

March 24, 2021

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Device: BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B

EUA Number: EUA203152

Company: Becton, Dickinson and Company (BD)

Indication: 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.

Authorized Laboratories: Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Dear Ms. Fiechtner:

This letter is in response to your¹ request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,² pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

¹ For ease of reference, this letter will use the term “you” and related terms to refer to Becton, Dickinson and Company (BD).

² For ease of reference, this letter will use the term “your product” to refer to the BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.

Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.³

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is included in the Instructions for Use (identified below). There is an FDA-approved/cleared test for the qualitative detection and identification of SARS-CoV-2, influenza A virus, and influenza B virus (among other organism types), but this is not an adequate and available alternative to your product. Respiratory viral infections caused by the influenza A and B viruses and SARS-CoV-2 can have similar clinical presentation and diagnostic considerations. Thus, to differentially detect SARS-CoV-2, information from a test that detects and differentiates the virus that causes COVID-19 and the common influenza viruses that cause seasonal epidemics of flu, influenza A and B (not influenza C) is needed during the flu season that coincides with the COVID-19 pandemic.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19 through the simultaneous detection and differentiation of SARS-CoV-2, and/or influenza A virus and influenza B virus protein antigens and that the known and potential benefits of your product when used for such use, outweigh the known and potential risks of your product; and
3. There is no adequate, approved, and available alternative to the emergency use of your product.⁴

³ U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

⁴ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act. There is an FDA-approved/cleared test for the qualitative detection and identification of SARS-CoV-2, influenza A virus, and

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is rapid chromatographic digital immunoassay intended for the in vitro, 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. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

Performance characteristics for influenza A and B were established during January through March of 2011 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled “Update: Influenza Activity—United States, 2010–2011 Season, and Composition of the 2011–2012 Influenza Vaccine.” Minor changes were made to the BD Veritor System for Rapid Detection of Flu A+B device to accommodate the addition of SARS-CoV-2 detection reagents. Performance characteristics for influenza A and B were not re-established with the modified device and may vary from previous performance. Performance characteristics may vary against other emerging influenza viruses. This test is not intended to detect influenza C antigens.

These SARS-CoV-2 nucleocapsid protein and Influenza A and B viral nucleoproteins viral antigens are generally detectable in anterior nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative SARS-CoV-2 results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be treated as presumptive, do not rule out either Influenza or SARS-CoV-2, and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient’s recent exposures, history and the presence of clinical signs and symptoms consistent with one of these infections. Negative results for SARS-CoV-2 should be confirmed with a molecular assay, if necessary, for patient management. Negative results for influenza A and B should be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay.

If infection with a novel influenza virus is suspected based on current clinical and

influenza B virus (among other organism types), but this is not an adequate and available alternative to your product.

epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. A viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Testing of anterior nasal swab specimens using your product run on the BD Veritor Plus Analyzer Instrument as outlined in the “BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B” Instructions for Use, is limited to laboratories certified under CLIA that meet the requirements to perform moderate, high, or waived complexity tests. This test is authorized for use at the POC, i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

To use your product, the anterior nasal swab specimen is directly placed in the extraction reagent tube. After processing the swab in the extraction reagent, the specimen is added to the BD Veritor System test device. Any SARS-CoV-2 or influenza A or B antigens present in the specimen then bind to antibodies conjugated to detector particles in the test strip. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibodies bound on the membrane. Test results of the BD Veritor System test device are read using the BD Veritor Plus Analyzer Instrument, or other authorized instrument, when the 15-minute assay development time is complete. The Analyzer interprets the strength of the signal at the test and control line positions on the reaction membrane and applies a cut-off algorithm to determine the assay result presented to the user on the result screen only as positive or negative for each target analyte. No additional user interpretation is required.

The BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B includes the following materials or other authorized materials: BD Veritor System Test Devices, Reagent D, Specimen sampling swabs, SARS-CoV-2 (+) Control Swab, Flu A (+) Control Swab, Flu B (+) Control Swab and Paperboard tube stands.

In addition to the positive and negative internal/procedural controls described above, you require use of the external quality controls, or other authorized controls (as may be requested under Condition N. below), that are run as outlined in the Instructions for Use:

- SARS-CoV-2 (+) Control Swab - SARS-CoV-2 antigen (inactive recombinant nucleocapsid protein)
- Flu A (+) Control Swab - influenza A antigen (inactive recombinant nucleoprotein)
- Flu B (+) Control Swab - influenza B antigen (inactive recombinant nucleoprotein)

Your product also requires the use of additional authorized materials that are not included with your product and are described in the Instructions for Use.

The labeling entitled “BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B” Instructions for Use, “Quick Reference Instructions - Use of BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B with the BD Veritor Plus Analyzer for SARS-CoV-2 & Flu A+B,” “BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B Proper Nasal Swab Sample Collection” (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>), and the following fact sheets pertaining to the emergency use, is required to be made available as

set forth in the Conditions of Authorization (Section IV), and are collectively referred to as “authorized labeling”:

- Fact Sheet for Healthcare Providers: Becton, Dickinson and Company (BD) - BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B
- Fact Sheet for Patients: Becton, Dickinson and Company (BD) - BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Becton, Dickinson and Company (BD) (You) and Authorized Distributor(s)⁵

- A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).
- B. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.
- C. You and authorized distributor(s) must make available on your website(s) the authorized labeling.
- D. You and authorized distributors must include a physical copy of the authorized “BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B” Instructions for Use, “Quick Reference Instructions - Use of BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B with the BD Veritor Plus Analyzer for SARS-CoV-2 & Flu A+B,” and the “BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B Proper Nasal Swab Sample Collection” with each shipped product to authorized laboratories.
- E. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.
- F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute your product and number they distribute.
- G. You and authorized distributor(s) must collect information on the performance of your product. You will report to FDA any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware.
- H. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and

⁵ “Authorized Distributor(s)” are identified by you, Becton, Dickinson and Company (BD), in your EUA submission as an entity allowed to distribute your product.

does not exceed, the terms of this letter of authorization.

Becton, Dickinson and Company (BD) (You)

- I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).
- J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).
- K. You must comply with the following requirements pursuant to FDA regulations: Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).
- L. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.
- M. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.
- N. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and shall not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA prior to implementation.
- O. You must evaluate the analytical limit of detection and assess traceability⁶ of your product with any FDA-recommended reference material(s). After submission to and review and concurrence with the data by FDA, you must update labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- P. You must further evaluate the influenza A and influenza B clinical performance of your product in the agreed upon prospective clinical evaluation study within 12 months of the

⁶ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

- Q. You must complete the agreed upon real-time stability study for your product and notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results. After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling to reflect the additional testing if requested by FDA. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- R. You must have a process in place to track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803.

Authorized Laboratories

- S. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.
- T. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.
- U. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- V. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- W. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (by contacting BD Customer Support Services at 800.638.8663 (in the U.S.)) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- X. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

Becton, Dickinson and Company (BD) (You), Authorized Distributor(s) and Authorized Laboratories

- Y. You, authorized distributor(s), and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

- Z. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act and FDA implementing regulations.

- AA. No descriptive printed matter, advertising, or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

- BB. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories;
- This product 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; and,
- The emergency use of this product is 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.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure