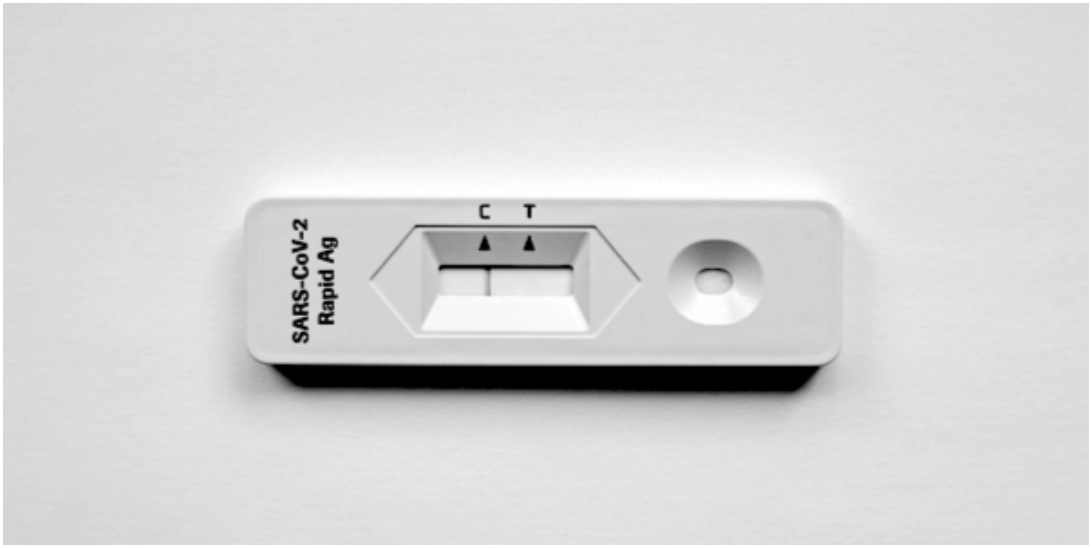
The Innova scandal Part 3: The US says 'Throw the tests in the trash'

By **Sonia Elijah** June 14, 2021



This is the third instalment of a now four-part investigation into the scandal of the British Government's procurement of the flawed Innova Covid-19 lateral flow test now trashed in America by the FDA whose scathing critique of the test, the UK Government, with contracts with Innova to date totalling £3.2billion, has decided to discount. You can read Part 1 here and Part 2 here.

IN AN unanticipated announcement at the end of last week, the US Food and Drug Administration (FDA) warned the public to stop using the Innova lateral flow test. In the most stringent of terms, it stated: 'The FDA has significant concerns that the performance of the test has not been adequately established, presenting a risk to health.'

It told anyone who has the test in their possession to destroy it by putting in the bin, or as the Americans say, the trash.

The Innova SARS-CoV-2 Antigen Rapid Qualitative Test is the very same test that was correctly described that night in the BBC's *Newsnight*'s BBC iPlayer – Newsnight – 11/06/2021 report of this news as the 'cornerstone' of the British

Government's anti-Covid strategy. The FDA's press release, they said, was 'scathing and damning' about the Innova test while Allyson Pollock, a public health doctor appearing on the programme, declared it unfit for purpose, adding for good measure that there is no evidence that mass-testing and 'Test and Trace' reduces transmission.

As I reported in Part 2 of my investigation, this is the test that was favoured by the UK above 120-plus other contenders for its Covid mass screening programme (initially called Moonshot but renamed NHS Test and Trace) after the operation had to shift from sole reliance on the flawed PCR test.

It is the test to which both Sir John Bell, Regius Professor of Medicine at Oxford, and Susan Hopkins from Public Health England (PHE) gave their imprimatur.

It is the test for which the Department of Health (DHSC) committed hundreds of millions of UK taxpayer pounds to a Californian start-up company some six/seven weeks *before* the clinical evaluation overseen by Sir John Bell was published or the piloting of the finally chosen Innova test completed.

It is also the test that made one brand new California-based company the largest single financial beneficiary of UK Covid contracts, for which the Government has committed £3.2billion to date.

The FDA's press release reported that some weeks earlier, on April 23, 2021, Innova Medical Group (IMG) had sent a medical recall letter to all those using the Innova test manufactured between September 1, 2020 and March 3, 2021 as a result of which at least 77,339 of the Innova SARS-CoV-2 Antigen Rapid Qualitative Test in the US were recalled. The FDA identified this recall as a Class I recall, the most serious type of recall.

Curiously, the same type of test used in the UK, not in the thousands but in the hundreds of millions, has not been recalled. Millions have been purchased by our government since the April 23 recall. Is the UK test any way different? There is nothing to suggest that it is or that the same basis for recall does not exist in Britain.

The FDA criticised: 'Labelling distributed with certain configurations of the test includes performance claims that did not accurately reflect the performance estimates observed during the clinical studies of the tests'. It also stated that 'the performance characteristics of the test have not been adequately established, presenting a risk to health.'

