U.S. FOOD & DRUG ADMINISTRATION

May 24, 2022

Jacek Gorzowski
Associated Director Regulatory Affairs
Abbott Laboratories Diagnostics Division
100 Abbott Park Road
Abbott Park, IL 60064

Device:	SARS-CoV-2 IgG
Company:	Abbott Laboratories Inc.
Indication:	Qualitative detection of IgG antibodies to SARS-CoV-2 in human serum (including collected using a serum separator tube), and plasma (ACD, CPD, CPDA-1, dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin in a separator tube, sodium citrate, or sodium heparin). Intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. 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 Mr. Gorzowski:

On April 26, 2020, based on your[1] request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the SARS-CoV-2 IgG assay pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the indications stated in the letter.[2] Subsequently based on your requests, FDA granted updates to the authorized labeling on May 9, 2020,[3] June 22, 2020,[4] September 18,

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Abbott Laboratories Inc.
[2] The April 26, 2020, letter authorized the SARS-CoV-2 IgG assay for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum (including collected using a serum separator tube), and plasma (ACD, CPD, CPDA-1, dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin in a separator tube, sodium citrate, or sodium heparin). Intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. 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.
[3] On May 9, 2020, your request was granted to include the Alinity i instrument platform as an additional authorized instrument for the SARS-CoV-2 IgG assay.
[4] On June 22, 2020, your request was granted to update the Instructions for Use (IFU) of the SARS-CoV-2 IgG

2020[5] and December 1, 2020[6]and January 14, 2021.[7] 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.[8]

On December 14, 2021, you requested to amend your EUA. Based on that request, and having concluded that revising the April 26, 2020, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the April 26, 2020, letter in its entirety with the revisions incorporated.[9] 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[10] 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

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assay run on the ARCHITECT i and Alinity i systems to: (1) add endogenous and exogenous interference studies, (2) extend the calibration interval stability from 7 days to 30 days, (3) remove daily maintenance procedures to prevent potential interactions based on a cross-contamination study, and (4) make some additional minor edits and clarifications.

[5] On September 18, 2020, your request was granted to (1) replace the detergent formulation in the calibrator and positive control of the ARCHITECT and Alinity SARS-CoV-2 IgG tests to comply with European REACH regulations, (2) transfer the bulk manufacturing, filling and labeling of the calibrator and controls to the Ireland facility, and (3) add stability studies for the calibrator and positive control with the new detergent formulation to the ongoing stability study outlined in EUA200422. The intended use has also been updated to reflect language used in more recent authorizations regarding results reporting.

[6] On December 1, 2020, your request was granted to update the Fact Sheet for Healthcare Providers of the Abbott SARS-CoV-2 IgG, to include a limitation - "*Due to the risk of false positive results, confirmation of positive results should be considered – using a second, different antibody assay that detects the same type of antibodies*." FDA also made minor updates to the IFU, the Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients to reflect more recent authorizations.

[7] On January 14, 2021, your request was granted via email acknowledgement to include minor updates to the IFUs with respect to formatting and symbols.

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

[9] The revisions to the April 26, 2020, letter and authorized labeling include: (1) update to the intended use to clarify that testing is limited to laboratories "that meet requirements" to perform moderate or high complexity tests, (2) add use of Product Information Cards that will accompany the shipped product, (3) updates to the letter for consistency with language and newer conditions used in more recent authorizations, (4) incorporation of Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (Conditions U. and V. below), (5) removal of Condition of Authorization U. from the April 26, 2020 letter that was fulfilled, (6) updating the Fact Sheet for Recipients and Fact Sheet for Healthcare Providers to reflect the minor updates to the intended use and/or to reflect language used in more recent authorizations and (7) remove "assay" from the device name in the letter.

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

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 included in the "SARS-CoV-2 IgG for use with ARCHITECT" and the "SARS-CoV-2 IgG for use with Alinity i" 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 recent or prior infection with SARS-CoV-2 by identifying individuals with an adaptive immune response to the virus that causes COVID-19, and that the known and potential benefits of your product when used for such use, 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 chemiluminescent microparticle immunoassay (CMIA) intended for the qualitative detection of IgG antibodies against SARS-CoV-2 in human serum (including collected using a serum separator tube), and plasma (ACD, CPD, CPDA-1, dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin in a separator tube, sodium citrate, or sodium heparin). The product is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is

[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).

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

unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The SARS-CoV-2 IgG assay should not be used to diagnose acute SARS-CoV-2 infection.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C 263a, that meet requirements to perform moderate or high complexity tests.

To use your product, the clinical specimen is tested and the results interpreted according to the test procedures described in the authorized labeling (described below). The SARS-CoV-2 IgG includes the materials or other authorized materials (as may be requested under Condition M. below) required to perform testing with your product as described in the authorized labeling (described below).

Your product requires authorized calibrators (SARS-CoV-2 IgG Calibrator Kit for use with ARCHITECT and SARS-CoV-2 IgG Calibrator Kit for use with Alinity i), which are not included with the kit but are available from you with the "SARS-CoV-2 IgG Calibrator Kit for use with ARCHITECT" or "SARS-CoV-2 IgG Calibrator Calibrator Kit for use with Alinity i" package inserts, or other authorized calibrators (as may be requested under Condition M. below) to be run as outlined in these calibrator package inserts.

Your product also requires the use of the SARS-CoV-2 IgG Control Kit for use with ARCHITECT and SARS-CoV-2 IgG Control Kit for use with Alinity i, which are not included with the kit but are available from you with the "SARS-CoV-2 IgG Control Kit for use with ARCHITECT" or "SARS-CoV-2 IgG Control Kit for use with Alinity i" package inserts, or other authorized controls (as may be requested under Condition M. below), to be run as outlined in these control package inserts.

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 "SARS-CoV-2 IgG for use with ARCHITECT" Instructions for Use, the "SARS-CoV-2 IgG for use with Alinity i" Instructions for Use, the "SARS-CoV-2 IgG Calibrator Kit for use with ARCHITECT" package insert, the "SARS-CoV-2 IgG Calibrator Kit for use with Alinity i" package insert, the "SARS-CoV-2 IgG Control Kit for use with ARCHITECT" package insert, and "SARS-CoV-2 IgG Control Kit for use with Alinity i" package insert, (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), the two Product Information Cards (PIC cards; one for ARCHITECT and one for Alinty i) 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 Laboratories Inc. - SARS-CoV-2 IgG
- Fact Sheet for Recipients: Abbott Laboratories Inc. - SARS-CoV-2 IgG

The above described product, when accompanied by the authorized labeling a 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 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 recent or prior infection with SARS-CoV-2 by identifying individuals with an adaptive immune response to the virus that causes 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 Laboratories Inc. (You) and Authorized Distributor(s)[13]

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

A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.

C. You and authorized distributor(s) must make available on your website(s) the Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients.

D. You and authorized distributor(s) must include a physical copy of the applicable ARCHITECT or Alinity i authorized PIC card with each shipped product and will make the "SARS-CoV-2 IgG for use with ARCHITECT" and the "SARS-CoV-2 IgG for use with Alinity i" 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 your product and number they distribute.

G. You and authorized distributor(s) must collect information on the performance of your product. You must report 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) any suspected occurrence of false positive and 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 materials (SARS-CoV-2 IgG Control Kit for use with ARCHITECT or the SARS-CoV-2 IgG Control Kit for use with Alinity i) with the "SARS-CoV-2 IgG Control Kit for use with ARCHITECT" package insert or "SARS-CoV-2 IgG Control Kit for use with Alinity i" package insert and the calibrator materials (SARS-CoV-2 IgG Calibrator Kit for use with ARCHITECT or SARS-CoV-2 IgG Calibrator Kit for use with Alinity i) with the

"SARS-CoV-2 IgG Calibrator Kit for use with ARCHITECT" package insert or "SARS-CoV-2 IgG Calibrator Kit for use with Alinity i" package insert, or other authorized control materials (as may be requested under Condition M. below), at the same time as your product.

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

N. You must evaluate the performance and assess traceability[14] of your product with any FDA-recommended reference material(s) or established panel(s) of characterized clinical specimens. 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.

O. 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.

P. 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.

Q. 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

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

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.

R. You must complete the agreed upon real-time stability study for your product. After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, you will update your product labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

S. If requested by FDA, you must participate in a National Cancer Institute study on the evaluation of your product. After submission to and concurrence with the data by FDA you will update your product labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

T. If requested by FDA, you must periodically submit new lots for testing at the National Cancer Institute, or by another government agency designated by FDA, to confirm continued performance characteristics across lots. In addition, FDA may request records regarding lot release data for assays to be distributed or already distributed. If such lot release data are requested by FDA, you must provide it within 48 hours of the request.

U. 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.

V. 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

W. 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.

X. Authorized laboratories using your product must use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

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

Z. 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.

AA. 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 (https://www.corelaboratory.abbott/us/en/offerings/segments/infectious-disease/sars-cov-2) 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.

BB. All laboratory personnel using your product must be appropriately trained in automated immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.

Abbott Laboratories 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 will 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 detecting the presence of IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens. (Note: except not included in calibrator and control instructions)

- 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. § 360bbb3(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