BD Life Sciences 7 Loveton Circle PO Box 999 Sparks, MD 21152

bd.com



April 2021

Dear Valued BD Customer,

BD is pleased to announce the recent <u>Emergency Use Authorization</u> (EUA) granted for the **BD Veritor**^M System for Rapid Detection of SARS-CoV-2 & Flu A+B. COVID-19 and Influenza present with similar symptoms, so this new product will assist clinicians in quickly differentiating between COVID-19 and Influenza with a single sample and test. This product will be available in the summer of 2021 in preparation for the upcoming Flu season. This system is **only** compatible with BD Veritor^M Plus Analyzers with v5.50 Firmware or higher.

The system is indicated for simultaneous qualitative detection and differentiation of SARS-CoV-2 nucleocapsid antigen and/or influenza A and B nucleoprotein antigens directly from anterior nasal swab samples taken from individuals who are suspected of a viral respiratory infection consistent with COVID-19 by a healthcare provider, within the first six days of symptom onset. Emergency use of this test is limited to authorized laboratories.

Product information

Product Description: BD Veritor[™] System for Rapid Detection of SARS-CoV-2 & Flu A+B **BD SKU:** 256088

Required hardware: BD Veritor[™] Plus Analyzer with v5.50 firmware or higher. Note, Analyzers with v5.40 firmware or lower are not able to be updated to v5.50 or higher. As new Analyzer will need to be ordered from BD to run this assay if current Analyzers have v5.40 firmware or lower.

Kit contents: 30 nasal swabs, 30 unitized reagent tubes, 30 test devices, 1 SARS-CoV-2 positive control swab, 1 Flu A positive control swab, 1 Flu B positive control swab, Proper Nasal Swab Sample Collection Guide, Quick Reference Instructions, link to digital eIFU.

Specimen Type: Dual anterior nares collection

Time to result: 15 minutes, test device can be read at 15 minutes but no later than 20 minutes

EUA Letter Instructions for Use Fact Sheet for Healthcare Providers Fact Sheet for Patients

We are excited to offer this product as a solution for the upcoming 2021-2022 Flu season. If you have additional questions about testing with the BD Veritor[™] Plus System, please contact us at **1-844-823-5433** or <u>VeritorCares@bd.com</u>.

Kind Regards,

Lucy Turland Associate Director - US Point of Care BD Life Sciences Integrated Diagnostic Solutions