

March 11, 2022

Sara Kastrup Shah
Siemens Healthcare Diagnostics, Inc.
511 Benedict Avenue
Tarrytown, NY 10591

Device: Atellica IM SARS-CoV-2 Antigen (CoV2Ag)
EUA Number: EUA210568
Company: Siemens Healthcare Diagnostics, Inc.
Indication: Qualitative detection of SARS-CoV-2 nucleocapsid antigen in anterior nasal (AN) swab specimens collected in Siemens Healthineers Sample Inactivation Media, from individuals who are suspected of COVID-19 by their healthcare provider within the first 7 days of symptom onset. 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 the requirements to perform moderate or high complexity tests.

Dear Ms. Kastrup Shah:

This letter is in response to your¹ request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,² pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in

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

² For ease of reference, this letter will use the term “your product” to refer to the Atellica IM SARS-CoV-2 Antigen (CoV2Ag) used 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.³

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is included in the “Atellica IM SARS-CoV-2 Antigen (CoV2Ag)” 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, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and
3. There is no adequate, approved, and available alternative to the emergency use of your product.⁴

II. Scope of Authorization

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 detection of SARS-CoV-2 nucleocapsid antigen in anterior nasal (AN) swab specimens collected in Siemens Healthineers Sample Inactivation Media, from individuals who are suspected of COVID-19 by their healthcare provider within the first 7 days of symptom onset, using the Atellica IM Analyzer. Your product does not differentiate between SARS-CoV and SARS-CoV-2 viruses.

The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in anterior nasal swab

³ U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

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

specimens during the acute phase of infection. Positive results indicate the presence of the viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Testing of anterior nasal swab specimens collected in Siemens Healthineers Sample Inactivation Media using your product, as outlined in the "Atellica IM SARS-CoV-2 Antigen (CoV2Ag)" Instructions for Use, is limited to laboratories certified under CLIA that meet the requirements to perform moderate or high complexity tests.

The anterior nasal swab specimen collected in Siemens Healthineers Sample Inactivation Media, described in the "Siemens Healthineers Sample Inactivation Media" Product Insert, is tested with your product according to the "Atellica IM SARS-CoV-2 Antigen (CoV2Ag)" Instructions for Use. The Atellica IM SARS-CoV-2 Antigen (CoV2Ag) includes the materials, or other authorized materials (as may be requested under Condition O. below), necessary to collect, process and test anterior nasal swab specimens as described in the "Atellica IM SARS-CoV-2 Antigen (CoV2Ag)" Instructions for Use.

Your product requires use of the Atellica IM SARS-CoV-2 Antigen Calibrator (CoV2Ag CAL) and the Atellica IM SARS-CoV-2 Antigen Quality Control (CoV2Ag QC) which are not included with the kit but are available from you with the "Atellica IM SARS-CoV-2 Antigen Calibrator (CoV2Ag CAL)" Instructions for Use and the "Atellica IM SARS-CoV-2 Antigen Quality Control (CoV2Ag QC)" Instructions for use, or other authorized control materials (as may be requested under Condition O. below). All controls must generate expected results in order for a test to be considered valid, as outlined in the "Atellica IM SARS-CoV-2 Antigen (CoV2Ag)" 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 "Atellica IM SARS-CoV-2 Antigen (CoV2Ag)" Instructions for Use.

The labeling entitled "Siemens Healthineers Sample Inactivation Media" Product Insert, "Atellica IM SARS-CoV-2 Antigen Calibrator (CoV2Ag CAL)" Instructions for Use, "Atellica IM SARS-CoV-2 Antigen Quality Control (CoV2Ag QC)" Instructions for use and the "Atellica IM SARS-CoV-2 Antigen (CoV2Ag)" 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 fact sheets pertaining to the emergency use, are 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 Diagnostics, Inc. - Atellica IM SARS-CoV-2 Antigen (CoV2Ag)
- Fact Sheet for Patients: Siemens Healthcare Diagnostics, Inc. - Atellica IM SARS-CoV-2 Antigen (CoV2Ag)

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 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:

Siemens Healthcare Diagnostics, Inc. (You) and Authorized Distributor(s)⁵

- 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 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 authorized labeling.
- D. You and authorized distributor(s) must include a physical copy of the applicable PIC card with each shipped Siemens Healthineers Sample Inactivation Media, Atellica IM SARS-CoV-2 Antigen Calibrator (CoV2Ag CAL), Atellica IM SARS-CoV-2 Antigen Quality Control (CoV2Ag QC), and the Atellica IM SARS-CoV-2 Antigen (CoV2Ag) to authorized laboratories, and will make the “Siemens Healthineers Sample Inactivation Media” Product Insert, “Atellica IM SARS-CoV-2 Antigen Calibrator (CoV2Ag CAL)” Instructions for Use, “Atellica IM SARS-CoV-2 Antigen Quality Control (CoV2Ag QC)” Instructions for use and the “Atellica IM SARS-CoV-2 Antigen (CoV2Ag)” 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 distributed.
- G. You and authorized distributor(s) must collect information on the performance of your product. You will 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) (via email: CDRH-EUA-Reporting@fda.hhs.gov) any suspected occurrence of false positive or false negative results and significant deviations

⁵ “Authorized Distributor(s)” are identified by you, Siemens Healthcare Diagnostics, Inc., in your EUA submission as an entity allowed to distribute your product.

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 Siemens Healthineers Sample Inactivation Media and the calibrator and control materials (Atellica IM SARS-CoV-2 Antigen Calibrator (CoV2Ag CAL), Atellica IM SARS-CoV-2 Antigen Quality Control (CoV2Ag QC)) with the “Siemens Healthineers Sample Inactivation Media” Product Insert, “Atellica IM SARS-CoV-2 Antigen Calibrator (CoV2Ag CAL)” Instructions for Use, and the “Atellica IM SARS-CoV-2 Antigen Quality Control (CoV2Ag QC)” Instructions for use (refer to condition D.) or other authorized materials (as may be requested under Condition O. 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 revisions 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 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 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 shall not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to DMD/OHT7-

OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

- P. You must evaluate the analytical limit of detection and assess traceability⁶ of your product with any FDA-recommended reference material(s). After submission to and review and concurrence with the data by FDA, you must update labeling to reflect the additional testing. Such labeling updates must 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 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 (via email: CDRH-EUAREporting@fda.hhs.gov).
- S. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA, such as those related to the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- T. You must complete the agreed upon real-time stability study for your product and notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results as they become available until completion of the study. After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling to reflect the additional testing if requested by FDA. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.
- U. You must complete the agreed upon specimen stability study in Siemens Healthineers Sample Inactivation Media for your product within 2 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling to reflect the additional testing if requested by FDA. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- V. You must submit your product for any independent evaluation to confirm the performance characteristics of your test, if requested by FDA, and in the manner requested by FDA. After submission to and concurrence with the data by FDA, you will

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

update your labeling to reflect the additional evaluation. Such labeling 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 this labeling may be used, which may include mass media.
- X. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized 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 (Siemens Healthineers Technical Support: <https://www.siemens-healthineers.com/en-us/>; tel: 1-877-229-3711) 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 this product must be appropriately trained in automated immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use this 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 this product.

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

- CC. 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

- 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 by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of proteins 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,

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

Enclosure