



New Covid 19 Diagnostic Tests

Note: *This live document will be updated further as more detail become available. Last updated 8 November 2020*

Summary

General Note:

Notwithstanding the rapid Covid 19 tests now being introduced it should be noted there is no valid test for a virus whose genome is unknown, has not been isolated or identified. Moreover the gaps in a hypothetical genome of Sars-Cov-2 were filled-in using a computer modelling programme.

DnaNudge test

Rapid test supplied by DnaNudge with roll-out from 10 August 2020. Detects Covid 19 and other winter viruses in 90 minutes. Does not require trained health professionals and can therefore be used in non-clinical settings. DNA "nudgebox" machines are used to analyse DNA in nose swabs providing a positive or negative result for Covid 19 in 90 minutes at point of care. Machines will process up to 15 tests on the spot each day without the need for a laboratory. It should be noted that the test does not rule out other bacterial RNA or other Sars-Cov-2 viral "fragments" that could lead to a false positive result. No review undertaken to date by "*Medicines and Healthcare Products Regulatory Agency*" [M H R A] to establish whether the device is working as intended and able to diagnose Covid 19 infection.

LamPORE test

LamPORE swab test supplied by Oxford Nanopore with roll-out from 10 August 2020. Process swab and saliva samples to detect the presence of Covid 19 in 60 to 90 minutes. Desk top GridION machine can process up to 15,000 tests a day. The palm-sized MinION can process up to 2,000 tests a day for deployment in a near-community "popup" laboratory. The test does not rule out other bacterial RNA or other Sars-Cov-2 viral "fragments" that could lead to a false positive result. It is a matter of concern that a lower cycle test that provides a negative result is to be recorded as invalid, whilst a positive test is to be considered positive regardless of the number of cycles used. No review undertaken to date by M H R A to establish whether the device is working as intended and able to diagnose Covid 19 infection.

LumiraDx test

Rapid Covid 19 testing service provided by Boots Pharmacy. LumiraDx devices process swab tests and provide results in 12 minutes as a cost of £120 per test. The test does not rule out other bacterial RNA or other Sars-Cov-2 viral "fragments" that could lead to a false positive result. No review undertaken to date by M H R A to establish whether the device is working as intended and able to diagnose Covid 19 infection. Enquiries are continuing to establish how the results from this private testing service is recorded and incorporated into the public testing system funded by UK Government and how data is made available to the Office for National Statistics [ONS].

Lateral Flow test

Mass testing pilot programme in Liverpool November 2020. A mix of existing swab tests and new lateral flow test which can provide a result within an hour without the need to use a laboratory. The test does not rule out other bacterial RNA or other Sars-Cov-2 viral "fragments" that could lead to a false positive result. 2000 military personnel used to plan and deliver the tests. No review undertaken to date by M H R A to establish whether the device is working as intended and able to diagnose Covid 19 infection.

Excerpts From BGB's Correspondence Journal

DnaNudge & 90 minute LamPORE swab test

An abstract from a "Department of Health and Social Care [DHSC]" press release published 3 August 2020 is reproduced below.

"Roll-out of two new rapid coronavirus tests ahead of winter. Millions of new rapid coronavirus tests will be rolled out across NHS hospitals, care homes and labs from next week. Both tests will be able to detect COVID-19 and other winter viruses in just 90 minutes. New tests will hugely increase testing capacity ahead of winter, delivering fast results that will help to break chains of transmission quickly. Millions of ground-breaking rapid coronavirus tests will be rolled out to hospitals, care homes and labs across the UK to increase testing capacity ahead of winter. The tests will enable clinicians and NHS Test and Trace to quickly advise on the best course of action to stop the spread of the virus. Two new tests – both able to detect the virus in just 90 minutes – will be made available to NHS hospitals, care homes and labs. The 2 tests will be able to detect both COVID-19 and other winter viruses such as flu and respiratory syncytial virus (RSV). The tests do not require a trained health professional to operate them, meaning they can be rolled out in more non-clinical settings. This will help to further strengthen the coronavirus response this winter, arming both clinicians and NHS Test and Trace with the ability to distinguish between COVID-19 cases, which have specific self-isolation requirements, and other winter viruses. Health Secretary Matt Hancock said: We're using the most innovative technologies available to tackle coronavirus. Millions of new rapid coronavirus tests will provide on-the-spot results in under 90 minutes, helping us to break chains of transmission quickly. The fact these tests can detect flu as well as COVID-19 will be hugely beneficial as we head into winter, so patients can follow the right advice to protect themselves and others. I am hugely grateful for the excellent work done by DnaNudge and Oxford Nanopore to push forward these life-saving innovations in coronavirus testing. A new test that uses DNA to detect the virus will be rolled out across NHS hospitals from September, with 5,000 DNA machines, supplied by DnaNudge, to provide 5.8 million tests in the coming months. Separately, 450,000 90-minute LamPORE swab tests will also be available across adult care setting and laboratories from next week, supplied by Oxford Nanopore. DNA testing for coronavirus 5,000 DNA 'Nudgebox' machines, supplied by DnaNudge, will be rolled out across NHS hospitals in the UK to analyse DNA in nose swabs, providing a positive or negative result for COVID-19 in 90 minutes, at the point of care. The machines will process up to 15 tests on the spot each day without the need for a laboratory. The DNA COVID-19 test machines are currently operating in 8 London hospitals: St Mary's Hospital in Paddington Charing Cross Hospital West Middlesex University Hospital Chelsea and Westminster Hospital Royal Hospital Chelsea Queen Charlotte's and Chelsea Maternity Hospital the Renal Transplant Centre at Hammersmith Hospital the Tower Hamlets Centre

for Mental Health at Mile End Hospital. The machines are located in cancer wards, A&E and maternity wards to protect those most at risk. The government is signing contracts with more companies to produce machines for DNA coronavirus testing. Rapid LamPORE tests The new rapid LamPORE test will be able to process swab and saliva samples to detect the presence of COVID-19 in 60 to 90 minutes. The new test has the same sensitivity as the widely used PCR swab test, but can be used to process swabs in labs, as well as on-location through 'pop up' labs. The desktop GridION machine can process up to 15,000 tests a day, or the palm-sized MinION can process up to 2,000 tests a day for deployment in a near-community 'popup' lab. 450,000 of the new LamPORE tests will be available from next week across adult care settings, NHS laboratories and lighthouse laboratories, with millions more tests to be rolled out later in the year. Details of positive test results will be shared with NHS Test and Trace, so close contacts can self-isolate in line with guidance."

The press release prompted enquiries directed to the regulator "Medicines and Healthcare Products Regulatory Agency [M H R A]" based at Canary Wharf London. These enquiries resulted in the following agreed statement setting out the current position in October 2020.

Statement

"CE marking for 'professional use only tests' is a self-declaration process undertaken by the test kit manufacturer with no review of performance data by any EU Government Body or Notified Body. The Medicines and Healthcare Products Regulatory Agency [M H R A], as competent authority, does not approve such products. M H R A does monitor the market place to ensure that such devices are working as intended. M H R A has not reviewed the two new rapid coronavirus tests [referred to in the D H S C press release published 3 August 2020] prior to the test kits being placed on the market in August 2020 but may undertake future reviews to establish whether the devices are working as intended and able to diagnose Covid 19 infection and other winter viruses."

End of statement

The statement raises serious concerns regarding the marketing of new Covid 19 test kits prior to review by the regulator to establish whether the devices are safe and operating as intended and able to diagnose Covid 19 infection.

LumiraDx testing service - Boots UK

An abstract from a "Liverpool Echo" press release published 26 October 2020 is reproduced below.

*"Boots is set to release a "rapid" **coronavirus** testing service which could give results in as little as 12 minutes. The pharmacy chain said the LumiraDx devices, which are able to quickly process swab tests to give customers same-day results, will be rolled out in selected stores over the next few weeks. Boots already operates a 48-hour testing service, currently available in 10 stores across London, Birmingham, Manchester, Edinburgh and Glasgow, with plans to extend the program to more than 50 outlets across the nation. The service, costing £120, is available as a private pre-flight test for customers who require one before travelling abroad, or as a solution for those who would prefer peace of mind before seeing friends and family. Seb James, managing director of Boots UK and ROI, said the programme was being implemented as a way to help ease the pressure on the nation's health services. "Boots has supported the government's Covid-19 testing programme from the very start and offering this new in-store service is the next step in our efforts to fight against the*

pandemic," he said. "We hope that by offering this testing option in local community stores, Boots can help ease pressure on the NHS and the Government by providing additional access to testing and crucial reassurances for people across the UK."

The press release prompted enquiries, directed initially 26 October 2020 to "Boots U K" in order to establish whether the "LumiraDx device" has been reviewed / endorsed by the regulator M H R A prior to operational use, to ensure the product does not compromise patient safety and users, and is designed and manufactured to achieve the performance specified by the manufacturer for the stated purpose, and able to diagnose Covid 19 infection. A response from "Boots U K" is currently awaited.

Clarification was also requested from the Department for Health and Social Care [DHSC] press office 3 November 2020 on how the results from this private Covid 19 testing service [costing £120] are recorded and incorporated into the public testing system funded by U K Government, and whether DHSC is responsible for collating these private test results to ensure that those who test positive self-isolate. It remains unclear how this is administered by the devolved administrations in Wales, Scotland and Northern Ireland and whether the data is made available to the Office for National Statistics [ONS] and included in the daily positive "case number" totals reported by the British Broadcasting Corporation [BBC] in daily news bulletins. A response from DHSC is awaited.

New Lateral Flow Covid 19 diagnostic test

An abstract from BBC News dated 3 November 2020 is reproduced below.

"People in Liverpool will be offered regular Covid-19 tests under the first trial of whole city testing in England. Everyone living or working in the city will be offered tests, whether or not they have symptoms, with follow-up tests every two weeks or so. Some will get new tests giving results within an hour which, if successful, could be rolled out to "millions" by Christmas, the government says. Liverpool has one of the highest rates of coronavirus deaths in England. The Liverpool pilot aims to limit the spread of the virus by identifying as many infected people as possible, and taking action to break chains of transmission. The pilot will start this week and will include a mix of existing swab tests and new lateral flow tests, which can provide a result within an hour without the need to use a lab. New test sites will be set up across the city, including in care homes, schools, universities and workplaces. People will be able to book online, turn up in person, or wait for an invitation from the local authority. Around 2,000 military personnel will help plan the logistics and deliver tests. "I hesitate to use the word game-changer because it gets overused, but it is a significant step forward in the testing arena," said Sir John Bell, of Oxford University, who has been advising the government on tests. He said the rapid tests "genuinely have a turnaround time of about 15 to 20 minutes".

The press release prompted a request, on 3 November 2020, to Public Health England [PHE] for a copy of the "**technical product information sheet**" for the "new lateral flow test" for Covid 19 where results are available within one hour, without the requirement for laboratory RT-PCR test. The response from PHE is awaited.