September 23, 2020

Kristen Bankert, PhD
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Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Device:	BD SARS-CoV-2 Reagents for BD MAX System
Company:	Becton, Dickinson and Company (BD)
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in nasal, nasopharyngeal, mid-turbinate, and oropharyngeal swab specimens, nasopharyngeal wash/aspirate or nasal aspirates obtained from individuals suspected of COVID-19 by their healthcare provider. 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 requirements to perform moderate or high complexity tests.

Dear Dr. Bankert:

On April 8, 2020, based on your[1] request that the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of your product,[2] for the qualitative detection of nucleic acid from SARS-CoV-2 in nasal, nasopharyngeal and oropharyngeal swab samples from individuals suspected of COVID-19 by their healthcare provider, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). The April 8, 2020 letter authorizing emergency use of your product limited testing to laboratories certified under CLIA to perform moderate and high complexity tests. Based on your request, FDA has also granted updates to the authorized labeling.[3]

[1] For ease of reference, this letter will use the term "you" and related terms to refer to the Becton, Dickinson and Company (BD).
[2] For ease of reference, this letter will use the term "your product" to refer to the BD SARS-CoV-2 Reagents for BD MAX System used for the indication identified above.
[3] On June 11, 2020, your request was granted to update the Instructions for Use (IFU) of your product to; (1) update Intended Use to include mid-turbinate swab specimens and nasopharyngeal wash/ aspirate or nasal aspirates as additional specimen types, with the associated limitation, (2) update external control recommendations and the interpretation table, (3) update the inclusivity *in silico* data, (4) add data to support nasal swab specimens and remove the nasal swab limitation, (5) revise the color compensation setting of the User Defined Protocol (UDP), (6) update the materials provided section to include the extraction reagents as part of the BD SARS-CoV-2 Reagents for BD MAX System, and the associated update to the catalog number and outer box labeling, (7) and make some minor

On July 17, 2020, you requested to amend your Emergency Use Authorization (EUA). Based on this request, and having concluded that revising the April 8, 2020, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the April 8, 2020, letter in its entirety with the revisions incorporated.[4] Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, this test is now authorized for use consistent with the indication described above.

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.[5]

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 contained in the Instructions for Use (identified below).

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;

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clarifications and edits to the IFU, (8) revise the External Control preparation white paper to add the Microbiologics Helix Elite Inactivated Standard Negative Cellularity Control (Inactivated Pellet) as an RNaseP Control and correct a dilution error identified for Microbiologics Helix Elite Synthetic Standard SARS-CoV-2 Synthetic RNA (N gene Targets) controls, along with some other minor clarifications and edits, and (9) update the Heathcare Provider and Patient Fact Sheets.

[4] The revisions to the April 8, 2020, letter and authorized labeling include: (1) revisions to the intended use to indicate that "Positive results should be treated as presumptive and should be tested with a different authorized or cleared molecular test" and other minor revisions to reflect more recent authorizations, (2) updates to the threshold value used to determine a positive result, (3) added limitation for presumptive positive results, (4) revisions to the performance sections including updated Limit of Detection and Clinical Evaluation data, (5) additional conditions of authorization, (6) updates to the External Control preparation white paper, and, (7) updates to the Healthcare Provider and Patient Fact Sheets to reflect more recent authorizations.

[5] 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).

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, and that the known and potential benefits of your product when used for diagnosing COVID-19, 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.[6]

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 a qualitative test for the detection of nucleic acid from SARS-CoV-2 nasal, nasopharyngeal, mid-turbinate, and oropharyngeal swab specimens, nasopharyngeal wash/aspirate or nasal aspirates obtained from individuals suspected of COVID-19 by their healthcare provider. The SARS-CoV-2 nucleic acid is generally detectable in respiratory samples during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Positive results should be treated as presumptive and should be tested with a different authorized or cleared molecular test. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing is limited to laboratories certified under CLIA that meet requirements to perform moderate or high complexity tests.

