Large study in UK NHS labs shows gold-standard accuracy of Oxford Nanopore's COVID-19 test LamPORE

OXFORD, UK, December 21, 2020 /EINPresswire.com/ -- A study of more than 23,000 samples carried out by teams across the UK shows Oxford Nanopore's COVID-19 test, LamPORE, is highly accurate for the detection of SARS-CoV-2, in both symptomatic and asymptomatic population settings.

The study was performed on both swab and saliva samples across four NHS sites, showing very high LamPORE test accuracy, as follows:

LamPORE assay on swabs from asymptomatic patients: 34 positive, 3,932 negative samples. Sensitivity: 100% (95 CI 85.2-100%), Specificity: 99.72% (95% CI 99.5-99.7%)

LamPORE assay on saliva from asymptomatic patients: 299 positive, 18,136 negative samples. Sensitivity: 98.9% (95% CI 96.2-99.9%) , Specificity: 99.39% (95% CI 99.26-99.49%)

LamPORE assay on swabs from patients with respiratory symptoms: 745 positive, 116 negative samples. Sensitivity: 100% (95% CI 85.18-100%) , Specificity: 100%

These data support the use of LamPORE for testing of both symptomatic people, and those without symptoms. It also provides positive data on the use of LamPORE to detect SARS-CoV-2 from saliva samples, providing the potential to further streamline the testing workflow following relevant regulatory approvals.

Professor Andrew Beggs, of the Institute of Cancer & Genomic Sciences at the University of Birmingham said: "We were very pleased to be able to assess the LamPORE assay on real-world patient samples. The test represents a real leap forward in the ability to produce a new type of quick, highly accurate test. This type of technology can also be used to test for other respiratory illness and so will have great utility within healthcare"

This publication comes in addition to a study published in September 2020 of over 500 samples from Oxford, PHE Porton Down, and Sheffield, that found 99.1% sensitivity and 99.6% specificity, where the authors noted that "This indicates that LamPORE has a similar performance to RT-PCR for the diagnosis of SARS-CoV-2 infection in symptomatic patients, and offers a promising approach to high-throughput testing."

LamPORE is CE marked for in vitro diagnostic use and LamPORE devices are currently being piloted in a number of NHS labs, to support expanded high-accuracy testing for the UK. Oxford Nanopore is intending to submit an Emergency Use Authorisation application to the US FDA for LamPORE Covid-19 in the coming weeks.

Dr Gordon Sanghera, CEO of Oxford Nanopore, said: “This remarkable study is a testament to the scientific teams who worked so hard over the summer to validate a new generation of diagnostic test.

“We believe there are phenomenal opportunities here: not only to deliver high quality, rapid COVID testing, but to catalyse the development and delivery of real-time, data-rich clinical testing using nanopore sequencing. This has the potential to tackle infectious disease and to reach into cancer, rare disease, and tissue typing/immunology.”

Infectious Disease:

The LamPORE COVID-19 test, currently performed on the high-throughput GridION, is also in development to detect multiple viruses including influenza and RSV. The palm-sized MinION Mk1C is also in the process of being CE marked for LamPORE, unlocking the potential for further distributed adoption of LamPORE in smaller laboratories.

Methods to use nanopore sequencing to rapidly characterise even broader ranges of pathogens are developing rapidly — often using metagenomics, where sequencing characterises all of the pathogens present in a sample. These, and methods for simultaneous detection of genes that cause drug resistance with a view to more accurate antibiotic prescribing and stewardship, are in advanced stages of development with leading UK laboratories.

Epidemiology:
The GridION and MinION have become instruments of choice for rapid sequencing of SARS-CoV-2, where the sequence data is contributed to public databases and is critical for viral surveillance by public health teams, in the UK and internationally. For example, teams using nanopore sequencing technology have been characterising new variants such as that seen in mink and in the South East of England. This information is being used to identify potential barriers to successful testing and vaccination, and to understand how the virus is changing and being transmitted over time.
Oxford Nanopore is committed to supporting the UK and global efforts to prevent future outbreaks turning into pandemics.

Other potential future tests:
There are myriad methods now coming online to use nanopore sequencing for rapid and rich analyses in cancer, including for cell-free DNA; for rapid HLA analysis for tissue typing, and for rare disease diagnosis. Through collaborative innovation, Oxford Nanopore’s sequencing

technology offers an opportunity for novel, rapid, near-patient diagnostics to be brought to NHS laboratories around the UK.

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