U.S. FOOD & DRUG ADMINISTRATION

May 10, 2023

B. Scott Ferguson, Ph.D.
CEO
Aptitude Medical Systems, Inc.
125 Cremona Drive, Suite 100
Goleta, CA 93117

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| Device: | Metrix COVID-19 Test |
| EUA Number: | EUA220389 |
| Company: | Aptitude Medical Systems Inc. |
| Indication: | Non-prescription home use for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal (nares) swab and saliva specimens, self-collected from any individual aged 14 years or older, or adult-collected from any individual aged 2 years or older, including individuals without symptoms or other epidemiological reasons to suspect COVID-19. |

Dear Dr. Ferguson:

On October 18, 2022, based on your[1] request, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the Metrix COVID-19 Test, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the indication stated in the letter.[2] Subsequently, FDA granted your request to update the authorized labeling on February 10, 2023.[3]

On April 18, 2023, FDA received a request from you to amend your EUA. In response to this request, and having concluded that revising the October 18, 2022, EUA is appropriate to protect

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Aptitude Medical Systems Inc.
[2] The October 18, 2022, letter authorized the Metrix COVID-19 Test for non-prescription home use for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal (nares) swab and saliva specimens, self-collected from any individual aged 14 years or older, or adult-collected from any individual aged 2 years or older, including individuals without symptoms or other epidemiological reasons to suspect COVID-19.
[3] On February 10, 2023, your request was granted to update the Instructions for Use of the Metrix COVID-19 Test to; (1) include usability testing results of saliva collection from two and three year old children (assisted by an adult) completed to fulfill Condition of Authorization T. of the Letter of Authorization issued on October 18, 2022, (2) add an alternative supplier for nasal swabs for use with the test, (3) add a new packaging configuration to include 25 tests in one kit per Condition of Authorization N. of the Letter of Authorization issued on October 18, 2022, and (4) provide minor edits.

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 October 18, 2022, letter in its entirety with the revisions incorporated.[4] Pursuant to section 564 of the Act, Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product[5] is now intended for the indication described above.

On February 4, 2020, as amended on March 15, 2023, 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, or a significant potential for a public health emergency, that affects, or 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.[6]

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 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

[4] The revisions to the October 18, 2022, letter and authorized labeling include: (1) addition of clinical performance data for saliva specimens from asymptomatic individuals completed to fulfill Condition of Authorization S. of the Letter of Authorization issued on October 18, 2022, (2) addition of clinical performance data to remove the presumptive negative claim for anterior nasal (nares) swab specimens from asymptomatic individuals from the Intended Use, (3) deletion of Condition of Authorization T. in the October 18, 2022, Letter of Authorization as fulfilled, (4) and minor edits.

[5] For ease of reference, this letter will use the term "your product" to refer to the Metrix COVID-19 Test, used for the indication identified above.

[6] 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*. February 4, 2020. 85 FR 7316 (February 7, 2020). U.S. Department of Health and Human Services, Amended Determination of a Public Health Emergency or Significant Potential for a Public Health Emergency Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b). March 15, 2023. 88 FR 16644 (March 20, 2023) ("Amended Determination").

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.[7]

## 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 single-use molecular in vitro diagnostic test for the qualitative detection of nucleic acid from SARS-CoV-2, the virus that causes COVID-19. This test is authorized for non-prescription home use with anterior nasal (nares) swab and saliva specimens, self-collected from any individual aged 14 years or older, or adult-collected from any individual aged 2 years or older, including individuals without symptoms or other epidemiological reasons to suspect COVID-19.

This test utilizes nucleic acid amplification technology, similar to PCR, for the detection of SARS-CoV-2. SARS-CoV-2 viral RNA is generally detectable in anterior nasal (nares) swab and saliva samples during the acute phase of infection.

Positive results indicate the presence of viral RNA, but clinical correlation with past medical 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. The agent detected may not be the definite cause of disease. Individuals who test positive with the Metrix COVID-19 Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results from saliva samples are presumptive and should be confirmed by molecular testing of an alternative sample type if clinically indicated. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or management decisions for the individual, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19. Individuals who test negative and continue to experience COVID-19-like symptoms of fever, cough, and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow-up care with their physician or healthcare provider.

Individuals should report all results obtained with this product to their healthcare provider and the Aptitude secure web portal. This Aptitude secure web portal will report all test results received from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED

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

codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the CDC.

Your product is performed using anterior nasal (nares) swab and saliva samples from individuals aged 2 years or older. When using your product, the individual performing the test must follow the instructions provided in the "Metrix COVID-19 Test Instructions" when collecting the specimen, running the test procedure and interpreting the results.

The Metrix COVID-19 Test includes the materials, or other authorized materials (as may be requested under Condition M. below), required to collect the anterior nasal (nares) swab or saliva sample and perform the test procedure, as described in the "Metrix COVID-19 Test Instructions" and the "Metrix COVID-19 Test Instructions for Use for Healthcare Providers." Your product also requires use of the reusable Metrix Reader device, which you provide separately from the test and along with the "Metrix Reader Quick Start Guide."

Your product includes an internal control that is processed along with the specimen in the Metrix Reader. The internal control must generate the expected signal/result in the Metrix Reader for a test to be considered valid, as outlined in the "Metrix COVID-19 Test Instructions" and the "Metrix COVID-19 Test Instructions for Use for Healthcare Providers."

The labeling entitled "Metrix COVID-19 Test Instructions for Use for Healthcare Providers", "Metrix COVID-19 Test Instructions", "Metrix COVID-19 Test" box labels[8], "Metrix Reader Quick Start Guide" (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), and the following fact sheet 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[9]: Aptitude Medical Systems Inc. – Metrix COVID-19 Test

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 and used 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.

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[8] "Metrix COVID-19 Test" box labels include boxes for 1 and 25-test kits and "Metrix COVID-19 Test" box labels for additional test kits numbers/options as may be requested, and for which you receive appropriate authorization, in accordance with Condition N. below. Metrix COVID-19 Test kits numbers/options are described in the "Metrix COVID-19 Test Instructions" and the "Metrix COVID-19 Test Instructions for Use for Healthcare Providers."

[9] Note that the information typically found in a Fact Sheet for Individuals is contained in the authorized "Metrix COVID-19 Test Instructions", that will be available to end users as set forth in the Conditions of Authorization (Section IV).

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:

### Aptitude Medical Systems Inc. (You) and Authorized Distributor(s)[10]

A. Your product must comply with the following labeling requirements: 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 the "Metrix COVID-19 Test Instructions" for your product in the shipped kit using the "Metrix COVID-19 Test"

[10] "Authorized Distributor(s)" are identified by you, Aptitude Medical Systems Inc., in your EUA submission as an entity allowed to distribute your product.

box label (see Footnote 5) and electronically on your website.

C. You and authorized distributor(s) must make available the Metrix Reader device with the "Metrix Reader Quick Start Guide" instructions for use at the same time as your product and make the "Metrix Reader Quick Start Guide" available electronically on your website.

D. You and authorized distributor(s) must maintain customer complaint files and report to FDA any significant complaints about usability or deviations from the established performance characteristics of which you and authorized distributor(s) become aware.

E. 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/or authorized labeling.

F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the locations (e.g. pharmacies, doctor's offices, etc.) to which your product is distributed, and the number of tests distributed to each location.

G. You and authorized distributor(s) must collect information on the performance of your product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which you become aware, and report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7): Office of In Vitro Diagnostics/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUAReporting@fda.hhs.gov).

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) using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

**Aptitude Medical Systems 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, including the authorized labeling.

L. You must make the authorized "Metrix COVID-19 Test Instructions," the "Metrix COVID-19 Test Instructions for Use for Healthcare Providers," and the Fact Sheet for Healthcare Providers electronically available on your website. Additionally, you must provide the opportunity to request a copy of the "Metrix COVID-19 Test Instructions," the "Metrix COVID-19 Test Instructions for Use for Healthcare Providers," and the Fact Sheet for Healthcare Providers in paper form, and after such request, promptly provide the requested labeling at no additional cost.

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 DMD/OHT7/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

N. You may request new box labels to allow additional test kits numbers/options for your product. Such additional labeling requests to this EUA should be submitted to and require concurrence of DMD/OHT7/OPEQ/CDRH prior to implementation.

O. 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).

P. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the product released for distribution have the clinical and analytical performance claimed in the authorized labeling.

Q. If requested by FDA, you must submit your 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 evaluate the analytical limit of detection and assess traceability[11] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you must update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

S. You must submit to FDA a summary report within 90 calendar days of product launch summarizing the results of any testing performed using your product during that timeframe, including how many products were distributed, and how many individuals

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

reported results to the Aptitude secure web portal as encouraged by the "Metrix COVID-19 Test Instructions."

T. 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-EUA-Reporting@fda.hhs.gov).

U. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

**Conditions Related to Printed Materials, Advertising and Promotion**

V. 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.

W. 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.

X. 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;
- 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 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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Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure