Oxford University and PHE confirm high-sensitivity of lateral flow tests

- Findings from independent evaluation of lateral flow tests published
- Findings from PHE Porton Down and Oxford University shows newly deployed lateral flow tests are highly reliable, sensitive and accurate in multiple settings
- Lateral flow tests deployed in Liverpool shown to have over 99.6% specificity

Extensive clinical evaluation from Public Health England (PHE) and the University of Oxford show lateral flow tests are accurate and sensitive enough to be used in the community, including for asymptomatic people.

Lateral flow tests are rapid turnaround tests that can process COVID-19 samples on site without the need for laboratory equipment, with most generating results in under half an hour.

As part of the government's strategy for testing the effectiveness of this new technology, these new tests are being piloted across England. This includes a 2-week whole-city pilot in Liverpool, which was launched last week.

Prior to commencing these pilots, DHSC commissioned independent research to gain further information on the specificity and sensitivity of the tests in different settings including hospitals, schools, and universities

The swabbing and processing of these tests must currently be conducted at a dedicated testing site by a trained personnel.

The devices are designed to be intuitive and require minimal training to operate, and PHE and the University of Oxford are now looking at how this test could be self-administered.

PHE's world-leading Porton Down lab and University of Oxford undertook this work and have since been putting a number of tests through a 4-phase assessment process. This includes the test being used in Liverpool, and those that are being sent to directors of public health across the country to use for their local communities, and are also being used in schools, universities and workplace settings.

40 different lateral flow devices were put forward, of which 9 met the criteria to continue to full evaluation. Six made it to the third phase, and the Innova SARS-CoV-2 Antigen Rapid Qualitative Test, the test being used in the Liverpool pilot, is nearing completion of the 4-stage process.

PHE Porton Down's labs have shown 4 lateral flow tests to have a sensitivity of more than 70% of all PCR-positive cases but importantly catch all those with high viral loads, meaning they are effective in identifying the cases who are infectious and are most likely to transmit the disease. The fast

turnaround also allows positive people to isolate quickly also reducing spread.

Health Minister Lord Bethell said:

> We are absolutely committed to using the latest testing technology to make asymptomatic testing available in more areas.
>
> It is right we've taken a dual-track approach to evaluating this technology – by piloting them in the field so we can understand how to best to make these tests available, and by getting our world-leading academics and clinicians to undertake rigorous evaluation of their ability to detect the virus.
>
> I'm delighted that both are already demonstrating that lateral flow tests can be the reliable, highly sensitive technology we need to help get this virus under control, and return to as close to normality as possible.

The evaluation published today concludes that the Innova, and other tests which meet PHE and Oxford's standards, should be used in asymptomatic, as they offer the advantage of reducing risk and increasing capacity in addition to Lighthouse and NHS labs.

Susan Hopkins, Chief Medical Adviser, NHS Test and Trace, said:

> These tests are proving to be accurate and reliable. And, importantly they're able to detect COVID-19 in people without symptoms who could unknowingly be passing the virus onto others.
>
> Our evaluation work and the ongoing pilots are helping us to understand how lateral flow tests work in the field and how we may use them to help stop the spread of the virus.
>
> We are confident that these new tests, which have been rigorously evaluated, will make a real difference in how we protect people from this disease and help break chains of transmission.

The results of the Innova evaluation published today show:

- the specificity of the test was recorded as 99.68% – the overall false positive rate was 0.32%, although this was lowered to 0.06% in a lab setting
- it has an overall sensitivity of 76.8% for all PCR-positive individuals but detects over 95% of individuals with high viral loads, and minimal difference between the ability of the test to pick up viral antigens in symptomatic and asymptomatic individuals

Sensitivity means the proportion of people with a disease that have a

positive test, whereas specificity means the proportion of people without the disease that have a negative test.

Sir John Bell, regius professor of medicine at the University of Oxford, said:

> The data in this validation report demonstrates that these inexpensive, easy-to-use tests can play a major role in our fight against COVID-19.
>
> They identify those who are likely to spread the disease and when used systematically in mass testing could reduce transmissions by 90%.
>
> They will be detecting disease in large numbers of people who have never previously even received a test.

Using lateral flow technology to test asymptomatic individuals will help identify those who unknowingly have the virus and enable those who test positive and their contacts to self-isolate, which can help drive down the R rate locally and save lives.

This is crucial to break the chains of transmission of the virus and to support critical industries, key workers and institutions. With lower rates of transmission, those at highest risk from the virus will be more protected and residents will feel more confident in getting back to their day-to-day lives.

Asymptomatic testing is offered in addition to the wider government testing programme offering swab tests for those with symptoms.

The government has also committed to providing the devolved authorities with access to new testing technologies as they are made available, as part of UK-wide collaboration to stop the spread of the virus. Eligibility and deployment of testing in devolved administrations will be determined by the respective administrations.

See the full evaluation.

The 4-stage process is:

- phase 1 – desktop review to identify tests with potentially high specificity and sufficient sensitivity
- phase 2 – pre-clinical evaluation in lab
- phase 3a – secondary healthcare evaluation
- phase 3b – community research evaluation using volunteer patients and staff
- phase 4 – community pilot field service evaluation in a variety of settings