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The Race Is On To Launch COVID-19 Antibody Home-Test In The UK

by David Ridley

Feature: Public Health England has revealed it is only a week away from approving a COVID-19 antibody test for distribution via Amazon. HBW Insight looks at the race to place the first, government-approved coronavirus home-test on the UK market.

The race is on to produce an effective and validated COVID-19 antibody test that can be used at home by consumers to find out if they have had the virus, are immune and can therefore safely go back to work.

According to government officials, COVID-19 self-tests could soon be available to buy in the UK and elsewhere based on a variety of sampling methods, for example using serum, plasma or blood from a finger prick to test for the presence of virus-beating antibodies.

However, there is little information on the accuracy of the tests, or on how a patient's antibody response develops or changes during COVID-19 infection.

"It is not known whether either a positive or negative result is reliable. Currently there is no published evidence about the suitability of these tests for diagnosing COVID-19 infection in a community setting," warns Public Health England.

Which is why PHE is currently rapidly evaluating a sample of these tests in Oxford – taken from a batch of 3.5m antibody home-tests the UK government has purchased from an unnamed company – to find out if they really do work as they are claimed to do.

Once they have been evaluated, these tests would be distributed to the British public as soon as next week, PHE revealed in a recent UK Parliament Science and Technology Committee meeting.

COVID-19 Tests On Amazon?

Interestingly, the tests would be made available via Amazon or through high-street retailers such as Boots, the authority suggested.

Visibly surprised by the news, Members of Parliament at the meeting – including Committee chair and Conservative MP for Tunbridge Wells, Greg Clark – then quizzed PHE's director of the National Infection Service, Professor Sharon Peacock, on its implications.

Firstly, Peacock clarified that there would be a minimal charge for the tests, implying that these products would be in some sense "over the counter," much in the same way that pregnancy tests can be bought without a prescription and used at home.

While the tests would be simple to use – using the finger-prick method described above, and like home pregnancy tests, present the results on the testing device within a certain length of time – Peacock assured MPs that, once they were rolled out, a program would run in which PHE goes into people's homes and performed a blood test alongside the home tests to check they worked.

And finally, Peacock said PHE would prioritize certain groups crucial to fighting the virus and getting the country back to work, such as National Health Service workers.

Unanswered Questions

However, many unanswered questions remain, not just which company made the 3.5m tests purchase by the UK government, but also how these tests will be classified and distributed once the first ones hit the market.

"PHE's statements provided considerable stimulus for discussion and speculation, but left a great deal unclear," the British In Vitro Diagnostic Association's chief operations officer, John Bagshaw, told HBW Insight.

"Blood samples require the provision of a lancet in the kit, and often a small pipette or capillary to apply the drop of blood to the device," he explained. "However, not everyone would be happy or competent to do this for themselves."

"There is also a question of interpretation, as tests with no positive control line would be invalid, and most tests of this kind require reasonably accurate timing and the recording of even a faint line as positive, therefore good light conditions and eyesight," he added.

Self-testing in general also remained a controversial practice, Bagshaw pointed out. (Also see "*Direct-To-Consumer Tests Opening The Door To Personalized Medicine*" - HBW Insight, 16 Jan, 2020.)

"At some point in the future it may be that people can reliably self-test, as they do for HIV," he

reflected. “For now, with this disease being so new, we recommend people rely on the National Health Service to provide testing for those that need it.”

Who Is The Supplier?

As for the identity of the PHE test manufacturer, BIVDA said it couldn’t comment at this time.

HBW Insight asked industry expert Catherine Longworth – who recently wrote a piece on COVID-19 antibody tests for MedTech Insight – if she could provide any more information on which company might be have provided PHE’s with the tests. (Also see "*UK Govt Buys 3.5M 15-Minute COVID-19 Antibody Home Tests From Mystery Manufacturer*" - Medtech Insight, 26 Mar, 2020.)

“PHE’s Peacock mentioned it was a brand-new test,” Longworth commented. “My research showed that there are companies developing self-tests such as the UK’s Alpha BioLabs which has an antibody test fitting the description on their website and told me it would be available from 31 March.”

Warrington-based company Alpha BioLabs claims to have a rapid finger-prick antibody test for SARS-CoV-2. The CE-marked single-use qualitative test detects both early and late marker IgG/IgM antibodies in human finger-prick blood samples.

To run the test, a sample of blood is collected and added to the sample well of the test cassette along with two or three drops of a sample buffer, according to Alpha BioLabs, which said the test can yield results within 15 minutes.

Results Even Quicker

HBW Insight identified another UK company claiming to have developed a test that can detect coronavirus infection within 10 minutes and render both self-isolation and incubation unnecessary.

Derby-based Sunscreen Diagnostics’ new coronavirus lateral flow test – which also uses a finger-prick procedure like that described by PHE – had an accuracy of 98.7%, had been validated in China and was already being used in the UK, Ireland, Germany, Spain, Switzerland, Netherlands, Turkey, UAE, Kuwait and Oman, the company claimed.

“We’ve been working hard to produce a coronavirus test that can be used at the patient side, with capillary blood, easily taken from someone’s fingertip and diagnose them within 10 minutes,” commented Sunscreen director David Campbell.

“There is a big problem with the diagnosis of the disease currently because the standard method of screening is to send samples to the laboratory, which takes a lot of time,” he continued.

“Meanwhile, someone could be spreading the virus without knowing, or having the issue of self-isolation.”

Sunscreen’s self-tests – which Campbell said were “ready to go with clinical data behind it” – had already been ordered by “one multinational oil and gas firm and a cruise liner firm,” with the manufacturer claiming to be able to produce 500,000 tests a week.