To use your product, SARS-CoV-2 nucleic acid is extracted, isolated and purified from samples using the BD MAX ExK TNA-3 Sample Buffer Tube, BD MAX TNA Unitized Reagent Strip (TNA) and the BD MAX ExK TNA Extraction Tube (B4) materials included with your product. The patient sample is first transferred to the Sample Buffer Tube (SBT) before being placed in the BD MAX System, or other authorized instruments, were the purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using the materials or other authorized materials included in the BD SARS-CoV-2 Reagents for BD MAX System, which includes the following: BD SARS-CoV-2 Reagents for BD MAX System Primers and Probes (Dried primers and probes for SARS-CoV-2), BD MAX TNA MMK (Dried PCR Master Mix containing dNTPs and RT-polymerase).

Your product requires the following RNase P (RP) control, or other authorized control materials, that are processed in the same way as the patient samples when tested with your product. The control listed below must generate expected results in order for a test to be considered valid, as outlined in the Instructions for Use:

[6] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

- RP control serves as both a sample extraction control (EC) and an internal amplification control (IAC): The RP primer and probe set is included in each run to test for human RP, which controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.

You also recommend use of external positive and negative controls, or other authorized controls, to be run as outlined in the Instructions for Use. Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the Instructions for Use.

Your product described above is authorized to be accompanied with the labeling submitted as part of the EUA request (listed below), and as described in the "BD SARS-CoV-2 Reagents for BD MAX System" Instructions for Use (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas), and the following product-specific information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Becton, Dickinson and Company (BD) - BD SARS-CoV-2 Reagents for BD MAX System
- Fact Sheet for Patients: Becton, Dickinson and Company (BD) - BD SARS-CoV-2 Reagents for BD MAX System

The above described product, when accompanied by the Instructions for Use (identified above), the Preparation of External Positive and Negative Controls for BD SARS-CoV-2 Reagents for BD MAX System white paper, and the two Fact Sheets (collectively referenced as "authorized labeling") 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 for the qualitative detection of SARS-CoV-2 and 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 when used consistent with 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 (You) and Authorized Distributor(s)[7]

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 U.S.C. 352(f)), (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) will make your product available with the authorized labeling to authorized laboratories.

C. You and authorized distributor(s) will make available on your website(s) the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

D. You and authorized distributor(s) will inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product, authorized labeling and authorized Fact Sheets.

E. Through a process of inventory control, you and authorized distributor(s) will maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.

[7] "Authorized Distributor(s)" are identified by you, BD, in your EUA submission as an entity allowed to distribute your device.

F. You and authorized distributor(s) will collect information on the performance of your product. You will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the product of which you become aware.

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

Becton, Dickinson and Company (You)

H. You will notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

I. You will provide its authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

J. 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 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.

K. You will comply with the following requirements under 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 will evaluate the analytical limit of detection and assess traceability[8] of your product with any FDA-recommended reference material(s). After submission to and

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

concurrence with the data by FDA you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

O. You will complete the agreed upon clinical study of your product in an FDA agreed upon post authorization prospective clinical evaluation study [within 3 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH)]. After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, you will 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.

P. You will complete the agreed upon customer inspections/services of the BD MAX Systems using your product to check instrument normalization within 1 month of the date of this letter. You will submit to FDA and DMD/OHT7-OIR/OPEQ/CDRH a report summarizing any issues found during the customer inspections/services and how they were addressed.

Q. You will have a process in place in accordance with 21 CFR Part 803 to track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803.

Authorized Laboratories

R. Authorized laboratories using your product will include with test result reports of your product, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

S. Authorized laboratories using your product will use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

T. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.

U. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

V. Authorized laboratories will 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 (Customer Technical Support 1.800.638.8663) 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.

W. All laboratory personnel using your product must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

Becton, Dickinson and Company (You), Authorized Distributors and Authorized Laboratories

X. You, authorized distributors, and authorized laboratories using your product will 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

Y. All descriptive printed matter, including 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 the applicable requirements set forth in the Act and FDA regulations.

Z. No descriptive printed matter, including 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.

AA. No descriptive printed matter, including advertising and promotional materials, relating to the use of your product shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests 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 authorization is terminated or 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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure