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Covid-19: Government buried negative data on its favoured antibody test

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The UK government delayed the findings of a Public Health England (PHE) study that question the accuracy of a leading covid antibody test just as it was about to announce that it had spent £75m (€84.3m; $99.4m) on buying one million of the tests.

The study,[1] published online this week at bmj.com, is the first independent assessment of the test and finds it to be significantly less accurate than a manufacturer funded study has claimed. If the test is used in the community as intended, and assuming that 10% of recipients have previously been infected, around one in five positive AbC-19 tests would be a false positive, the findings suggest.

The AbC-19 Rapid Test uses a drop of blood from a finger prick to see whether someone has previously been infected with SARS-CoV-2. It gives results in 20 minutes, without the need to go to a laboratory, and is approved for use by health professionals in the UK and the EU.

The study findings contrast with those of an earlier study[2]—published as a preprint and not yet peer reviewed, which was funded by some of the consortium developing and producing the test—that suggested that the test gave no false positive results.

The authors of the *BMJ* study, from PHE and the universities of Bristol, Cambridge, and Warwick, warned, "If the AbC-19 test were to be used for mass population screening in a relatively low prevalence setting, we would anticipate a large number of false positive results (eg, 18 900 for every 1 million tests carried out)."

"Minimal mention"

Researchers tested blood samples in a laboratory from 2847 key workers in England in June 2020. Unlike previous studies, researchers estimated the test's sensitivity in the real world, not in a laboratory setting.

In a linked editorial published on bmj.com,[3] researchers say that this study "identifies notable limitations of the UK government's antibody test of choice and provides good evidence that its specificity in a 'real-life' setting is highly unlikely to be 100%."

They add, "Apart from limited surveillance to estimate the proportion of a population that has been infected, widespread use of this assay in any other role could risk considerable harm."

Emails seen by *The BMJ* show a discussion between PHE and the Department of Health and Social Care on how to handle an announcement by the health minister James Bethell that the government had bought £75m worth of tests from Abingdon Health.

The plan, a department email said, was for "minimal mention" of the PHE study in Bethell's announcement, "but we do need to mention it as we will get asked."

PHE staff warned of "significant risks" in not publishing the PHE evaluation showing the low accuracy of the tests and asked whether holding back the results had been agreed by ministers. The department replied, "Yes everyone is aligned as far as I know. No 10 now aligned."

Department reply

A Department of Health and Social Care spokesperson said that the one million tests it had bought were not intended for "widespread public use."

They explained, "These tests are approved for use in surveillance studies, which is what they were purchased for. They were never intended for, and have never been issued for, widespread public use, and it is misleading and unnecessarily inflammatory to purposefully ignore this fact.

"This robust evaluation was carried out by PHE at the department's request before any purchase was made, and PHE approved the test for use in surveillance studies."

The findings of the *BMJ* study suggest that the test can deliver a sufficient degree of accuracy for surveillance studies of the population, but laboratory confirmation of positive results is likely to be needed if these tests are to be used to provide evidence of protection from the virus.

1 Mulchandani R, Jones HE, Taylor-Phillips S, etalEDSAB-HOME and COMPARE Investigators. Accuracy of UK Rapid Test Consortium (UK-RTC) "AbC-19 Rapid Test" for detection of previous SARS-CoV-2 infection in key workers: test accuracy study. *BMJ* 2020;371:m4262.

2 SARS-CoV-2 antibody testing in a UK population: detectable IgG for up to 20 weeks post infection. *medRxiv* 2020.09.29.20201509; doi: 10.1101/2020.09.29.20201509.

3 Gill D, Ponsford MJ. Testing for antibodies to SARS-COV-2. *BMJ* 2020;371:m4288.