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Covid-19: Rapid test missed over 50% of positive cases in Manchester pilot

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A rapid covid-19 test due to be rolled out to healthcare staff in Liverpool next week missed more than 50% of positive cases in a pilot in Greater Manchester, it has emerged.

The government has spent £323m (€358m; \$425m) on securing the technology to deliver 20 minute saliva tests to give to asymptomatic staff at hospitals and care homes as part of its Operation Moonshot mass testing programme.¹

But a letter seen by the *Guardian* newspaper² reported concerns from scientists in Greater Manchester about the accuracy and sensitivity of the OptiGene Direct RT-LAMP (loop mediated isothermal amplification) tests, which identified only 46.7% of infections during a pilot last month.

The Department of Health and Social Care said that the results of the Greater Manchester pilot differed from successful trials at three other labs, which had validated the test's effectiveness.

Mark Wilcox, co-chair of the department's Technical Validation Group, said, "The direct LAMP tests used in Manchester have been validated in other laboratories and in real world testing for use in different settings.

"It is incorrect to claim the tests have a low sensitivity, with a recent pilot showing overall technical sensitivity of nearly 80% rising to over 96% in individuals with a higher viral load, making it important for detecting individuals in the infectious stage. The challenge now is to understand the reasons for the difference in claimed sensitivity in one evaluation versus those in multiple others."

The OptiGene RT-LAMP assay has two formats. The rapid Direct RT LAMP tests saliva for presence of the virus and does not require RNA to be extracted, while RNA RT-LAMP takes longer because RNA must be extracted first from nose and throat swabs.

In June the department launched a pilot of OptiGene's saliva tests in Southampton,³ but it has yet to publish the results of this trial. The department said that small volumes of the rapid tests would be given to NHS staff in Liverpool hospitals from next week as part of the UK's first city-wide mass testing initiative.⁴

1 Iacobucci G, Coombes R. Covid-19: Government plans to spend £100bn on expanding testing to 10 million a day. *BMJ* 2020;370:m3520. doi: 10.1136/bmj.m3520 pmid: 32907851

2 Halliday J, Boseley S. Operation Moonshot: rapid Covid test missed over 50% of cases in pilot. *Guardian* 2020 Nov 5. <https://www.theguardian.com/world/2020/nov/05/operation-moonshot-rapid-covid-test-missed-over-50-of-cases-in-pilot>.

3 Department of Health and Social Care. Trial of rapid coronavirus test launched in Hampshire. 21 May 2020. <https://www.gov.uk/government/news/trial-of-rapid-coronavirus-test-launched-in-hampshire>.

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

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