U.S. FOOD & DRUG ADMINISTRATION

October 26, 2021

Katerina Capkova, Ph.D.
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10210 Genetic Center Drive
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Device:	Aptima SARS-CoV-2 assay
EUA Number:	EUA200734
Company:	Hologic, Inc.
Indication:	This test is authorized for the following indications for use: Qualitative detection of RNA from SARS-CoV-2 isolated and purified from nasopharyngeal (NP) and oropharyngeal (OP) swab specimens, nasopharyngeal washes/aspirates or nasal aspirates (collected by a healthcare provider) and anterior nasal (nasal) and mid-turbinate nasal swab specimens (collected under observation of or by a healthcare provider) from individuals who meet COVID-19 clinical and/or epidemiological criteria. Qualitative detection of RNA from SARS-CoV-2 isolated and purified from NP and OP swab specimens (collected by a healthcare provider) and nasal and mid-turbinate nasal swab specimens (collected under observation of or by a healthcare provider) from any individual, including from individuals without symptoms or other reasons to suspect COVID-19. Qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 5 individual NP or OP swabs (collected by a healthcare provider), or nasal or mid-turbinate nasal swabs (collected under observation of or by a healthcare provider), where each specimen is collected using individual vials containing transport media. 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 high complexity tests.

Dear Dr. Capkova:

On May 14, 2020, based on your[1] request the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Aptima SARS-CoV-2 assay for the qualitative detection of nucleic acid from SARS-CoV-2 isolated and purified from nasopharyngeal (NP), nasal, mid-turbinate and oropharyngeal (OP) swab specimens, nasopharyngeal wash/ aspirate or nasal aspirates obtained from individuals meeting COVID-19 clinical and/or epidemiological criteria pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing was limited to laboratories certified under CLIA to perform high complexity tests. Based on your request, FDA has also granted updates to the authorized labeling on July 24, 2020,[2] September 15, 2020,[3] January 22, 2021,[4] and March 26, 2021.[5] Based on your request, FDA also reissued the letter in its entirety on October 5, 2020[6], May 24, 2021[7] and July 22, 2021.[8]

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[1] For ease of reference, this letter will use the term "you" and related terms to refer to Hologic, Inc.

[2] On July 24, 2020, your request was granted to update the Instructions for Use (IFU) of your product to: (1) add Aptima Specimen Transfer Tube workflow for use with the assay and supporting analytical and clinical validation, (2) add the Aptima Unisex Swab Specimen Collection Kit, (3) update specimen stability claims and acceptable media based on the provided bridging study to directly compare sensitivity of Aptima and Panther Fusion SARS-CoV-2 assays, and (4) revise minor errors identified in the current IFU.

[3] On September 15, 2020, your request was granted to update the IFU of your product to: (1) add an uncapped workflow for testing with the Aptima SARS-CoV-2 assay on the Panther and Panther Fusion systems and (2) add updated in silico inclusivity study results (3) add LoD study results obtained with additional commercial materials to aid in laboratory verification, (4) revise minor errors identified in the current IFU, (5) minor updates to the intended use to reflect more recent authorizations and reporting recommendations, and (6) updates to the Healthcare Provider and Patient Fact Sheets to reflect more recent authorizations.

[4] On January 22, 2021, your request was granted to update the Panther and Panther Fusion System Software Version 7.2 authorized for use with the Aptima SARS-CoV-2 assay to include pooling features.

[5] On March 26, 2021, your request was granted to update the IFU of your product to: to update the Instructions for Use (IFU) of the Aptima SARS-CoV-2 Assay to; (1) include the Hologic Direct Load Capture Cap (DLC) Collection Kit – CLASSIQSwab and the Hologic Direct Load Tube (DLT) Collection Kit as authorized collection kits and (2) change the formulation of the Enzyme Reagent. In addition, FDA added a statement in the IFU regarding clinical performance with circulating variants as well as updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in more recent authorizations.

[6] On October 5, 2020, revisions to the May 14, 2020, letter and authorized labeling included: (1) revisions to the intended use and authorized labeling documents to include minor updates to language describing testing of upper respiratory specimens (such as nasopharyngeal, nasal, mid-turbinate, and oropharyngeal swab specimens, nasopharyngeal wash/aspirates or nasal wash) obtained from individuals who meet COVID-19 clinical and/or epidemiological criteria, and (2) revisions to the intended use and authorized labeling documents to include testing of upper respiratory specimens (such as nasopharyngeal, nasal, mid-turbinate, and oropharyngeal swab specimens) collected from an individual, including from individuals without symptoms or other reasons to suspect COVID-19 infection, (3) revisions to the intended use and authorized labeling documents to include testing of pooling individual upper respiratory swab specimens (nasopharyngeal, nasal, mid-turbinate, or oropharyngeal swabs), where each specimen is collected under observation or by a healthcare provider using individual vials containing transport media, (4) revisions to the Healthcare Provider and Patient Fact Sheets to reflect the intended use updates and language more consistent with recent authorizations (5) revisions to the Conditions of Authorization as a result of the new intended uses and for consistency with recent authorization.

[7] On May 24, 2021, revisions to the October 5, 2020 letter and authorized labeling included: (1) updates to the intended use to reflect language used in more recent authorizations, (2) updates to include results of a Precision/Reproducibility Study, (3) incorporation/addition of the collection kits and associated labeling described in the Scope of Authorization (Section II), (4) updates to the Fact Sheet for Healthcare Providers to reflect the revised intended use, and (5) removal of Condition O. from the October 5, 2020, letter (which was fulfilled).

[8] On July 22, 2021, the revisions to the May 24, 2021, letter and authorized labeling include: (1) revisions to the

On September 3, 2021,you requested to revise your Emergency Use Authorization (EUA). Based on that request, and having concluded that revising the July 22, 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 July 22, 2021, letter in its entirety with the revisions incorporated.[9] Accordingly, your product[10] is hereby authorized pursuant to section 564 of the Act when used pursuant to the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter.

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.[11]

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 "Aptima SARS-CoV-2 Assay (Panther System)" 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 (as 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:

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intended use to clarify appropriate collection of indicated specimens, (2) revisions to the Healthcare Provider Fact Sheet to reflect the intended use updates, (3) addition of the Aptima SARS-CoV-2 product information card (PIC) to the authorized labeling, (4) addition of Condition D. to include the PIC with each shipped product to authorized laboratories, and (5) addition of Conditions Q. and R. (in the July 22, 2021 letter) to evaluate the impact of SARS-CoV-2 viral mutations on product performance.

[9] The revisions to the July 22, 2021, letter and authorized labeling include: 1) extension of reagent on-board stability from 72 to 120 hours, 2) modification of the number of extractions that can be performed with the Hologic Specimen Lysis Tube (PRD-06660) from two to one extraction, 3) update the collection kit IFUs to include the use of the collection kits with the Aptima SARS-CoV-2/Flu assay, 4) updates to the Conditions of Authorization to add a new Condition for a required stability study (Condition R below) 5) update the Letter of Authorization to include information about assay controls (including Condition I below), and 6) updates to the assay IFU, the Fact Sheets for Healthcare Providers and Patients to reflect language used in more recent authorizations.

[10] For ease of reference, this letter will use the term "your product" to refer to the Aptima SARS-CoV-2 assay used for the indication identified above.

[11] 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).

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.[12]

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 RNA from SARS-CoV-2 isolated and purified from nasopharyngeal (NP) and oropharyngeal (OP) swab specimens, nasopharyngeal washes/aspirates or nasal aspirates (collected by a healthcare provider) and anterior nasal (nasal) and mid-turbinate nasal swab specimens (collected under observation of or by a healthcare provider) from individuals who meet COVID-19 clinical and/or epidemiological criteria, as well as NP and OP swab specimens (collected by a healthcare provider) and nasal and mid-turbinate nasal swab specimens (collected under observation of or by a healthcare provider) from any individual, including from individuals without symptoms or other reasons to suspect COVID-19.

This test is also for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 5 individual NP or OP swabs (collected by a healthcare provider), or nasal or mid-turbinate nasal swabs (collected under observation of or by a healthcare provider) where each specimen is collected using individual vials containing transport media. Negative results from pooled testing should not be treated as definitive. If a patient's clinical signs and symptoms are inconsistent with a negative result or if results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing. For specific patients, whose specimen(s) were the subject of pooling, a notice that pooling was used during testing must be included when reporting the result (refer to Condition Y below).

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory specimens 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

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

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 high complexity tests.

The Aptima SARS-CoV-2 assay combines the technologies of target capture, Transcription Mediated Amplification, and Dual Kinetic Assay. The Aptima SARS-CoV-2 assay is performed on the Panther and Panther Fusion system, or other authorized instrument, which is an integrated nucleic acid testing system that fully automates all steps necessary to perform various Panther Fusion assays from sample processing through amplification, detection, and data reduction. The Aptima SARS-CoV-2 assay includes the following materials or other authorized materials: Aptima SARS-CoV-2 Refrigerated Box (Aptima SARS-CoV-2 Amplification Reagent, Aptima SARS-CoV-2 Enzyme Reagent, Aptima SARS-CoV-2 Probe Reagent Aptima SARS-CoV-2 Internal Control), and Aptima SARS-CoV-2 Room Temperature Box (Aptima SARS-CoV-2 Amplification Reconstitution Solution, Aptima SARS-CoV-2 Enzyme Reconstitution Solution, Aptima SARS-CoV-2 Probe Reconstitution Solution, Aptima SARS-CoV-2 Selection Reagent, Aptima SARS-CoV-2 Target Capture Reagent, Reconstitution Collars and Master Lot Barcode Sheet).

Your product requires the positive and negative controls which are not included in the kit but are available from you with the Control Product Information Card (PIC), or other authorized control materials (as may be requested under Condition L below), that are processed in the same way as the patient samples and are required to be included with each batch of specimens tested with your product. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Instructions for Use:

- Internal Control – non-infectious RNA nucleic acid in a buffered solution added to each specimen reaction and must be detected in all samples that are negative for SARS-CoV-2.
- Positive Control – non-infectious nucleic acid in a buffered solution containing less than 5% detergent. The positive control must provide a positive result.
- Negative Control – buffered solution containing less than 5% detergent . The negative control must provide a negative result.

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.

The labeling entitled "Aptima SARS-CoV-2 Assay (Panther 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 Aptima SARS-CoV-2 product information card, the Control Kit Product Information Card and the following product-specific information 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: Hologic, Inc. - Aptima SARS-CoV-2 assay
- Fact Sheet for Patients: Hologic, Inc. - Aptima SARS-CoV-2 assay

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.

The following collection kits, which you recommend be used with the Aptima SARS-CoV-2 assay and are available separately, are authorized to be distributed and used as set forth in this EUA: 1) the Hologic Direct Load Capture Cap Collection Kit — CLASSIQSwabs when accompanied by the "Hologic Direct Load Capture Cap Collection Kit — CLASSIQSwabs" Instructions for Use, 2) Hologic Direct Load Tube Collection Kit when accompanied by the "Hologic Direct Load Tube Collection Kit" Instructions for Use, and 3) Hologic Direct Load Capture Cap Collection Kit —FLOQSwabs when accompanied by the "Hologic Direct Load Capture Cap Collection Kit — FLOQSwabs" Instructions for Use.

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 authorized 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, 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 the Aptima SARS-CoV-2 assay 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:

Hologic, Inc. (You) and Authorized Distributor(s)[13]

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 Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

D. You and authorized distributor(s) must include the Aptima SARS-CoV-2 Product Information Card with each shipped Aptima SARS-CoV-2 Assay, and the Control Product Information Card with each Aptima SARS-CoV-2 Controls Kit to authorized laboratories and will make the authorized "Aptima SARS-CoV-2 Assay (Panther System)" Instructions for Use 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 the test and number of tests they distribute.

G. You and authorized distributor(s) must collect information on the performance of your product. You will report to 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) any suspected occurrence of false positive or false

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

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

I. You and authorized distributor(s) must make available the control materials at the same time as your product.

Hologic, Inc. (You)

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

K. 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).

L. 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 DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

M. You must comply with the following requirements under 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).

N. 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.

O. 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.

P. You must evaluate the analytical limit of detection and assess traceability[14] of your product with any FDA-recommended reference material(s). After submission to FDA and FDA's review and concurrence with the data, you will update labeling to reflect the

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

additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

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

R. You must evaluate specimen stability of your product in an FDA agreed upon post-authorization specimen stability study within 2 months of the date of this letter (unless otherwise agreed to with FDA). After submission to and concurrence with the data by FDA, you will update authorized labeling to reflect the additional testing.

S. 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 performance of your device, you must notify FDA immediately.

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

Authorized Laboratories

U. 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.

V. 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.

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

X. 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.

Y. Authorized laboratories using specimen pooling strategies when testing patient specimens with your product must include with test result reports for specific patients whose specimen(s) were the subject of pooling, a notice that pooling was used during testing

and that "*Patient specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing*."

Z. Authorized laboratories implementing pooling strategies for testing patient specimens must use the "Appendix A: Specimen Pooling Implementation and Monitoring Guidelines" available in the authorized labeling to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.

AA. Authorized laboratories must keep records of specimen pooling strategies implemented including type of strategy, date implemented, and quantities tested, and test result data generated as part of the Protocol for Monitoring of Specimen Pooling Testing Strategies. For the first 12 months from the date of their creation, such records will be made available to FDA within 48 business hours for inspection upon request, and will be made available within a reasonable time of FDA's request after 12 months from the date of their creation.

BB. 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 (molecularsupport@hologic.com) 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.

CC. All laboratory personnel using your product must be appropriately trained in Transcription Mediated Amplification techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

Hologic, Inc. (You), Authorized Distributor(s) and Authorized Laboratories

DD. 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

EE. 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.

FF. 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.

GG. 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 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