This was the conclusion (and the concern) articulated by other experts in the UK about the test within days of the PHE Porton Down evaluation publication early last November – expert criticism that the DHSC ignored, as I reported in Part 2.

In fact key limitations of the test were acknowledged by the manufacturer and are to be found in the original instructions for use of the Innova SARS-CoV-2 Antigen Rapid Qualitative Test. Namely that it was only ever intended for use in patients with Covid-19 symptoms (i.e. symptomatic patients) meaning that the Innova SARS-CoV-2 rapid antigen test was never designed to screen the asymptomatic but only to detect active infections (when symptoms are present).

The instructions say: 'The SARS-CoV-2 Antigen Rapid Qualitative Test is . . . intended for the qualitative detection of nucleocapsid antigens from SARS-CoV-2

in human nasal swabs or throat swabs from individuals who are suspected of COVID-19 by their healthcare provider. within the first five days of the onset of symptoms.' [Punctuation as in the leaflet.]

This of course makes a complete mockery of the UK government's Test and Trace mass screening intention, and of their fundamental justification for buying 20million of these tests in October 2020 (prior to the test's evaluation) and sundquent purchase of millions more, all with the main intention to catch infections in asymptomatic people (those showing no symptoms)!

The Innova tests, however, were repackaged for the NHS with a different version of the instructions, which stated (in the November 24, 2020 NHS version):

'You can use this self-test kit if you have symptoms or if you are asymptomatic (you do not have symptoms).'

Alarmingly, the NHS instructions have been updated since then, with the removal of the referenced sentence above in the January 16, 2021 version.

The original Innova instructions also state that the test 'is intended for use by trained clinical laboratory personnel . . . and individuals similarly trained in point of care settings.'

In the NHS Test and Trace version, the test is intended for use by any member of the public aged 12-plus.

Included in the original Innova instructions are the limitations of the procedure. These are omitted in the NHS version.

The Innova instructions say:

1.Clinical performance was evaluated with frozen samples, and test performance may be different with fresh samples.

2.Users should test specimens as quickly as possible after specimen collection.

3.Positive test results do not rule out co-infections with other pathogens.

4.Results from SARS-CoV-2 Antigen Rapid Qualitative Test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.

5.A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection.

This disparity was picked up by the *Daily Mail* in January, which headlined its article: 'Department of Health puts NHS branding on rapid Covid tests so it can get around manufacturer's instructions that people should NOT swab themselves.'

Scandalously the government appear to have ignored this, spending further millions with Innova for school and home testing.

The *Telegraph* also noted a 'confusion' with the conflicting instructions for use, reporting that the 'Chinese-made lateral flow tests handed to millions of schoolchildren' included the original manufacturer's instructions inside the box. The paper said the 'out of date' instructions 'erroneously' stated that the tests were for use by people 'suspected of Covid-19 by their healthcare provider'.

Had the *Telegraph* pursued their investigations in the way they should, they would have found that the original manufacturer (Xiamen Biotime Biotechnology sold through Innova) did *not* make a mistake.

The instructions were *not* out of date – the only factor that had changed was the Government's mendacious 'repurposing' of the test to catch virus infections in

asymptomatic individuals, which they chose – without evidence – to believe comprised in one of every three Covid carriers.

The *Telegraph* article went on to state that the official guidelines are that 'people with symptoms are supposed to get a PCR laboratory test, the results of which are reported automatically, triggering the contact tracing process'.

This still contradicts the NHS instructions which are that Innova test is to be used in both the asymptomatic and symptomatic.

The Telegraph quoted a Downing Street spokesman as saying that lateral flow tests had been 'rigorously evaluated and we believe they are both accurate and incredibly useful in terms of being able to spotasymptomatic cases of the virus'.

The truth is as Professor Allyson Pollock of Newcastle University told the paper: 'The whole mass testing programme is confusing, chaotic and the antithesis of good public health practice.

'If you do mass testing you need to do proper evaluation beforehand, which would identify problems like this.'

'Lateral flow testing should have gone through the UK National Screening Committee for proper evaluation.'

So, who is responsible for these scandalous errors and this £3billion plus fiasco?

· The joint PHE and Oxford University's evaluation led by Sir John Bell, was inexplicably quick to approve the Innova Test, leading the UK government to spend billions on another inaccurate test.

· The Department of Health who changed the manufacturer's original instructions for intended use, rebranding it as an NHS Covid-19 self-test kit with its very different version of instructions, and blamed the manufacturer for including 'out of date' and 'erroneous' instructions.

Footnote: At this point IMG have decided to revamp their website. This is what was showing last night.

Updated 15.6.21

The final part of this investigation will shine a light on the Wuhan-born businessman Dr Charles Huang, the owner of Innova Medical Group and the main beneficiary of this British scandal.