



Mobidiag offers complete diagnostic solution for the detection of novel coronavirus infections with both PCR and antibody tests

- *CE-IVD marked molecular diagnostic tests on the Novodiag® and Amplidiag® platforms for rapid detection of COVID-19 infections to support decisions for efficient patient isolation, treatment and release*
- *Antibody test for detection of past COVID-19 infections*
- *Secure supply chain and in-house manufacturing capabilities to meet demand*

FINLAND, Espoo, June 2nd, 2020 – Mobidiag Ltd., a revenue generating, molecular diagnostics company with complementary platforms that address infectious diseases, antimicrobial resistance and other areas of unmet diagnostic need, today announces that it has received CE-IVD markings for its [Novodiag® COVID-19](#) and [Amplidiag® COVID-19](#) molecular diagnostic tests for the early detection of the SARS-CoV-2 virus, responsible for novel coronavirus infection (COVID-19).

These tests complement the Company's already available antibody test, [Anti-SARS-CoV-2 Rapid Test](#), that Mobidiag is distributing from its joint venture partner in China, Autobio Diagnostics. Mobidiag is now able to commercially offer a comprehensive diagnostic solution for novel coronavirus infections for hospital and lab based settings.

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 (e.g. inhouse production of enzymes and the development of our proprietary mNAT™ Medium sample buffer and collection tubes).

Tuomas Tenkanen, CEO of Mobidiag, said, “With the CE-IVD mark approvals for our Novodiag COVID-19 and Amplidiag COVID-19 molecular diagnostic tests and our distribution of the Anti-SARS-CoV-2 Rapid antibody test, Mobidiag is now able to provide a complete diagnostic solution for the detection of COVID-19 infections across the life cycle of the virus.”

“Mobidiag has leveraged its existing technologies and expertise, including supply chain management and manufacturing, to ensure we are able to deliver a full range of diagnostic solutions to our customers.”

The [Novodiag® COVID-19](#) and [Amplidiag® COVID-19](#) molecular diagnostic tests are able to rapidly and reliably detect COVID-19 infections at an early stage in patients with signs and symptoms of respiratory infection. They have already earlier been granted emergency use authorisation in Finland, Sweden and France. The tests have been designed using dual targets of SARS-CoV-2 (orf1ab & N genes) to include at least one conserved region and one specific region to mitigate the effects of genetic drift and avoid cross-reaction with other endemic coronaviruses.

The [Novodiag® COVID-19](#) assay allows qualitative determination of SARS-CoV-2 (orf1ab and N genes) directly from nasopharyngeal swabs. The test operates using the [Novodiag®](#) rapid 'sample-in, result-out' system, allowing the on demand fully automated detection of COVID-19 in approximately 1 hour. In addition, Novodiag® solution is 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 and decentralized settings without the need for highly trained personnel.

The [Amplidiag® COVID-19](#) assay complements the Novodiag® COVID-19 on demand test. Based on well-established high-throughput qualitative PCR technology, 48 samples can be processed in less than three hours while running on Mobidiag's [Amplidiag® Easy platform](#), which enables to clinicians an optimized sample screening process with automated DNA/RNA extraction and PCR plate setup.

In addition to these molecular tests, Mobidiag is distributing an antibody test allowing qualitative determination of Anti-SARS-CoV-2 (IgG and IgM antibodies of SARS-CoV-2) in human serum, plasma or whole blood in less than 15 minutes without any instrumentation. The [Anti-SARS-CoV-2 Rapid Test](#) is manufactured by Mobidiag's joint venture partner in China, Autobio Diagnostics.

Please note that these 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