

## Britain's NHS Using 'Flawed' COVID-19 Test

Hancock under pressure to resign as leaked documents show NHS is using knowingly flawed tests for coronavirus

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NHS laboratories are using a flawed test for coronavirus, according to a leaked Public Health England document seen by openDemocracy. Experts warn that the test fails to detect up to 25% of positive COVID-19 results.

Although the current test is known to be inconsistent, NHS labs are nonetheless being advised to continue using it, while an urgent "migration" or shift to a commercially available test takes place.

The leaked document from the National Infection Service (NIS) will put intense pressure on Health Secretary Matt Hancock to explain why the NHS has been using knowingly flawed tests for many weeks, as national death rates have spiralled.

Hancock – who promised 100,000 tests a week by the end of April – recently said that "no test is better than a bad test". Yet the documents reveal that senior government advisers have known for some weeks that the UK's critical coronavirus test was not entirely reliable.

Among the leading scientists who have seen the NIS document, the reaction has been one of outrage. One said: "There should be mass resignations, both at the top of PHE and in the government. We should expect better."

Jon Ashworth, Labour's shadow health secretary, said:

"Ministers boasted we were world leading in developing this test back in January. If there have been concerns about its accuracy, senior figures have a duty to be clear and transparent with the public. Given the Secretary of State has promised 100,000 tests a day by the end of the month we now need total clarity on what these tests are and who will be processing them."

Throughout the pandemic, the government has regularly stated that at "all times" medical and scientific advice has been followed, and that the "right thing has been done at the right time".

A testing 'catastrophe'

Despite two months of reviewing the key test used in the UK to detect the virus – officially known as the 'PHE SARS-CoV-2RdRp assay' – no minister, leading scientific or medical adviser has publicly acknowledged that the test is not fully reliable.

Although a numerical evaluation of the test's reliability is not included in the NIS document, openDemocracy has learned from a leading pathologist with knowledge of the NIS's ongoing review that the test misses 25 percent of positive cases.

That, according to one leading epidemiologist, is a "catastrophe". It means that those given a virus-free status in error since testing first began two months ago would not have known they were infected.

As such, they would have continued spreading the disease among their close family and – if they continued going to work or not practising social distancing – among the wider community.

The UK is currently projected to have one of the worst infection and death rates of any country in Europe.

The NIS document seen by openDemocracy is authorised by Dr Susan Hopkins, Professor Maria Zambon and Professor Andrew Mumford: all senior research directors who report to the chief executive of Public Health England, Duncan Selbie, and ultimately to Matt Hancock as Health Secretary.

UK 'bottom of the queue' for reliable tests

Evidence of "quality assurance difficulties" for key reagents – essentially the test's chemical makeup – is quoted in the document as one of the contributing factors for the test's unreliable performance.

The document says that Public Health England (PHE) has reviewed its own COVID-19 test and has agreed "immediate actions" to mitigate or rectify the problems. Among the advice given to laboratories using the PHE test is to be careful before "calling" a result negative, to "retest ambiguous samples", and to move towards using commercial tests.

Private-sector tests are sold by major pharmaceutical firms such as Hoffmann-La Roche, Abbott Laboratories and others. Commercial laboratories and academic institutions, such as the Crick Institute in London, largely use commercially available tests and not the PHE test.

However due to the worldwide demand for COVID-19 testing, these commercially available tests are now in short supply. If all NHS labs were to suddenly be mandated to switch to commercial products, one leading professor said: "We would find ourselves simply at the bottom of a very large queue for these critical materials."

The three advisers who authorised the document make it clear that use of the flawed PHE test cannot continue.

But, given the lack of an immediate alternative, they advise NHS labs in the meantime to take care in interpreting the results.

A "shortage of swabs" and the specialist fluid used to "transport" the swabs to laboratories are also identified in the documents as causing variations in the performance of the Public Health England SARS test in NHS laboratories.

The importance of accuracy in test results was emphasised late last month by Professor

Chris Whitty, the government's chief medical officer. At a time when questions about the reliability of the PHE test would have been surfacing internally, Professor Whitty discussed the use of tests that might detect the presence of antibodies in those who had recovered from the virus.

He said tests needed to be "incredibly accurate," adding: "If they are not accurate, we will not release any of them."

Last month Health Secretary Matt Hancock authorised the purchase of £20m antibody tests from China. The tests were later found to be unreliable and effectively junked. It is understood the Chinese tests were 60 percent reliable.

You can read the full leaked document here

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