

Novodiag® COVID-19, a fully automated molecular diagnostic test, granted emergency use authorization in Finland for novel coronavirus

- Real-time RT-PCR-based test enables fast, on demand and fully automated detection of early COVID-19 infections for rapid isolation and treatment guidance;
 - provides safety for users with a closed system;
 - easy to use with no need for highly trained personnel enabling decentralized testing.

FINLAND, Espoo, April, 22nd, 2020 – Mobidiag Ltd., a revenue generating, molecular diagnostics company with complementary platforms that address antimicrobial resistance and other areas of unmet diagnostic need, today announces that it has received emergency use authorization in Finland for its Novodiag® COVID-19 molecular diagnostic test for the rapid and fully automated detection of the SARS-CoV-2 virus, responsible for novel coronavirus infection (COVID-19). The <u>Novodiag® COVID-19</u> is now available for use in Finland*. The process for obtaining emergency use authorization is now ongoing in Sweden, UK and France.

The Novodiag® COVID-19 assay allows qualitative determination of SARS-CoV-2 (orf1ab and N genes) directly from nasopharyngeal swabs. The test will operate using the Novodiag® rapid 'sample-in, result-out' system, allowing the fully automated detection of novel coronavirus in approximately 1 hour. In addition, Novodiag® has a closed system which ensures the protection of laboratory staff and healthcare professionals from possible contamination. The user-friendly nature of the system means that the Novodiag® system can also be used in high risk and hard to reach areas without the need for highly trained personnel.

This new test complements the emergency use test, <u>Amplidiag® COVID-19*</u>, which is suitable for high-throughput screening, <u>launched on 14 April 2020</u>. This test is now available in Finland and routinely used in the main Finnish clinical laboratories as well as in France where it has been validated by the National Center of Reference – Institut Pasteur.

Due to the high demand for diagnostic devices and tests globally, Mobidiag has ensured that its supply chain and manufacturing capabilities are robust and able to support its customers. This includes for example the sourcing and acquisition of various consumables to cover the complete workflow from sample collection to the results, inhouse production of enzymes, the development of our proprietary mNAT™ sample buffer and collection tubes.

Tuomas Tenkanen, CEO of Mobidiag, said, "The coronavirus pandemic is a global challenge that needs all parts of industry to respond with innovative solutions for multiple settings. Early detection of COVID-19 infections is critical in supporting clinical decisions to efficiently manage epidemiological and infection control measures to isolate patients in a timely manner and to globally improve patient care. At Mobidiag, we have harnessed our existing technologies and expertise, including supply chain management and manufacturing, to rapidly develop and supply two coronavirus diagnostics tests, providing clinicians solutions suited to their own laboratory capacities. We are pleased that from today we are able to offer Novodiag® COVID-19 which can be used in smaller units without the need for highly trained personnel and Amplidiag® COVID-19 which can be used in larger laboratories for high-throughput testing".

* Amplidiag® COVID-19 is now available in Finland and France as an emergency use test. Novodiag® COVID-19 is available in Finland only at this time. Please note that Mobidiag tests are not home testing kits. They are only available for healthcare professionals, and not for patients directly. Please follow the recommended processes and guidance for your location if you believe you could be infected by SARS-CoV-2.

Contacts

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Notes to editors

About Mobidiag Ltd

Mobidiag is a commercial stage, fast growing molecular diagnostics company whose fast, cost-effective, widely applicable and robust technology makes the power of molecular diagnostics available to address the spread of infectious diseases and antimicrobial resistance (AMR) by rapid detection of pathogens and their potential resistance to antibiotics. Through its Amplidiag® and Novodiag® solutions, Mobidiag offers a comprehensive range of molecular diagnostic solutions for the detection of infectious diseases to laboratories of all sizes.

Mobidiag is headquartered in Espoo, Finland, with subsidiaries in France, UK and Sweden. To learn more, visit www.mobidiag.com