



April 2, 2021

Joel Peek, Ph.D.
CEO
Alimetrix, Inc.
800 Hudson Way, Suite 2200
Huntsville, AL 35806

Device: Alimetrix SARS-CoV-2 RT-PCR Assay

EUA Number: EUA202074

Laboratory: Alimetrix, Inc.

Indication: This test is authorized for the following indications for use:

Qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, oropharyngeal, anterior nasal and mid-turbinate nasal swab specimens, as well as nasopharyngeal washes/aspirates or nasal aspirates and bronchoalveolar lavage (BALs) specimens from individuals suspected of COVID-19 by their healthcare provider.

This test is also for use with mid-turbinate nasal swab specimens that are self-collected at home or in a healthcare setting, using the Alimetrix COVID-19 Home Collection Kit, by individuals (18 years of age or older) suspected of COVID-19 when determined to be appropriate by a healthcare provider.

Testing is limited to the Alimetrix, Inc. located at 800 Hudson Way, Suite 2200, Huntsville, AL 35806 which is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

Dear Dr. Peek:

On September 30, 2020, based on your¹ request the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Alimetrix SARS-CoV-2 RT-PCR Assay for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, oropharyngeal, anterior nasal and mid-turbinate nasal swab specimens, as well as nasopharyngeal washes/aspirates or nasal aspirates and bronchoalveolar lavage (BALs) specimens from

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

individuals suspected of COVID-19 by their healthcare provider pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing was limited to the Alimetrix, Inc. located at 800 Hudson Way, Suite 2200, Huntsville, AL 35806 which is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

On December 18, 2020, you requested to revise your Emergency Use Authorization (EUA). Based on that request and having concluded that revising the September 30, 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 September 30, 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 product³ is now intended for the indications 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 contained in the EUA Summary (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.

² The revisions to the September 30, 2020, letter and authorized labeling include (1) update the intended use to include testing of mid-turbinate nasal swab specimens collected at home or in a healthcare setting using the Alimetrix COVID-19 Home Collection Kit by individuals (18 years of age or older) suspected of COVID-19 by their healthcare provider, (2) addition of the Alimetrix COVID-19 Home Collection Kit Sample Collection Instructions for Use to the authorized labeling, (3) update the EUA summary to include additional in silico inclusivity data and to include results of FDA Reference Panel testing and other updates to reflect language used in more recent authorizations, (4) update the standard operating procedures to include limitations related to the performance with circulating variants and detection of RNase P, and additional updates to reflect language used in more recent authorizations, (5) update the HealthCare Provider Fact Sheet to include information regarding self-collection of specimens and update the HealthCare Provider and Patient Fact Sheets to reflect language use in more recent authorizations, and (6) revise the Letter of Authorization to reflect language used in more recent authorizations, and add Conditions of Authorization related to authorized distributor(s) and specimen self-collection with the Alimetrix COVID-19 Home Collection Kit COA.

³ For ease of reference, this letter will use the term “your product” to refer to the Alimetrix SARS-CoV-2 RT-PCR Assay used 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. 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.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 reverse transcription polymerase chain reaction (RT-PCR) test with microarray detection intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, oropharyngeal, anterior nasal and mid-turbinate nasal swab specimens, as well as nasopharyngeal washes/aspirates or nasal aspirates and bronchoalveolar lavage (BALs) specimens collected from individuals suspected of COVID-19 by their healthcare provider.

This test is also for use with mid-turbinate nasal swab specimens that are self-collected at home or in a healthcare setting, using the Alimetrix COVID-19 Home Collection Kit, by individuals (18 years of age or older) suspected of COVID-19 when determined to be appropriate by a healthcare provider.

The SARS-CoV-2 nucleic acid is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The Alimetrix COVID-19 Home Collection Kit includes the following: return box, prepaid return label, biohazard bag with absorbent pad, polyester swab, collection tube containing 1mL of 0.85% saline, ID barcode for collection tube, and instructions for self-collection. Individuals should follow all instructions when using the kit.

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

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from the specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using microarray hybridization as described in the authorized labeling (described below).

The product uses all commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories as described in the authorized labeling.

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition P below), that are processed in the same way as the patient samples and are required to be included with each batch of specimens tested with your product. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the authorized labeling:

- Specimen Collection Control - RNase P (RP) control in clinical samples: The RP primer and probe set is included in each run to test for human RP, which controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.
- Internal Control - MS2 bacteriophage control added to each clinical sample and external control prior to extraction: monitors each step of the assay from extraction through hybridization.
- External Positive Control - Heat Inactivated SARS-CoV-2. Monitors for failures of the extraction and rRT-PCR reagents and reaction conditions.
- External Negative Control (no template) – 1X DNA/RNA Shield Solution. Monitors for cross-contamination during RNA extraction, RT-PCR, and hybridization.

The above described product is authorized to be accompanied by the EUA Summary (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>), as well as the “Alimetrix COVID-19 RTPCR Sample Extraction (MagBead) Standard Operating Procedure” and the “Alimetrix COVID19-RTPCR Sample Extraction (QiaVac) Standard Operating Procedure” and the following fact sheets pertaining to the emergency use, which are required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Alimetrix, Inc. - Alimetrix SARS-CoV-2 RT-PCR Assay
- Fact Sheet for Patients: Alimetrix, Inc. - Alimetrix SARS-CoV-2 RT-PCR Assay

The above described product, when accompanied by the EUA Summary, the “Alimetrix COVID19-RTPCR Sample Extraction (MagBead) Standard Operating Procedure” the “Alimetrix COVID19-RTPCR Sample Extraction (QiaVac) Standard Operating Procedure” laboratory procedures, the “Alimetrix Receiving and Accessioning of SARS-CoV-2 Clinical Specimen Standard Operating Procedure” the EUA Summary (identified above) and the two Fact Sheets (collectively referenced as “authorized labeling”) is authorized to be used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable

federal law.

The Alimetrix COVID-19 Home Collection Kit with the “Alimetrix COVID-19 Home Collection Kit Sample Collection Instructions” is authorized to be distributed and used as part of the above described product as set forth in this EUA.

“Authorized labeling” refers to “Alimetrix COVID-19 Home Collection Kit Sample Collection Instructions”, EUA Summary, “Alimetrix COVID19-RTPCR Sample Extraction (MagBead) Standard Operating Procedure”, “Alimetrix COVID19-RTPCR Sample Extraction (QiaVac) Standard Operating Procedure”, “Alimetrix Receiving and Accessioning of SARS-CoV-2 Clinical Specimen Standard Operating Procedure”, two fact sheets and the “Alimetrix COVID-19 Home Collection Kit Sample Collection Instructions.”

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, and storage of your product.

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Alimetric, 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 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 available on your website(s), if applicable, the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.
- C. You and authorized distributor(s) must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.
- D. You and authorized distributor(s) must make available all instructions related to the self-collection of anterior nasal swab specimens using the Alimetric COVID-19 Home Collection Kit, both in the shipped kit and on your website.
- E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which the Alimetric COVID-19 Home Collection Kit is distributed.
- F. You and authorized distributor(s) must maintain customer complaint files on record. You must report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.
- G. 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.
- H. You and authorized distributor(s) must ensure that any records associated with this EUA, including test usage, are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

Alimetric, Inc. (You)

- I. You must notify FDA of any authorized distributor(s) of the Alimetric COVID-19 Home Collection Kit, including the name, address, and phone number of any authorized distributor(s).
- J. You must provide authorized distributor(s) with a copy of this EUA and communicate to

⁶ “Authorized distributor(s)” are identified by you, Alimetric, Inc., in your EUA submission as an entity allowed to distribute the Alimetric COVID-19 Home Collection Kit.

authorized distributor(s) any authorized revisions that might be made to this EUA and its authorized accompanying materials.

- K. You must notify the relevant public health authorities of your intent to run your product.
- L. You must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- M. You 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.
- N. You must use your product as outlined in the authorized labeling. Deviations from the authorized laboratory procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and/or authorized materials required to use your product are not permitted.
- O. When testing authorized specimens self-collected using the Alimetrix COVID-19 Home Collection Kit, you must follow any specimen accessioning protocols provided with the self-collection kit when accepting specimens for testing.
- P. 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.
- Q. You must evaluate the analytical limit of detection and assess traceability of your product with any FDA-recommended reference material(s), if requested by FDA.⁷ After submission to and concurrence by FDA, DMD/OHT7-OIR/OPEQ/CDRH will update the EUA summary to reflect the additional testing.
- R. You must submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using specimens collected with the Alimetrix COVID-19 Home Collection Kit for use with your product during that timeframe, including how many specimens were received, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate

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.

for specimens collected with the authorized self-collection kit.

- S. You must further collect and submit information regarding patients' sampling experience with self-collecting mid-turbinate nasal swab specimens consistent with the indication of your product in an FDA agreed upon post authorization study within 3 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH).
- T. You must have a process in place to track adverse events, including any occurrence of false results with your product, including with the Alimetrix COVID-19 Home Collection Kit, and report any such events to FDA pursuant to 21 CFR Part 803. Serious adverse events, including unexpected biosafety concerns, and adverse sampling events occurring with the Alimetrix COVID-19 Home Collection Kit must immediately be reported to DMD/OHT7- OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).
- U. You 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) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which you become aware.
- V. All laboratory personnel using your product must be appropriately trained in molecular techniques and use appropriate laboratory and personal protective equipment when handling this product, and use your product in accordance with the authorized laboratory procedure.

Conditions Related to Printed Materials, Advertising and Promotion

- W. 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.
- X. 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.
- Y. 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 the authorized laboratory;
 - This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and

- The emergency use of this 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,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure