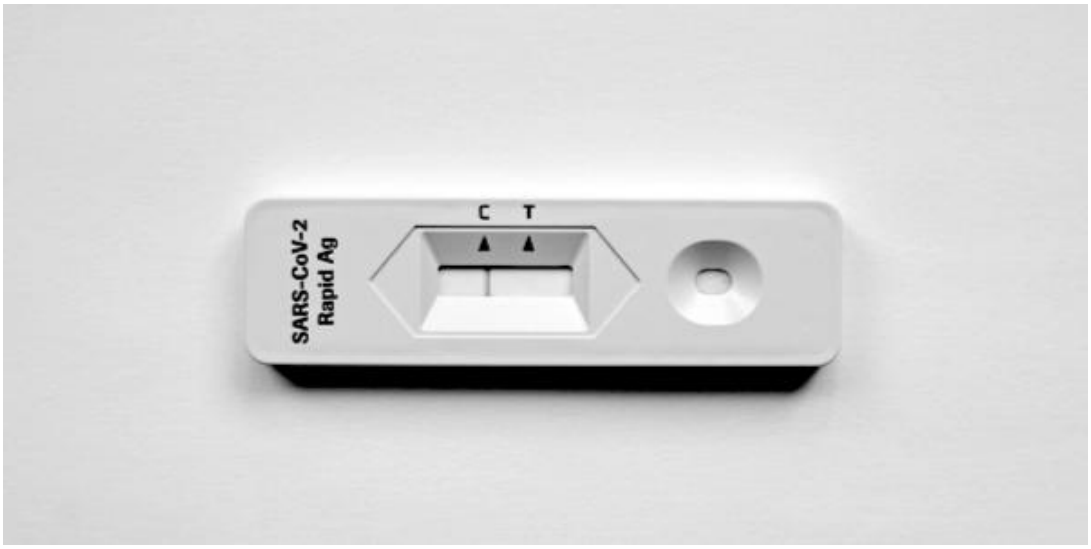
The Innova tests: another Covid scandal in the making? Part 2

By **Sonia Elijah** June 10, 2021



This is the second instalment of my three-part investigative report for *TCW* on the Chinese-made Innova lateral flow test. On Monday I examined the background to the Government decision to commit vast sums of UK taxpayers' money to a California start-up for tests that, like the PCR test, manifested significant problems from the start.

A JOINT report by Public Health England (PHE) Porton Down and Oxford University published early last November gave the Government the green light to invest in and roll out the new lateral flow test (LFT). The 'newly deployed lateral flow tests are highly reliable, sensitive and accurate in multiple settings' and 'sensitive enough to be used in the community, including for asymptomatic people', they announced, singling out the Innova Medical Group's SARS-CoV-2 Antigen Rapid Qualitative Test, selected for a Liverpool pilot scheme starting that same week. This, they explained, was because only Innova's LFT was reported to be nearing completion of the 4-stage process at the time.

Led by an oversight group chaired by Sir John Bell, Regius Professor of Medicine at Oxford University, the evaluation programme had begun a few months earlier in August. Of the 120-plus LFTs submitted for this review, 40 passed phase 2 validation, 24 passed phase 3a validation and just four tests showed a sensitivity rate (the proportion of people who have the disease and get a positive result) of more than 70 per cent. The report focused on just one of these, Innova, and listed its attributes: a test specificity recorded as 99.68 per cent; an overall false positive rate of 0.32 per cent, and an overall sensitivity of 76.8 per cent for all PCR-positive individuals – 'over 95 per cent of individuals with high viral loads' – and showing a 'minimal difference between the ability of the test to pick up viral antigens in symptomatic and asymptomatic individuals'.

These high sensitivity rates were recorded when the test was conducted by laboratory scientists. However, when used by trained members of the public, the

rate dropped to 57.5 per cent. Surprisingly, this was not flagged as a problem by either Sir John Bell, who oversaw the report, or Susan Hopkins from PHE. Both concluded that the Innova test had 'sufficient sensitivity'.

Within days of the publication of the evaluation, other experts warned in the *BMJ* that, to the contrary, the Innova lateral flow test was not fit for this 'test and release' strategy as the tests 'may miss as many as half of Covid-19 cases, depending on who is using them'.

Jon Deeks, professor of biostatistics at the University of Birmingham and leader of the Cochrane Collaboration's Covid-19 test evaluation activities, could not have made his criticism clearer: 'Independent evaluations for the World Health Organisation 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.'

Another damning article in the BMJ a few weeks later claimed the Innova lateral flow tests were 'highly inaccurate'. It reported 'early results [of pilot studies] from students testing at the University of Birmingham and universities in Scotland showed that tests had a sensitivity of just 3 per cent and that 58 per cent of positive test results were false.'

Their warnings might have proved a new blow to the UK government's ambitious plans for mass testing, but they were ignored. No brakes were applied. The use of the Innova Lateral Flow Test for the NHS Test and Trace scheme, to be rolled out to universities, hospitals, care homes and all secondary schools, was planned regardless.

Impervious to the critiques, a later PHE and Oxford University performance evaluation of the Innova LFT against the PCR test (co-authored by Susan Hopkins and published in March 2021) found: 'In phase 2 and 3a, where the same sample was used for both PCR and LFD specificity analyses, no false positives were detected.'

Such confidence as to the efficacy of the Innova tests curiously *predates* as well as postdates their UK clinical evaluation, and by some months. Examination of the government's purchase contracts for tests from IMG (Innova Medical Group) shows their first contract was agreed as early as September 2020 for £103.6million. Subsequent contracts with IMG made before Christmas, before and after PHE and University of Oxford published the results of their evaluation, totalled just under one billion pounds.

Here is their time line government's contracts with Innova Medical Group.

Professor Tim Peto of Oxford University, chief investigator for lateral flow tests (overseen by Sir John Bell), admitted, 'We had to buy before we knew they worked' arguing that 'there was huge worldwide demand'. Officially the justification for using Innova as the sole supplier without a call for competition was that it was in accordance with Article 32 of the contract conditions:

'Innova are the only available supplier of home use lateral flow tests for Covid-19 as there is currently no other supplier whose Covid-19 tests are authorised by the relevant regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), for self-test use in the UK . . . No reasonable alternative or substitute exists: there is currently no other supplier of lateral flow devices that has MHRA authorisation for the self-test use needed to satisfy DHSC's (Department of Health) requirement.'

But why so many pre-orders for such huge numbers and amounts of money given the uncertainty surrounding them? The DHSC justification looked increasingly tenuous from January onwards when the Liverpool School of Tropical Medicine announced that the Excalibur Rapid SARS-CoV-2 Antigen Screening test, validated by LSTM, had been granted MHRA approval, stating:

'Now, following approval from the Medicines & Healthcare Products Regulatory Agency (MHRA), the Excalibur Rapid SARS CoV-2 Antigen Screening test *can be deployed for widespread mass screening of populations* to rapidly track down infectious individuals capable of spreading the disease.' (My italics).

It's striking that after January, further huge contracts were granted by the Government to Innova alone.

The largest of these, for £1.2billion, was agreed *after* Excalibur's MHRA approval; it stated a contract delivery date of 13 March to 28 April, and used the same legal justification for use of Article 32.

How was it that the UK-based firm Excalibur Health Care Services, led by Professor Sir Christopher Evans, a leading biosciences, medical and healthcare entrepreneur, was overlooked by the UK government in favour of Innova, an obscure US start-up?

Nevertheless, armed with the Innova kit, the mass testing rollout planned by the government to coincide with the return to school and college on March 8 this year, went ahead. Secondary school and college students were to take an initial three tests at school and then twice weekly at home, *all to be administered by themselves*, not by trained professionals.

Further plans for expanding community testing were announced in April in which everyone was to be given access to two free tests a week.

Today, the Government's contracts with the mysterious Innova Medical Group total £3.2billion, an astonishing sum to go to one single start-up company based in California for a test that has proved to be unreliable, on the basis only that it would quickly be able to supply the vast quantities of the test the Government assumed it needed. Daniel Elliott, IMG's chief executive, explained: 'There was a lot of discussion of course about the technology, but it also came down to our ability to supply. Nobody else was anywhere near our production capacity.'

How did this fledgling California start-up get so far ahead of the game in being able to supply vast quantities of tests, not only to the UK but (it says) also delivering 'over 500million Innova SARS-CoV-2 rapid antigen test kits to over 20 countries'?

Closer inspection suggests that the UK contracts were integral to this new company's success. IMG was set up only 15 months ago, in March 2020, in Nevada, the US state that happens to have the most personal liability protection for directors over corporate wrongdoing and prevents creditors from pursuing companies' assets.

In a recent interview with the *Financial Times* Elliott claimed they 'were ahead of the competition in terms of developing these products but also scaling at mass'. He said: 'The UK is a key market to us . . . we've been a good partner to the government, the government's been a good partner to us.' They were certainly ahead in being given so much upfront UK taxpayer money.

The UK remains IMG's biggest market for its lateral flow devices. The company says it has spent more than £100million transporting them from China. Now it says that it plans to start manufacturing in the UK. A factory in Wales is promised to begin producing a million tests a day from this summer. Perhaps someone in Government has begun to worry about the billions already spent not benefiting the UK manufacturing industry or its workers?

You'd be forgiven for thinking that IMG, given its massive underwriting by the UK, was perhaps part owned by UK PLC but no, it is wholly owned by Pasaca Capital Inc, a private equity firm founded in 2017 by the Chinese-born billionaire Dr Charles Huang (PhD in marketing) who was born and studied in Wuhan, the centre of the pandemic.

IMG and Pasaca Capital are the same. The head office address for IMG is the same as Pasaca Capital's. The board of Pasaca Capital is the same as that of Innova. Prior to Covid-19, there was no history for IMG; their website domain 'innovamedgroup.com' was registered only on 15 May 2020, see below.

The following extract from Pasaca's website shows how closely intertwined IMG's start-up was with the UK's LFT order:

'In October 2020, as the world started to get a better understanding of the virus, the stellar team at Innova secured a significant order from the United Kingdom as it launched Project Moonshot – the British government's ambitious mass testing program. In a highly competitive and heavily scrutinized process led by scientific analysis conducted by the renowned experts at Porton Down and Public Health England, Innova won the contract due to the superior performance of its antigen tests and Innova's unparalleled capacity to supply.'

The facts appear to be otherwise – Innova won a significant tranche of the contracts well before the 'highly competitive and heavily scrutinised process' was completed.

It is hardly surprising then that, as the website says, 'In 12 months, Pasaca had transformed Innova from a small start-up to a multi-billion-dollar company, becoming the world's leading manufacturer and distributor of COVID-19 rapid antigen test kits.'

But it wasn't Pasaca Capital that has catapulted IMG from an obscure start-up to a so-called world leader of Covid-19 testing kits. It was the £2.8billon of UK taxpayers' money handed to the company as of April this year, making IMG the largest single recipient of payments from the UK government contracts during the pandemic.

CEO Daniel Elliott told the *Financial Times* that 'Pasaca Capital invested tens of millions in the early months of the pandemic'. The evidence would be welcome. It certainly made a good a return on whatever it did invest.

All that Pasaca's webpage tells us is that: 'In early 2020, as Covid hit the US and the world, Pasaca's founder, Dr Charles Huang, and the team of seasoned scientists, top analysts, and sales and marketing experts foresaw that the fight in stemming the spread of the virus necessarily must revolve around repeated mass testing.'

IMG's website states that after Huang set up IMG in March 2020, 'the Innova team, together with its primary contract manufacturer, Xiamen Biotime Biotechnology Co Ltd, based in Fujian, China, spent several months designing a highly accurate rapid antigen test for Covid-19.'

Thanks to its exclusive global rights to the mass-produced rapid antigen tests made by its 'partner' Xiamen Biotime Biotechnology in China, IMG has made itself the UK's sole supplier.

Below is the 'Qualification Certificate' found inside the NHS Test and Trace Covid-19 self-test kits.

In April this year the *Guardian* once again questioned the lack of transparency of the government's Covid contracts, saying that a fifth of them raise red flags for corruption thanks to Johnson's VIP lane set up by the Cabinet Office and the Department of Health and Social Care in the early days of the pandemic.

Innova's brief history raises other equally worrying questions. First, how did Huang of Pasaca Capital know in 'early 2020' that the world was going to need hundreds of millions of rapid Covid-19 testing devices when in early March there were only 35 reported cases in the UK and 89 cases in the US? When mass testing for a virus had never been conducted before?

How was his Chinese 'manufacturing partner' Xiamen Biotime able so quickly to provide a solution to the problem? Did they have some information that gave them a significant head start in forming a company with an 'unparalleled capacity to supply'?

In Part 3, I investigate the scandals involved with the instructions for use of the Innova Test. I also take a deeper look at Charles Huang's employment history and the obscure Northamptonshire-based company making a killing from being the sole distributor of the Innova test to the UK commercial market.