enable this test to be used here.”

Public Health England’s director of health improvement, John Newton, previously told MPs on the House of Commons science and technology select committee that he did not expect antibody tests to be available until at least May.²

1 World Health Organization. “Immunity passports” in the context of COVID-19—scientific brief. 24 Apr 2020. <https://www.who.int/news-room/commentaries/detail/immunity-passports-in-the-context-of-covid-19>.

2 Iacobucci G. Covid-19: Antibody tests will not be rolled out in UK until at least May, MPs hear. *BMJ* 2020;369:m1449. 10.1136/bmj.m1449 32273283

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