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## Covid-19: Innova lateral flow test is not fit for “test and release” strategy, say experts

Elisabeth Mahase

The government has claimed that rapid lateral flow covid-19 tests, which are being used in mass testing pilots in England and can provide results in 30 minutes, are “accurate and sensitive enough to be used in the community,” after evaluation results were published.<sup>1</sup>

However, experts warn that the tests may miss as many as half of covid-19 cases, depending on who is using them—making them unsuitable for a “test and release” strategy to enable people to leave lockdown or to allow students to go home from university.

The ongoing assessment, carried out by Public Health England’s Porton Down laboratory and the University of Oxford, tested a number of lateral flow devices in different settings including hospitals, schools, and universities.

The Innova SARS-CoV-2 Antigen Rapid Qualitative Test, which has been used in the Liverpool mass testing pilot to detect infections,<sup>2</sup> is the first test to near completion of the four stage evaluation process. A report reviewed 8774 Innova tests carried out across a number of groups including outpatients with SARS-CoV-2, healthcare staff, armed forces personnel, and school students aged 11-18.

It found an overall sensitivity of 76.8%, but this rose to over 95% in individuals with high viral loads. The overall specificity of the test was reported as 99.68%, meaning a false positive rate of 0.32% (22/6967 tests.)

The evaluation found that the test performed best when used by laboratory scientists when the sensitivity was 79% (156/197 positive: 79.2% (95% confidence interval 72.8% to 84.6%)).

Sensitivity dropped to 73% when used by trained healthcare staff (92/126 positive: 73.0% (64.3% to 80.5%)) and to 58% with self-trained members of the public (214/372 positive: 57.5% (52.3% to 62.6%)).

### Sensitivity

Jonathan Ball, professor of molecular virology at the University of Nottingham, said that these tests could offer some use in terms of community surveillance.

“Even though it won’t detect as many infected individuals as the PCR [polymerase chain reaction] test, it will identify those with the highest viral loads, and it’s those people who are most likely to go on to infect others,” he said. “It won’t replace other tests like PCR, but it is a useful additional tool for coronavirus control.”

Meanwhile, Jon Deeks, professor of biostatistics at the University of Birmingham and leader of the Cochrane Collaboration’s covid-19 test evaluation activities, highlighted concerns about the findings from the testing centre evaluation, where people

self-administered the test. The report said that the test’s sensitivity was 58% when used by the public and that the false positive rate was 0.38% (0.16% to 0.88%).

He said that, while 0.4% (400 in 100 000) was a very low rate, with a sensitivity of 58% and specificity of 99.6%, this would mean that 100 000 people being tested would find 630 positives—of which only 230 would actually have covid-19, while 400 would be false positives.

“The poor detection rate of the test makes it entirely unsuitable for the government’s claim that it will allow safe ‘test and release’ of people from lockdown and students from university,” he warned. “As the test may miss up to half of covid-19 cases, a negative test result indicates a reduced risk of infection but does not exclude covid-19.”

“Independent evaluations for the World Health Organization have shown that other lateral flow antigen tests are likely to outperform Innova, but even those do not have high enough sensitivity to rule out covid-19. The Innova test is certainly not fit for use for this purpose.”

Deeks added that it was of “immense concern that the [UK government’s] Moonshot plans have not undergone any scientific scrutiny by experts such as our National Screening Committee.”

The leaked Operation Moonshot documents, revealed by *The BMJ*,<sup>3</sup> showed that the government was planning to implement a testing for access scheme, which would use rapid turnaround testing to “give people assurance that, at least for a limited time, they are unlikely to have the virus and are at low risk of transmitting it to others.”

1 Preliminary report from the Joint PHE Porton Down & University of Oxford SARS-CoV-2 test development and validation cell: rapid evaluation of lateral flow viral antigen detection devices (LFDs) for mass community testing. 8 Nov 2020. [https://www.ox.ac.uk/sites/files/oxford/media\\_wysiwyg/UK%20evaluation\\_PHE%20Porton%20Down%20%20University%20of%20Oxford\\_final.pdf](https://www.ox.ac.uk/sites/files/oxford/media_wysiwyg/UK%20evaluation_PHE%20Porton%20Down%20%20University%20of%20Oxford_final.pdf).

2 Iacobucci G. Covid-19: Mass population testing is rolled out in Liverpool. *BMJ* 2020;371:m4268. doi: 10.1136/bmj.m4268 pmid: 33144291

3 Mahase E. Operation Moonshot: What do the leaked documents say? *BMJ* 2020;370:m3558. doi: 10.1136/bmj.m3558 pmid: 32917634

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