November 5, 2021

Jennifer Topor
Manager Regulatory Affairs
Abbott Molecular Inc.
1300 E. Touhy Ave.
Des Plaines, IL 60018

Device:	Alinity m SARS-CoV-2 assay
EUA Number:	EUA200572
Company:	Abbott Molecular Inc.
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal, mid-turbinate nasal, nasopharyngeal (NP) and oropharyngeal (OP) swabs and bronchoalveolar lavage (BAL) specimens collected from individuals suspected of COVID-19 by their healthcare provider (HCP). Qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal, mid-turbinate nasal, NP and OP swabs collected from any individual, including 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 upper respiratory specimens (i.e., anterior nasal, mid-turbinate nasal, NP and OP swabs) that are collected by an HCP using individual vials containing transport media. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing of non-pooled specimens is limited to 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. Testing of pooled specimens is limited to 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 Ms. Topor:

On May 11, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Alinity m SARS-CoV-2 assay for the qualitative detection of nucleic acid from SARS-CoV-2 in nasal swabs, self-collected at a health care location or collected by a healthcare worker, nasopharyngeal (NP) and oropharyngeal (OP) swabs collected by a healthcare worker, or bronchoalveolar lavage fluid (BAL) from patients suspected of COVID-19 by their health care provider, 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 the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate or high complexity tests. Based on your requests, FDA has granted updates to the Instructions for Use (IFU) on June 2, 2020,[2] July 20, 2020,[3] and August 24, 2020[4] as well as revised and reissued the letter on December 23, 2020 [5] and August 18, 2021. [6]

On August 21, 2021, you requested to further revise your Emergency Use Authorization (EUA). Based on this request, and having concluded that revising the August 18, 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 August 18, 2021, letter in its entirety with the revisions incorporated.[7] 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[8] is now authorized for use consistent with the indication described above.

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[1] For ease of reference, this letter will use the term "you" and related terms to refer to Abbott Molecular Inc.
[2] On June 2, 2020, your request was granted via email to update the Instructions for Use (IFU) to update the software from version 1.5.1 to version 1.5.2 as well as clarify the statement related to phosphate-containing buffers.
[3] On July 20, 2020, your request was granted to update the IFU to: (1) update the Alinity m software to improve resolution at low target concentrations and (2) provide clarity in the labeling.
[4] On August 24, 2020, your request was granted to update the IFU to: (1) change the formulation of the SARS-CoV-2 AMP kit, (2) increase the on-board storage time of the SARS-CoV-2 AMP kit, (3) remove the limitation "Phosphate-containing buffers may interfere with sample extraction for the Alinity m SARS-CoV-2 assay and therefore, are not recommended for use with this assay," (4) update the maximum fill volumes for associated Alinity m tubes, and (5) make the associated labeling changes in the IFU.
[5] On December 23, 2020, the revisions to the May 11, 2020, letter included: (1) addition of the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 5 individual upper respiratory specimens (i.e., nasal, NP and OP swabs) that are collected by an HCP using individual vials containing transport media, (2) qualitative detection of nucleic acid from SARS-CoV-2 in nasal, NP and OP swabs collected from any individual, including individuals without symptoms or other reasons to suspect COVID-19 infection, (3) new conditions of authorization specific to specimen pooling, (4) update and consolidation of conditions to reflect more recent authorizations, (5) inclusion of FDA Reference Panel testing data in the IFU, and (6) associated revisions to the IFU, healthcare provider fact sheet, and patient fact sheet to reflect additional indications.
[6] On August 18, 2021, the revisions to the December 23, 2020 letter and authorized labeling included: (1) changes to the sample tube type used in the Alinity m instrument, (2) update to the Application Specification file from version 3.00 to version 4.00, (3) updates to the lot release specifications for the positive and internal controls, (4) minor changes to the IFU, (5) removal of Condition P. (from the December 23, 2020 letter) which was fulfilled, (6) addition of Condition D. to include the Alinity m SARS-CoV-2 assay IFU in each shipped kit, and (7) addition of Conditions Q. and R. to evaluate device performance with viral mutations.
[7] The revisions to the August 18, 2021 letter and authorized labeling include: (1) modification of the liquid handling specifications, (2) update to the Application Specification file from version 4.00 to version 5.00, (3) update to the *in silico* inclusivity data in the IFU, and (4) addition of Condition S. to submit results of additional testing.
[8] For ease of reference, this letter will use the term "your product" to refer to the Alinity m SARS-CoV-2 assay used for the indication identified 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.[9]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is included in the Instructions for Use (identified below).

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 Section 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.[10]

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 real-time reverse transcriptase (RT) polymerase chain reaction (PCR) test intended for qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal, mid-turbinate nasal, nasopharyngeal (NP) and oropharyngeal (OP) swabs and bronchoalveolar lavage

[9] 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).

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

(BAL) specimens collected from individuals suspected of COVID-19 by their healthcare provider (HCP) as well as anterior nasal, mid-turbinate nasal, NP and OP swabs collected from any individual, including individuals without symptoms or other reasons to suspect COVID-19. Testing of non-pooled specimens is limited to 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.

Your product is also for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 5 individual upper respiratory specimens (i.e., anterior nasal, mid-turbinate nasal, NP and OP swabs) that are collected by an HCP using individual vials containing transport media. Testing of pooled specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C.§263a, that meet requirements to perform high complexity tests.

The SARS-CoV-2 nucleic acid is generally detectable in respiratory 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 or results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive 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.

The Alinity m SARS-CoV-2 assay is to be used with the Alinity m System, or other authorized instruments (as may be requested under Condition K. below) which performs sample preparation, RT-PCR assembly, amplification, detection, and result calculation and reporting. All steps of the Alinity m SARS-CoV-2 assay procedure are executed automatically by the Alinity m System, or other authorized instruments. The Alinity m SARS-CoV-2 assay includes the following materials or other authorized materials: Alinity m SARS-CoV-2 AMP Kit – that includes Alinity m SARS-CoV-2 AMP TRAY 1 and the Alinity m SARS-CoV-2 ACT TRAY 2, and the Alinity m SARS-CoV-2 CTRL Kit – that includes the Alinity m SARS-CoV-2 Negative CTRL and the Alinity m SARS-CoV-2 Positive CTRL.

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition K. 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 (extraction control) - Armored RNA with internal control sequences in negative human plasma: introduced into each specimen at the beginning of sample preparation, and controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.

- Alinity m SARS-CoV-2 Positive CTRL - Contains non-infectious, recombinant Sindbis virus containing SARS-CoV-2 RNA sequences. The positive control is used to monitor for failures of rRT-PCR reagents and reaction conditions.
- Alinity m SARS-CoV-2 Negative CTRL - buffer solution used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents.

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 "Alinity m SARS-CoV-2 AMP Kit" and "Alinity m SARS-CoV-2 CTRL Kit" 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), and the following fact sheets pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers: Abbott Molecular Inc.- Alinity m SARS-CoV-2 Assay
- Fact Sheet for Patients: Abbott Molecular Inc.- Alinity m 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.

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 (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.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

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:

Abbott Molecular Inc. (You) and Authorized Distributor(s)[11]

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)); any 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 a physical copy of the "Alinity m SARS-CoV-2 AMP Kit" and "Alinity m SARS-CoV-2 CTRL Kit" Instructions for Use with each shipped product to authorized laboratories.

E. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and/or authorized labeling.

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

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 FDA any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware.

H. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

Abbott Molecular Inc. (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, 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 the tests released for distribution have 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[12] of your product with any FDA-recommended reference material(s). After submission to and 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.

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

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 performance of your device, you must notify FDA immediately.

R. 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.

S. Within 2 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH), you must submit the results of the study evaluating your product which was agreed to with FDA on October 16, 2021. If updates to your authorized labeling are necessary, you must do so in consultation with and 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.

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

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 (email: molecularsupport@abbott.com; 1-800-553-7042) 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 using specimen pooling strategies when testing patient specimens with your product will 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."*

AA. Authorized laboratories implementing pooling strategies for testing patient specimens must use the "After Implementation of Pooling: Ongoing Monitoring of Pooling Strategy" protocol available in the authorized labeling to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.

BB. Authorized laboratories will 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 "After Implementation of Pooling: Ongoing Monitoring of Pooling Strategy" protocol. 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 and must be made available within a reasonable time after 12 months from the date of their creation.

Abbott Molecular Inc. (You), Authorized Distributors and Authorized Laboratories

CC. You, authorized distributors, 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

DD. 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.

EE. 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.

FF. 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