March 15, 2023

Aditya Sharma
Manager, Regulatory Affairs
Mesa Biotech Inc.
6190 Cornerstone Court, Suite 220
San Diego, CA 92121

Device:	Accula SARS-CoV-2 Test
EUA Number:	EUA200028
Company:	Mesa Biotech Inc.
Indication:	Qualitative, visual detection of nucleic acid from the SARS-CoV-2 in clinician-collected anterior nasal or nasal mid-turbinate swab samples or clinician-instructed self-collected (collected on site) anterior nasal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider. Emergency use of this test is limited to authorized laboratories using the Accula Dock or Silaris Dock.
Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet requirements to perform high, moderate, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Dear Aditya Sharma:

On March 23, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of the Accula SARS-Cov-2 Test, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the indications stated in the letter.[2] Subsequently, on April 30, 2020, August 24,

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Mesa Biotech Inc.
[2] The March 23, 2020, letter authorized the Accula SARS-Cov-2 Test for the qualitative detection of nucleic acid from the SARS-CoV-2 in throat swab and nasal swab specimens combined, collected from patients suspected of COVID-19 by their healthcare provider. Emergency use of this test was limited to authorized laboratories and other authorized testing locations using the Accula Dock or Silaris Dock. The March 23, 2020, letter defined "Authorized Laboratories and Other Authorized Testing Locations" as follows: Authorized laboratories - laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high and

2020, and February 3, 2021, FDA granted your request to revise the authorized labeling.[3, 4, 5] Based on your request, FDA also revised and reissued the letter on January 7, 2021,[6] May 16, 2022,[7] and August 17, 2022.[8] In addition, FDA established additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.[9]

On February 1, 2023, you requested to revise your EUA. Based on this request, and having

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moderate complexity tests. Other Authorized Testing Locations - patient care settings using the Accula Dock or Silaris Dock.

[3] On April 30, 2020, your request was granted to update the intended use for your product to change the specimen type from throat swab and nasal swab combined to nasal swab alone and the associated updates to the authorized labeling.

[4] On August 24, 2020, your request was granted to update the authorized labeling of your product to: (1) include mid-turbinate swab specimens as an authorized specimen, (2) update the intended use to reflect more recent authorizations, (3) update the acceptable swab types that may be included in or used with the Accula SARS-CoV-2 Test kit and the associated Technical Bulletin to inform customers, (4) added new clinical data to the performance section, and (5) updated the Healthcare Provider and Patient Fact Sheets to reflect language used in more recent authorizations.

[5] On February 3, 2021, your request was granted to update the authorized labeling of your product to: (1) include results of FDA Reference Panel testing, and (2) provide additional sample stability data to fulfill Condition P in the January 7, 2021, Letter of Authorization.

[6] On January 7, 2021, the revisions to the March 23, 2020, letter and authorized labeling included: (1) updates to the intended use and authorized labeling documents to revise the authorized specimens to be clinician-collected nasal or nasal mid-turbinate swab samples or clinician-instructed self-collected (collected on site) nasal swab specimens, (2) include in the authorized labeling a "Accula SARS-CoV-2 Test Quick Reference Guide for Nasal Swab Specimens" for the clinician-instructed self-collected (collected on site) nasal swab specimens, (3) addition of a "Kit Card" in the authorized labeling to instruct the end user where to electronically obtain copies of the authorized labeling, (4) update analytical reactivity/inclusivity data and add a limitation regarding the performance of the assay with SARS-CoV-2 variant with a recent prevalent N gene mutation, (5) update the limit of detection performance data, (6) update the specimen collection and storage processes, (7) add two additional swab types that can be used to manufacture the SARS-CoV-2 external control swabs, and (8) make other minor updates, including to the conditions of authorization to use language more consistent with recent authorizations.

[7] On May 16, 2022, the revisions to the January 7, 2021, letter and authorized labeling included: (1) update to the intended use and authorized labeling documents to clarify "nasal" as "anterior nasal" specimens, (2) various updates to IFU and Quick Reference Guide (QRG) to improve overall clarity, (3) update the manufacturing process for the Negative Control Swabs, (4) update the authorized distributor list, (5) incorporation of Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (Conditions U. and V.), and revise Condition D. to reflect current practice (6) removal of Condition of Authorization P. from the January 7, 2021 letter that was fulfilled, (7) addition of a new Condition of Authorization to perform an additional clinical evaluation, and (8) updating the Fact Sheet for Patients and Fact Sheet for Healthcare Providers to reflect the minor updates to the intended use and/or to reflect language used in more recent authorizations.

