BD gets EUA, CE mark for combo SARS-CoV-2, flu A+B test

Feb. 19, 2021–BD announced FDA emergency use authorization for its BD SARS-CoV-2/Flu assay, a molecular diagnostic test for SARS-CoV-2 and influenza A and B that can return results in two to three hours. The test also has been CE marked to the IVD directive.

The assay runs on the BD Max system and distinguishes between SARS-CoV-2 and influenza A and B, providing a positive or negative result for each virus using a single specimen. The EUA includes updated information in the test's instructions for use that addresses variants of the SARS-COV-2 virus, including variants from the U.K. and South Africa.

"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," Dave Hickey, president of life sciences for BD, said in a press release. "In addition, the new information provided on the test's ability to detect the U.K. and South African variants provides helpful guidance to health care practitioners as we look to identify and contain these new strains."

The BD Max can process hundreds of samples over a 24-hour period. The BD SARS-CoV-2/Flu kits are now available for order in the United States and Europe.