U.S. FOOD & DRUG ADMINISTRATION

August 11, 2021

Cem Sibay
Vice President, Amazon Labs
c/o Amazon Legal Dept.
410 Terry Avenue N.
Seattle, WA 98109

Device:	Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test ("Amazon Multi-Target Test")
EUA Number:	EUA210481
Company:	STS Lab Holdco (a subsidiary of Amazon.com Services LLC)
Indication:	This test is authorized for the following indications for use: Qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens that are self-collected by any individuals (18 years of age or older), including individuals without symptoms or other reasons to suspect COVID-19 (1) onsite at Amazon facilities using either (a) the Amazon COVID-19 Collection Kit under the supervision of a healthcare provider (HCP) or, (b) the Amazon On-Site COVID-19 Test Collection Kit unsupervised or (2) at home using the Amazon COVID-19 Test Collection Kit unsupervised. Qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to five individual anterior nasal swab specimens per pool that are self-collected in individual vials containing transport medium by any individual (18 years of age or older), including individuals without symptoms or other reasons to suspect COVID-19, (1) onsite at Amazon facilities using either (a) the Amazon COVID-19 Collection Kit under the supervision of a healthcare provider (HCP) or, (b) the Amazon On-Site COVID-19 Test Collection Kit unsupervised or (2) at home using the Amazon COVID-19 Test Collection Kit unsupervised. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories designated by STS Lab Holdco (a subsidiary of Amazon.com Services LLC) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

Dear Cem Sibay:

This letter is in response to your[1] 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).

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 contained in the EUA Summary (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.[4]

II. Scope of Authorization

---

[1] For ease of reference, this letter will use the term "you" and related terms to refer to STS Lab Holdco (a subsidiary of Amazon.com Services LLC) ("Amazon").

[2] For ease of reference, this letter will use the term "your product" to refer to the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test used for the indication identified above. You also refer to your product as the "Amazon Multi-Target Test."

[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.

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 an in vitro diagnostic real-time reverse transcription polymerase chain reaction (rRT-PCR) test for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens that are self-collected by any individuals (18 years of age or older), including individuals without symptoms or other reasons to suspect COVID-19 (1) onsite at Amazon facilities using either (a) the Amazon COVID-19 Collection Kit under the supervision of a healthcare provider (HCP) or, (b) the Amazon On-Site COVID-19 Test Collection Kit unsupervised or (2) at home using the Amazon COVID-19 Test Collection Kit unsupervised.

Your product is also intended for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to five individual anterior nasal swab specimens per pool that are self-collected in individual vials containing transport medium by any individual (18 years of age or older), including individuals without symptoms or other reasons to suspect COVID-19, (1) onsite at Amazon facilities using either (a) the Amazon COVID-19 Collection Kit under the supervision of a healthcare provider (HCP) or, (b) the Amazon On-Site COVID-19 Test Collection Kit unsupervised or (2) at home using the Amazon COVID-19 Test Collection Kit unsupervised.

Testing is limited to laboratories designated by STS Lab Holdco (a subsidiary of Amazon.com Services LLC) that are certified under CLIA, 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

The Amazon COVID-19 Collection Kit and the Amazon On-Site COVID-19 Test Collection Kit include the following in the kit for on-site collection: a nasal swab, collection tube, and biohazard bag. The Amazon COVID-19 Test Collection Kit includes the following in the kit for unsupervised, at-home collection: a nasal swab, collection tube, biohazard bag, and instructions for kit registration, sample collection, and drop-off. Individuals should follow all instructions when using the kit.

The SARS-CoV-2 nucleic acid is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; 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. 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 and 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.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from anterior nasal swab specimens self-collected using the Amazon COVID-19 Collection Kit, Amazon On-Site COVID-19 Test Collection Kit, or Amazon COVID-19 Test Collection Kit. 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 Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test uses all commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories as described in the authorized procedures submitted as part of the EUA request.

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition N. below), that are to be run as outlined in the procedures submitted as part of the EUA request. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the laboratory procedures submitted as part of the EUA request:

- Internal Control – primers and probe specific to RNaseP to determine the presence of human RNA in patient samples and positive controls.
- Positive Control – primers and probes specific to the assay targets used to monitor failures of rRT-PCR reagents and reaction conditions.
- Negative Control – RNase-free water used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents.

The above described product is authorized to be accompanied by the labeling listed below, and as described in the EUA Summary (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), and the following fact sheets pertaining to the emergency use, which are required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: STS Lab Holdco (a subsidiary of Amazon.com Services LLC) (“Amazon”) - Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test
- Fact Sheet for Patients: STS Lab Holdco (a subsidiary of Amazon.com Services LLC) (“Amazon”) - Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test

The above described product when accompanied by the “Amazon COVID-19 Collection Kit” supervised instructions, the “Amazon On-Site COVID-19 Test Collection Kit” unsupervised instructions, the “Amazon COVID-19 Test Collection Kit” unsupervised instructions, the “Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test and Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR DTC Test Laboratory Protocol”, the EUA Summary, and the

two fact sheets (collectively referred to 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.

The Amazon COVID-19 Collection Kit, with the "Amazon COVID-19 Collection Kit" supervised instructions, the Amazon On-Site COVID-19 Test Collection Kit with the "Amazon On-Site COVID-19 Test Collection Kit" unsupervised instructions, and the Amazon COVID-19 Test Collection Kit with the "Amazon COVID-19 Test Collection Kit" unsupervised instructions is authorized to be distributed and used as set forth in this EUA.

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:

STS Lab Holdco (a subsidiary of Amazon.com Services LLC) (You) and Authorized Distributor(s)[5]

A. Your product must comply with the following labeling requirements pursuant to 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 available on your website(s), if applicable, the Fact Sheet for Healthcare Providers, Fact Sheet for Patients, and all instructions related to the self-collection of anterior nasal swab specimens for the Amazon COVID-19 Collection Kit, Amazon On-Site COVID-19 Test Collection Kit, and Amazon COVID-19 Test Collection Kit.

C. You and authorized distributor(s) must make available all instructions related to the self-collection of anterior nasal swab specimens using the Amazon COVID-19 Collection Kit or Amazon On-Site COVID-19 Test Collection Kit provided in hard copy separately and/or on a static digital screen at the collection station. You and authorized distributor(s) must make available all instructions related to the self-collection of anterior nasal swab specimens using the Amazon COVID-19 Test Collection Kit in the shipped kit.

D. 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.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which the Amazon COVID-19 Test Collection Kit is distributed.

F. You and authorized distributor(s) must maintain customer complaint files on record. You must report to FDA any significant complaints about usability or 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.

STS Lab Holdco (a subsidiary of Amazon.com Services LLC) (You)

[5] "Authorized Distributor(s)" are identified by you, STS Lab Holdco (a subsidiary of Amazon.com Services LLC) ("Amazon"), in your EUA submission as an entity allowed to distribute the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test, Amazon COVID-19 Collection Kit, Amazon On-Site COVID-19 Test Collection Kit, and/or Amazon COVID-19 Test Collection Kit.

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

I. You must maintain records of the laboratories you designate as authorized laboratories and you will also maintain records of test usage by all such authorized laboratories.

J. 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.

K. 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 them within 48 hours of the request.

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 evaluate the stability of pre-spotted PCR reagents for use in the Amazon Multi-Target Test in an agreed upon study and submit the data for to FDA for review within 3 months of the data of authorization.

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 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 traceability[6] 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 will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. You must provide a summary report of the results obtained from the first 1000 anterior nasal swab specimens that are collected with the Amazon COVID-19 Test Collection Kit and tested individually using the Amazon Multi-Target Test. The report will include

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

analysis of positivity rate for each target analyte (including Ct values) and for the assay, as well as the failure rate for the RNase P endogenous control.

Q. You must have a process in place to track adverse events, including any occurrence of false results with your product, including with the Amazon COVID-19 Collection Kit, the Amazon On-Site COVID-19 Test Collection Kit, and the Amazon COVID-19 Test Collection Kit, and report any such events to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7- OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

R. 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.

S. 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

T. 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.

U. 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.

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

W. 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.

X. 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 (amazon-dx-labs@amazon.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.

Y. 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.

Z. Authorized laboratories testing specimens self-collected using the Amazon COVID-19 Collection Kit, the Amazon On-Site COVID-19 Test Collection Kit, and the Amazon COVID-19 Test Collection Kit must follow the sample assessioning procedures provided with your product when accepting specimens for testing.

AA. Authorized laboratories using specimen pooling strategies when testing patient specimens with your product must include with negative 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."*

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

CC. 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 must be made available to FDA within 48 business hours for inspection upon request. After 12 months from the date of their creation, upon FDA's request such records must be made available for inspection within a reasonable time.

STS Lab Holdco (a subsidiary of Amazon.com Services LLC) (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 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,

_____

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure