

Mobidiag receives CE-IVD marking for Amplidiag® RESP-4 for simultaneous detection of COVID-19, Flu A, Flu B and RSV

- Real-time PCR-based test enables high-throughput reliable detection of most prevalent respiratory infections, including COVID-19
- One single test determines the virus responsible for patient symptoms, guiding treatment decisions and rapid isolation strategy if required

FINLAND, Espoo, March 1st, 2021 – Mobidiag Ltd. today announces that it has received CE-IVD marking for its Amplidiag@RESP-4 molecular diagnostic test for the rapid and simultaneous detection of some of the most prevalent respiratory viruses: SARS-CoV-2 (responsible for COVID-19 infection), Influenza A, Influenza B and RSV.

These viruses present similar symptoms, making it difficult for physicians to determine accurately which virus a patient has. The Amplidiag® RESP-4 assay can rapidly and simultaneously determine an accurate diagnosis from one patient sample using nasopharyngeal swabs, helping to guide clinicians to the relevant treatment decision for each patient. The test runs on the Mobidiag Amplidiag® Easy platform, which provides clinicians with an optimized sample screening process, with automated DNA/RNA extraction and PCR plate setup. Based on well-established high-throughput PCR technology, the platform can process 46 samples in approximately three hours.

This new test further broadens Mobidiag's already available portfolio of diagnostics tests.

Tuomas Tenkanen, CEO of Mobidiag said, "We are very pleased to announce the CE-IVD marking for the Amplidiag® RESP-4 assay, which is highly relevant to both the traditional flu season and COVID-19. Symptoms caused by these viruses [SARS-CoV-2, Influenza A, Influenza B and RSV] can be very similar, and it is imperative that healthcare professionals are able to rapidly distinguish between them, in order to start the appropriate treatment for the benefit of patients.

In response to the growing need for fast and reliable diagnostics, at Mobidiag we are putting all our efforts into maintaining a high degree of autonomy in the production of our Amplidiag[®] tests by securing critical components to provide continuous support for our customers, as we all work together to control the spread of COVID-19."

Mobidiag is currently developing Novodiag® RESP-4, a molecular diagnostic test using its Novodiag® platform for the rapid and on-demand detection of SARS-CoV-2, Influenza A, Influenza B and RSV. This test will complement Amplidiag® RESP-4 and enable clinicians to

detect respiratory viruses to support early decisions in managing efficiently epidemiological and infection control measures, isolate patients in a timely manner, and ultimately improve patient care and outcomes.

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 have any symptoms of respiratory infections.

Contacts

For any orders or technical questions, please contact sales@mobidiag.com

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Notes to editors

About Mobidiag Ltd

Mobidiag is a fast-growing molecular diagnostics company whose rapid, 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