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FDA grants EUA to BD's SARS-CoV-2/Flu assay

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The BDÂ®Â SARS-CoV-2/Flu assay is run on the BD MAXâ?¢ System and distinguishes between SARS-CoV-2 and Influenza A+B, providing a positive or negative result for each virus using a single specimen



BD (Becton, Dickinson and Company), a leading global medical technology company, has announced that the US Food and Drug Administration (FDA) has granted Emergency Use Authorisation (EUA) for a new molecular diagnostic test for both SARS-CoV-2 and Influenza A+B that can return results in two to three hours. The new test also has been CE marked to the IVD Directive (98/79/EC).

The new EUA includes updated information in the test's instructions for use that addresses variants of the SARS-COV-2 virus, including variants from the UK and South Africa.

The BD® SARS-CoV-2/Flu assay is run on the BD MAX™ System and distinguishes between SARS-CoV-2 and Influenza A+B, providing a positive or negative result for each virus using a single specimen.

"The guidelines from the US Centers for Disease Control and Prevention (CDC) recommend testing for both Flu and SARS-CoV-2 for all patients who are hospitalised and for patients who will not be hospitalised but for whom a positive result will change clinical management," said Dr Charles K Cooper, Vice President, Medical and Scientific Affairs for Integrated Diagnostic Solutions, BD.

The BD® SARS-CoV-2/Flu for BD MAX™ System kits are now available for order in the United States and Europe. The test is the latest addition to the company's comprehensive COVID-19 diagnostics response.

"Our diagnostic solutions for COVID-19 and Flu will help inform timely diagnosis and, ultimately, may contribute to faster and clinically appropriate patient management and treatment," said Dave Hickey, President, Life Sciences BD.