Clinical evaluation confirms accuracy of LAMP test

· Findings from a technical and clinical evaluation of OptiGene RT-LAMP tests confirm high sensitivity to the virus.

· Evaluation carried out by NHS trusts and universities finds the test to be highly effective in identifying infectious cases, including for people not displaying symptoms.

A technical and clinical evaluation conducted by NHS trusts and universities has confirmed OptiGene RT-LAMP tests to be accurate and sensitive enough to be used for COVID-19 testing, including for those without symptoms.

The OptiGene RT-LAMP (loop-mediated isothermal amplification) test was found to have a sensitivity of 79% and specificity of 100%, meaning the test is effective in identifying the cases who are infectious and are most likely to transmit the disease. In samples with a higher viral load, the sensitivity of the test increased to 94% for saliva and 100% for swabs.

Unlike PCR tests, LAMP tests do not require sequential changes of temperature and so can turnaround test results more rapidly.

As part of the strategy to deliver asymptomatic testing to identify those who might otherwise unknowingly spread the virus, OptiGene RT-LAMP tests have been used to test some NHS staff and in asymptomatic testing pilots in Southampton, including at the University of Southampton which has seen 55,000 people tested.

Initial results from these pilots show the test as effective in identifying positive cases and breaking chains of transmission.

Health Minister Lord Bethell said:

“With up to a third of individuals with COVID-19 not displaying symptoms, we are rolling out asymptomatic testing to protect those at highest risk. Most importantly NHS staff who are at the forefront of fighting this virus. By broadening testing to identify those showing no symptoms and who can infect people unknowingly, we can find positive cases more quickly and break chains of transmission.

“We are using the latest technology to do this, and the country’s leading scientists have rigorously evaluated the Optigene LAMP test in the lab and in the field and confirmed its sensitivity for asymptomatic testing.”

Professor Dame Sue Hill, Chief Scientific Officer for England in NHS Test and Trace, who led the evaluation of the OptiGene RT-LAMP Assay for NHS Test and Trace said:

“We’ve shown through carefully conducted studies that the OptiGene LAMP test

is fast, reliable and easy to use and dependent on testing format can work directly with saliva samples as well as with swabs. It has been effective in the pilot study sites and can make a valuable contribution to our overall COVID-19 testing capability."

Professor Keith Godfrey, of the University of Southampton MRC Lifecourse Epidemiology Unit, who led the first phase of the Southampton saliva testing pilot said:

"The saliva LAMP project in Southampton has proved to be very easy for students to use, and is extremely popular with parents and staff. Participation among University of Southampton students has been very encouraging, with 80% of students in halls of residence and over two thirds of those in private accommodation registered for regular saliva LAMP testing.

"Targeted educational materials and effective continued engagement with the students and school staff have been an essential part of the programme's success, supported by well-developed laboratory, IT, enquiries and case contacting systems. During the pilot, with regular testing and participation rates exceeding 80 per cent among the school staff and students, there has been no evidence of any transmission of infection within the schools involved. Feedback from students, staff and parents has been amazingly positive."

- 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.

- RT-LAMP was used in four configurations – with and without RNA extraction and using swab or saliva samples. The results of the evaluation published today show that sensitivity and specificity across the dynamic range of viral loads demonstrated in this study were:

    - RNA RT-LAMP on Swabs: Sensitivity 95%; Specificity 99%

    - RNA RT-LAMP on Saliva: Sensitivity 80%; Specificity 100%

    - Direct RT-LAMP on Swabs: Sensitivity 70%; Specificity 100%

    - Direct RT-LAMP on Saliva: Sensitivity 79%; Specificity 100%

The sensitivity of the Direct RT-LAMP assay increases in samples with a higher viral load (CT <25 by RT-qPCR) to 100% (swabs) and 94% (saliva). All RT-LAMP assays shown to have over 99% specificity.

The Technical and Validation Group was established under NHS Test and Trace, inclusive of NHS and PHE experts and working closely with MHRA and research

bodies. The Technical and Validation function considers manufacturers of SARS-CoV-2 (COVID-19) tests for viral detection (including LAMP technologies) and registers their interest in the national procurement process if their test meets, or are intended to meet the requirements of the relevant Medicines and Healthcare Products Regulatory Agency (MHRA) Target Product Profiles.

Loop-mediated isothermal amplification (LAMP) is a single-tube technique for the amplification of DNA and a low-cost, rapid alternative to RT-qPCR. Reverse Transcription Loop-Mediated Isothermal Amplification (RT-LAMP) combines LAMP with a reverse transcription step to allow the detection of RNA.