June 28, 2022

Jennifer Topor
Manager Regulatory Affairs
Abbott Molecular Inc.
1350 East Touhy Ave, Suite 300W
Des Plaines, IL 60018

Device:	Alinity m Resp-4-Plex
EUA Number:	EUA202930
Company:	Abbott Molecular Inc.
Indication:	Simultaneous qualitative detection and differentiation of RNA from SARS-CoV-2, influenza A virus (flu A), influenza B virus (flu B), and/or Respiratory Syncytial Virus (RSV) in anterior nasal or nasopharyngeal swab specimens collected by a healthcare provider (HCP), or in anterior nasal swab specimens that are self-collected at a healthcare location, from individuals suspected by their HCP of respiratory viral infection consistent with 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 Ms. Topor:

On March 4, 2021, based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Alinity m Resp-4-Plex for the simultaneous qualitative detection and differentiation of RNA from SARS-CoV-2, influenza A virus (flu A), influenza B virus (flu B), and/or Respiratory Syncytial Virus (RSV) in anterior nasal or nasopharyngeal swab specimens collected by a healthcare provider (HCP), or in anterior nasal swab specimens that are self-collected at a healthcare location, from individuals suspected by their HCP of respiratory viral infection consistent with COVID-19, 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 10, 2021,[2] July 1,

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Abbott Molecular Inc.
[2] On June 10, 2021, your request was granted to update the Instructions for Use (IFU) of the Alinity m Resp-4-Plex to change to the Application Specification File (ASF) on the Alinity m System to Version 3.00.

2021,[3] February 7, 2022,[4] and March 30, 2022.[5] 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.[6]

On April 1, 2022, you requested to further revise your Emergency Use Authorization (EUA). Based on this request, and having concluded that revising the March 4, 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 March 4, 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.

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]

There is an FDA-approved/cleared test for the qualitative detection and identification of SARS-CoV-2, influenza A virus, and influenza B virus (among other organism types), but this is not

---

[3] On July 1, 2021, your request was granted to update the IFU to: (1) include data from additional inclusivity testing to fulfill Condition R (of the March 4, 2021 letter) and (2) update the format of the positive control vial labels, negative control vial label, AMP tray label, and ACT tray label.

[4] On February 7, 2022, your request was granted to update the IFU to provide data supporting modification to the reaction vessel clamp height resulting in an update to the Application Specification File from version 4.00 to version 5.00, as well as to update the authorized labeling of the Alinity m Resp-4-Plex to include use with pierceable caps on the Alinity m instrument and update the in silico inclusivity data.

[5] On March 30, 2022, your request was granted to update the IFU to update the Amp-Detect Motion Profile used with the Abbott Alinity m Resp-4-Plex assay to change the rate at which the ejector bar on the Amplification Detection Unit makes contact and lifts the Reaction Vessel out of the thermal block after thermocycling.

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

[7] The revisions to the March 4, 2021 letter and authorized labeling include: (1) modifications to the processing parameters for reaction vessel preparation to reduce the potential for liquid overflow at the AMP tray, (2) authorization of the Abbott Universal Collection Kit for collection of specimens for testing with the Alinity m Resp-4-Plex, (3) addition of the "Abbott Universal Collection Kit" IFU to the authorized labeling and the corresponding Condition of Authorization C., (3) minor updates to the Alinity m Resp-4-Plex IFU, including updates to the *in silico* inclusivity analysis, (4) updates to the Application Specification File IFU to reflect the version update, (5) addition of the "Alinity m Resp-4-Plex Application Specification File" Instructions for Use to the authorized labeling, (6) incorporation of Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 to the letter, and (7) removal of Conditions Q. and R. (from the March 4, 2021 letter) which were fulfilled.

[8] For ease of reference, this letter will use the term "your product" to refer to the Alinity m Resp-4-Plex used for the indication identified above.

[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).

an adequate and available alternative to your product. Respiratory viral infections caused by the influenza A and B viruses, RSV and SARS-CoV-2 can have similar clinical presentation and diagnostic considerations. Thus, to differentially detect SARS-CoV-2, information from a test that detects and differentiates the virus that causes COVID-19 and the common influenza viruses that cause seasonal epidemics of flu, and disease caused by RSV is needed.

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 "Alinity m Resp-4-Plex AMP Kit" 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 through the simultaneous detection and differentiation of SARS-CoV-2, influenza A virus, influenza B virus and/or RSV nucleic acids 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 a multiplex real-time reverse transcription polymerase chain reaction (RT-PCR) test for the simultaneous qualitative detection and differentiation of RNA from SARS-CoV-2, influenza A virus (flu A), influenza B virus (flu B), and/or Respiratory Syncytial Virus (RSV) in anterior nasal or nasopharyngeal swab specimens collected by a healthcare provider (HCP), or in anterior nasal swab specimens that are self-collected at a healthcare location, from individuals suspected by their HCP of respiratory viral infection consistent with COVID-19. Clinical signs

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

and symptoms of respiratory viral infection due to SARS-CoV-2, influenza, and RSV can be similar. Your product is not intended to detect influenza C virus. The flu A, flu B, RSV and SARS-CoV-2 RNA are generally detectable in respiratory samples during the acute phase of infection. Positive results are indicative of active infection but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Negative results do not preclude flu A, flu B, RSV, or 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.

The Alinity m Resp-4-Plex assay is to be used with the Alinity m System (includes the Alinity m System Operations Manual), or other authorized instruments (as may be requested under Condition L. below) which performs sample preparation, RT-PCR assembly, amplification, detection, and result calculation and reporting. All steps of the Alinity m Resp-4-Plex assay procedure are executed automatically by the Alinity m System, or other authorized instruments. The Alinity m Resp-4-Plex assay includes the materials (or other authorized materials) described in the Instructions for Use.

Your product requires control materials (or other authorized control materials as may be requested under Condition L. below), that are described in the Instructions for Use.

Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the Instructions for Use.

The labeling entitled "Alinity m Resp-4-Plex AMP Kit" Instructions for Use, "Alinity m Resp-4-Plex Application Specification File" Instructions for Use, "Alinity m Resp-4-Plex 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 Resp-4-Plex
- Fact Sheet for Patients: Abbott Molecular Inc. - Alinity m Resp-4-Plex

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 Abbott Universal Collection Kit, when accompanied by the "Abbott Universal Collection Kit" Instructions for Use, is an optional collection device that may be used with the Alinity m Resp-4-Plex and is available separately, 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:

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

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).

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

B. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories. You and authorized distributor(s) must include a physical copy of the "Alinity m Resp-4-Plex AMP Kit" Instructions for Use in each shipped Alinity m Resp-4-Plex product to authorized laboratories and must make the "Alinity m Resp-4-Plex Application Specification File" Instructions for Use electronically available.

C. You and authorized distributor(s) must include a physical copy of the "Abbott Universal Collection Kit" Instructions for Use in each shipped Abbott Universal Collection Kit.

D. You and authorized distributor(s) must make available on your website(s) the authorized labeling.

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 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.

I. You and authorized distributor(s) must make available the control material, Alinity m Resp-4-Plex CTRL Kit, with the "Alinity m Resp-4-Plex AMP Kit" Instructions for Use, or other authorized control materials (as may be requested under Condition L. below), at the same time as your product.

Abbott Molecular 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 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.

M. 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).

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[12] 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.

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 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

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

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 (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.

Abbott Molecular Inc. (You), Authorized Distributor(s) and Authorized Laboratories

Z. 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

AA. 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 sections 502(a), (q)(1) and (r) of the Act, as applicable, and FDA implementing regulations.

BB. 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.

CC. 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 been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection and differentiation of nucleic acid from SARS-CoV-2, influenza A, influenza B, and/or Respiratory Syncytial Virus, 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,

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

Enclosure