June 1, 2021

Matthew Gee
Senior Manager, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
511 Benedict Ave.
Tarrytown, NY 10591

Device:	Atellica IM SARS-CoV-2 Total (COV2T)
EUA Number:	EUA201367
Company:	Siemens Healthcare Diagnostics Inc.
Indication:	Qualitative and semi-quantitative detection of total antibodies (including IgG and IgM) to SARS-CoV-2 in human serum and plasma (potassium EDTA and lithium heparin) using the Atellica IM Analyzer. 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. Gee:

On May 29, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the Atellica IM SARS-CoV-2 Total (COV2T), pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3), for the qualitative detection of antibodies against SARS-CoV-2 in human serum and plasma (potassium EDTA and lithium heparin) using the Atellica IM Analyzer. Your product was 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.

On September 1, 2020, and November 23, 2020, you requested to amend your EUA. Based on these requests, and having concluded that revising the May 29, 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-

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

3(g)(2)(C)), FDA is reissuing the May 29, 2020, letter in its entirety with the revisions incorporated.[2] 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[3] 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.[4]

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 "Atellica IM SARS-CoV-2 Total (COV2T)" 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

[2] The revisions to the May 29, 2020, letter and authorized labeling include: (1) update the intended use to include semi-quantitative detection and additional edits to reflect language used in more recent authorizations, (2) update the healthcare provider (HCP) and recipient fact sheets to include information regarding semi-quantitative results and testing of individuals who have received a COVID-19 vaccine, and update the HCP fact sheet to include information related to performance with circulating variants, (3) edits to the Instructions for Use to add semi-quantitative result interpretation criteria, add a Master Curve Material (MCM) kit as an optional material available separately to assist with laboratory certification requirements in support of implementing the assay, add data related to modifications to the Solid Phase Reagent buffer, add limitations related to testing of individuals who have received a COVID-19 vaccine and information related to performance with circulating variants, extension of the upper limit of the measuring interval from 10.00 to 75.00 Index and other limitations related to laboratory personnel, cross-reactivity, and specimen type, addition of interference study data to include total protein interference and excess potassium interference, updates to specimen stability including acceptability of up to three freeze-thaw cycles, addition of sample random access and removal of requirement to perform batched testing and associated daily cleaning procedures prior to running other assays, edits to the Positive Percent Agreement Study and the Supplemental Clinical Agreement section and other minor edits for clarity and to reflect language used in more recent authorizations, and (4) revisions to the Letter of Authorization and Conditions of Authorization to reflect language used in more recent authorizations and consolidation of several conditions in new Condition M.

[3] For ease of reference, this letter will use the term "your product" to refer to the Atellica IM SARS-CoV-2 Total (COV2T) for the indication identified above.

[4] 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).

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.[5]

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 immunoassay intended for the qualitative and semi-quantitative detection of total antibodies (including IgG and IgM) to SARS-CoV-2 in human serum and plasma (potassium EDTA and lithium heparin) using the Atellica IM Analyzer (includes system online help). Your 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 unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Semi-quantitative results from your product should not be interpreted as an indication or degree of immunity or protection from infection. Testing is limited to laboratories certified under CLIA that meet requirements to perform moderate or high complexity tests.

Your product is an automated antigen sandwich immunoassay using acridinium ester chemiluminescent technology, in which antigens are bridged by antibodies present in the sample. The Solid Phase contains a preformed complex of streptavidin-coated microparticles and biotinylated SARS-CoV-2 recombinant antigen. This reagent is used to capture anti-SARS-CoV-2 antibodies in the sample. The Lite Reagent contains acridinium-ester-labeled SARS-CoV-2 recombinant antigen used to detect SARS-CoV-2 antibodies bound to the Solid Phase. A direct relationship exists between the amount of SARS-CoV-2 antibodies present in the sample and the amount of relative light units (RLUs) detected by the system. A result of reactive or nonreactive is determined according to the Index Value established with the calibrators, included in your product:

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

- Nonreactive: < 1.0 Index. These samples are considered negative for SARS-CoV-2 antibodies. Report nonreactive results as < 1.00 Index.
- Reactive: 1.0 to 75.0 Index. These samples are considered positive for SARS-CoV-2 antibodies. Report reactive results with the numeric Index Value for semi-quantitative measurements within the acceptable measuring range.
- Reactive: > 75.0 Index. These samples are considered positive for SARS-CoV-2 antibodies. Report reactive results above the measuring interval as "> 75.0 Index".

The Atellica IM SARS-CoV-2 Total (COV2T) includes the following materials or other authorized materials (as may be requested under Condition M. below): Lite Reagent, Solid Phase reagent, Atellica IM COV2T Calibrator and Atellica IM Multi-Diluent 2 ReadyPack ancillary reagent pack. The Atellica IM SARS-CoV-2 Total Master Curve Material (COV2T MCM) with the "Atellica IM SARS-CoV-2 Total Master Curve Material (COV2T MCM)" Instructions for Use is an optional material available separately to assist with laboratory certification requirements in support of implementing the assay.

Your product requires the use of the Atellica IM Total Quality Control (COV2T QC) which are not included with the kit but are available from you with the "Atellica IM Total Quality Control (COV2T QC)" Instructions for Use, or other authorized control materials (as may be requested under Condition M below):

- Atellica IM COV2T QC: consists of an external negative and positive control, and "Atellica IM Total Quality Control (COV2T QC)" Instruction for Use, and must be run as outlined in the "Atellica IM SARS-CoV-2 Total (COV2T)" Instructions for Use, described below.

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 "Atellica IM SARS-CoV-2 Total (COV2T)" Instructions for Use, (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), the two Product Information Cards (PICs) and the following product-specific information pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers: Siemens Healthcare - Atellica IM SARS-CoV-2 Total (COV2T)
- Fact Sheet for Recipients: Siemens Healthcare - Atellica IM SARS-CoV-2 Total (COV2T)

The above described product, when accompanied by the authorized labeling 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 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:

Siemens Healthcare Diagnostics Inc. (You) and Authorized Distributor(s)[6]

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

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

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 authorized PIC with each shipped Atellica IM SARS-CoV-2 Total (COV2T) kit, Atellica IM Total Quality Control (COV2T QC) kit or Atellica IM SARS-CoV-2 Total Master Curve Material (COV2T MCM) kit to authorized laboratories, and will make the "Atellica IM SARS-CoV-2 Total (COV2T)" Instructions for Use, the "Atellica IM Total Quality Control (COV2T QC)" Instruction for Use and the "Atellica IM SARS-CoV-2 Total Master Curve Material (COV2T MCM)" 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 FDA 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 material (Atellica IM Total Quality Control (COV2T QC)) with the "Atellica IM Total Quality Control (COV2T QC)" Instruction for Use or other authorized materials (as may be requested under Condition M below), at the same time as your product.

Siemens Healthcare Diagnostics 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 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.

N. You must evaluate the performance and assess traceability[7] 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 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 and concurrence with the data by FDA, you will update your labeling to

[7] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study in the event that we receive reports of adverse events concerning your product.

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.

Authorized Laboratories

U. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

V. Authorized laboratories must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instrument, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

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

X. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

Y. Authorized laboratories 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 to you (https://www.siemens-healthineers.com/en-us/ or by phone to 1-877-229-3711) any suspected occurrence of false reactive or false nonreactive results and significant deviations from the established performance characteristics of your product of which they become aware.

Z. 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.

Siemens Healthcare Diagnostics Inc. (You), Authorized Distributor(s) and Authorized Laboratories

AA. 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

BB. 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 and FDA implementing regulations.

CC. 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.

DD. 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 total antibodies to 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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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure