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

bd.com



July 7, 2021

Dear Valued Customer,

Thank you for your inquiry regarding the BD Veritor[™] Plus System (Part # 256082*, 256088*, 256089, 256111, & 256112) and its ability to detect coronavirus (COVID-19) and its known variants.

We are pleased to share that the BD Veritor[™] Plus System has been shown to successfully detect multiple strains of SARS-CoV-2, as shown in the table below.

WHO CLASSIFICATION	ASSOCIATED LOCATION (INITIAL/DISCOVERY)	OTHER NAMES
Alpha	United Kingdom	VOC-20DEC-01, 20B/501Y.V1
Beta	South Africa	VOC-20DEC-02, 501.V2, 20C/501Y.V2
Gamma	Brazil/Japan	VOC-21JAN-02, 20J/501Y.V3
lota	United States	
Карра	India	
Delta AY.2	India	

There are multiple strains of the Delta variant and BD has tested and confirmed detection of the Delta AY.2 variant. We understand the importance of confirming detection of the Delta AY.1 variant and will continue to search for a source to complete our testing.

We remain committed to the reliability of BD Veritor[™] Plus System, to keeping this device verified against emerging strains of this virus and to *advancing the world of health* together. We will provide further updates as they are available.

Thank you for your continued support of BD. Should you have any questions, please contact medical information services by calling 1-800-555-7422 and selecting option 6 or via e-mail at <u>medical.services@bd.com</u>.

Sincerely,

Charles K. Cooper

Dr. Charles K. Cooper VP, Medical & Scientific Affairs BD Integrated Diagnostic Solutions

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* These products have not been FDA cleared or approved; but have been authorized by FDA under EUA for use by authorized laboratories

* The BD Veritor[™] System for Rapid Detection of SARS-CoV-2 & Flu A+B has been authorized only for the detection of proteins from SARS-CoV-2, influenza A and influenza B, not for any other viruses or pathogens; the BD Veritor[™] System for Rapid Detection of SARS-CoV-2 has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and,

* These products are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.