February 14, 2022

Colton Muraira, J.D.
Staff Regulatory Affairs Specialist
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Device:	BD SARS-CoV-2 Reagents for BD MAX System
EUA Number:	EUA200159
Company:	Becton, Dickinson and Company (BD)
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, anterior nasal, mid-turbinate, and oropharyngeal swab specimens, as well as nasopharyngeal wash/aspirate or nasal aspirate specimens obtained from any individuals, including individuals without symptoms or other reasons to suspect COVID-19. 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 Colton Muraira:

On April 8, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the BD SARS-CoV-2 Reagents for BD MAX System, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3), 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. Testing was limited to laboratories certified under CLIA that meet requirements to perform moderate and high complexity tests. Based on your requests, FDA has granted updates to the authorized labeling on June 11, 2020[2] and September 25, 2020[3] as well as

[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] On June 11, 2020, your request was granted to update the Instructions for Use (IFU) 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

revised and reissued the letter on September 23, 2020[4], March 10, 2021[5], and April 23, 2021[6]. In addition, FDA established additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.[7]

On August 13, 2021 and November 17, 2021, you requested to further amend your Emergency Use Authorization (EUA). Based on these requests and having concluded that revising the April 23, 2021, 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 23, 2021, letter in its entirety with the revisions incorporated.[8] Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product[9] is now intended for the indication described above.

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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 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.

[3] On September 25, 2020, your supplement was acknowledged to update the IFU with results from testing with the FDA reference panel.

[4] On September 23, 2020, the revisions to the April 8, 2020, letter and authorized labeling included: (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] On March 10, 2021, the revisions to the September 23, 2020, letter and authorized labeling included: (1) revisions to the intended use to remove the limitation for presumptive positive results and other minor revisions to reflect more recent authorizations, (2) revisions to the IFU performance section to include performance data from a prospective clinical study and updated in silico inclusivity information, (3) removal of the limitation statements for presumptive positive results in the IFU and healthcare provider fact sheet, (4) addition of frozen specimen stability claims, (5) addition of limitation regarding performance with variants and addition of similar statement to the healthcare provider fact sheet, and (6) removal of two fulfilled Conditions of Authorization (Condition O. and P. of the September 23, 2020, letter).

[6] The revisions to the March 10, 2021, letter and authorized labeling included: (1) revisions to the intended use and authorized labeling documents, including the Fact Sheet for Healthcare Providers and Fact Sheet for Patients to reflect current information known about serial testing as outlined in the March 16, 2021, FDA "Supplemental Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing" (https://www.fda.gov/media/146695/download), which includes testing of individuals without symptoms or other epidemiological reasons to suspect COVID-19, and (2) updates to the Conditions of Authorization to require a post-authorization clinical study to support the serial testing claim.

[7] The Viral Mutation Revision Letter – September 23, 2021, can be accessed at: https://www.fda.gov/media/152406/download

[8] The revisions to the April 23, 2021, letter and authorized labeling include: (1) addition of data to support an asymptomatic screening claim and removal of Condition of Authorization P (from the April 23, 2021 letter) which was fulfilled, (2) revisions to the intended use to remove the serial testing requirement, (3) addition of data evaluating potential interfering substances and updates to the corresponding limitations, (4) updated *in silico* inclusivity data, and (5) removal of the BioGx External Positive Control as an acceptable control, and (6) addition of Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (Q. and R. below).

[9] For ease of reference, this letter will use the term "your product" to refer to the BD SARS-CoV-2 Reagents for BD

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.[10]

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;

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.[11]

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

MAX System used for the indication identified above.

[10] 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).

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

Your product is a qualitative test for the detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, anterior nasal, mid-turbinate, and oropharyngeal swab specimens, as well as nasopharyngeal wash/aspirate or nasal aspirate specimens obtained from any individuals, including individuals without symptoms or other reasons to suspect COVID-19. The SARS-CoV-2 nucleic acid is generally detectable in upper 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. 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.

To use your product, SARS-CoV-2 nucleic acid is extracted, isolated and purified from nasopharyngeal, anterior nasal, mid-turbinate, and oropharyngeal swab specimens, as well as nasopharyngeal wash/aspirate or nasal aspirate specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument. The BD SARS-CoV-2 Reagents for BD MAX System includes the materials (or other authorized materials as may be requested under Condition K. below) described in the authorized labeling (described below).

Your product requires control materials or other authorized control materials (as may be requested under Condition K. below) that are described in the authorized labeling.

You also recommend use of external positive and negative controls (not provided with your product), or other authorized controls (as may be requested under Condition K. below), that are run as outlined in the authorized labeling (described below).

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 authorized labeling (described below).

The labeling entitled "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/in-vitro-diagnostics-euas), the "Preparation of External Positive and Negative Controls for BD SARS-CoV-2 Reagents for BD MAX System" white paper, the "BD SARS-CoV-2 Reagents for BD MAX System / BD SARS-CoV-2/Flu for BD MAX System" flyer, and the following fact sheets pertaining to the emergency use, are 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 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 authorized labeling 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 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)[12]

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

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) 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 distributor(s) must include a physical copy of the "BD SARS-CoV-2 Reagents for BD MAX System / BD SARS-CoV-2/Flu for BD MAX System" flyer with each shipped product to authorized laboratories, and must make the authorized "BD SARS-CoV-2 Reagents for BD MAX System" Instructions for Use and the "Preparation of External Positive and Negative Controls for BD SARS-CoV-2 Reagents for BD MAX System" white paper electronically available with the opportunity to request a copy in paper form, and after such request, you must promptly provide the requested information without additional cost.

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 of your product they distribute.

G. You and authorized distributor(s) must collect information on the performance of your product. You must report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of your 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 does not exceed, the terms of this letter of authorization.

Becton, Dickinson and Company (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 amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

K. 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.

L. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 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).

M. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that your product released for distribution has the clinical and analytical performance claimed in the authorized labeling.

N. 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.

O. You must evaluate the analytical limit of detection and assess traceability[13] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA you must update your 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 have a process in place to track adverse events, including any occurrence of false results with your product and report to FDA in accordance with 21 CFR Part 803.

Q. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected

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

performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).

R. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding the impact of viral mutations on test performance. Such updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

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 these Fact Sheets 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 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.

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 (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.

X. 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 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 must 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, as applicable, 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 for emergency use by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, 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,

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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure