ICU MANAGEMENT & PRACTICE

FDA Grants Emergency Use Authorization for New COVID-19, Flu A, Flu B Combo Kit

One multiplex real-time PCR diagnostic kit can simultaneously detect and differentiate SARS-CoV-2, influenza A and influenza B

The U.S. Food and Drug Administration (FDA) has granted emergency use authorization (EUA) for the Applied Biosystems TaqPath COVID-19, Flu A, Flu B Combo Kit from Thermo Fisher Scientific, the company announced today.

The TaqPath COVID-19, Flu A, Flu B Combo Kit is a real-time PCR test for the detection and differentiation of RNA from the SARS-CoV2, influenza A and influenza B viruses in nasopharyngeal and nasal swabs.

"Understanding that the flu season would overlap with surges in COVID-19 infections, Thermo Fisher worked rapidly to develop a new multiplex real-time PCR diagnostic kit for detecting and differentiating SARS-CoV-2, influenza A and influenza B. These are illnesses which can present with similar clinical symptoms, but for which patient management, including quarantining measures, greatly differs," said Mark Smedley, president of Genetic Sciences for Thermo Fisher Scientific. Thermo Fisher. "This new kit offers clinical and public health laboratories a single test to help diagnose and monitor the spread of COVID-19 and the flu."

The TaqPath COVID-19, Flu A, Flu B Combo Kit helps labs expand their existing COVID-19 testing menu for respiratory samples while maintaining low operational costs and workflow simplicity. The kit includes Applied Biosystems Pathogen Interpretive Software to automatically convert genetic analysis data into a readable report, helping reduce risk of user interpretation error. For more information on the kit, visit thermofisher.com/covid19flu.

Testing with the TaqPath COVID-19, Flu A, Flu B Combo Kit is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform high-complexity tests, or by similarly qualified non-U.S. laboratories.

The TaqPath COVID-19, Flu A, Flu B Combo Kit has not been FDA cleared or approved and is only authorized for the duration of the EUA granted under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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