[8] On August 17, 2022, the revisions to the May 16, 2022, letter and authorized labeling included: (1) clarifying the name of the Kit Card as the Electronic Instructions for Use (eIFU) Card (as it is referred to in the Accula Test SARS-CoV-2 Test Instructions for Use) and minor updates to the warning statements, (2) update the manufacturing process for the Negative Control Swabs included in the Accula SARS-CoV-2 Control Kit and addition of the "Accula SARS-CoV-2 Control Kit Instructions for Use" to the list of authorized labeling, (3) update Condition of Authorization Q. (below) to maintain the original 6 month timeline afforded in the May 16, 2022, letter to 3 months, (4) addition of Condition of Authorization I. below concerning availability of the Accula SARS-CoV-2 Control Kit, and (5) minor update to the webpage links provided in the Fact Sheet for Healthcare Providers and also update the header date of the Fact Sheet for Healthcare Providers and Fact Sheet for Patients to match the date of re-issuance.

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

concluded that revising the August 17, 2022, 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 August 17, 2022, letter in its entirety with the revisions incorporated.[10] 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[11] 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.[12]

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 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

[10] The revisions to the August 17, 2022, letter and authorized labeling include: (1) addition of new clinical performance data to fulfill and remove Condition of Authorization Q. from the August 17, 2022, letter, (2) addition of a presumptive negative claim to the Intended Use based on the newly provided clinical performance data, (3) updates to the result interpretations to reflect the possibility of a presumptive negative result, (4) updates to the manufacturer contact information, (5) updates to the labeling where applicable to reflect use of "Accula Nasal Swab Buffer or Accula SARS-CoV-2 Buffer" instead of "Accula SARS-CoV-2 Buffer", (6) deletion of the listing of specimen collection swabs authorized for use with the Accula SARS-CoV-2 test in the Instructions for Use, and (7) provide minor updates.

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

[12] 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).

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.[13]

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 performed on the Accula Dock or the Silaris Dock is a molecular in vitro diagnostic test utilizing polymerase chain reaction (PCR) and lateral flow technologies for the qualitative, visual detection of nucleic acid from SARS-CoV-2 in clinician-collected anterior nasal or nasal mid-turbinate swab specimens or clinician-instructed self-collected (collected on site) anterior nasal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a,that meet requirements to perform high, moderate, or waived complexity tests. Your product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; 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. Testing facilities within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be confirmed with a different authorized or cleared molecular test in a CLIA-certified laboratory that meets the requirements to perform high or moderate complexity tests. 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/or epidemiological information.

Your product's Test Cassette, when used with the applicable authorized systems automates all aspects of nucleic acid testing including lysis of the virus, reverse transcription of viral RNA to cDNA, nucleic acid amplification, and detection of the SARS-CoV-2 targeted sequences as described in the authorized labeling (described below). Your product includes the materials (or

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

other authorized materials as may be requested under Condition L. below) described in the Instructions for Use.

Your product requires internal and external control materials, including the Accula SARS-CoV-2 Control Kit which is additionally available from you with the "Accula SARS-CoV-2 Control Kit Instructions for Use," or other authorized control materials (as may be requested under Condition L. below), that are described in the Instructions for Use.

The labeling entitled "Accula Test SARS-CoV-2 Test" Instructions for Use, "Accula Test SARS-CoV-2 Quick Reference Guide, For Use with the Accula or Silaris Dock, For Anterior Nasal or Mid-turbinate Nasal Swab Specimens," the "Accula Test SARS-CoV-2 Quick Reference Guide for Anterior Nasal Swab Specimens," the "Accula SARS-CoV-2 Control Kit 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 Electronic Instructions for Use (eIFU) Card, 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: Mesa Biotech Inc. - Accula SARS-CoV-2 Test
- Fact Sheet for Patients: Mesa Biotech Inc. - Accula SARS-CoV-2 Test

The above described product, with 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:

Mesa Biotech Inc. (You) and Authorized Distributor(s)[14]

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

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

C. You and authorized distributor(s) must make available on your website(s) the authorized labeling.

D. You and authorized distributors must include a physical copy of the authorized Kit Card, the "Accula Test SARS-CoV-2 Quick Reference Guide for Anterior Nasal Swab Specimens" and the "Accula Test SARS-CoV-2 Quick Reference Guide, For Use with the Accula or Silaris Dock, For Anterior Nasal or Mid-turbinate Nasal Swab Specimens" with each shipped product to authorized laboratories. The "Accula Test SARS-CoV-2 Test" Instructions for Use must be made 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

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

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 and patient care settings to which they distribute your product and number of your product 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 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 the 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) must make available the control material (Accula SARS-CoV-2 Control Kit with the "Accula SARS-CoV-2 Control Kit Instructions for Use") or other authorized control materials (as may be requested under Condition L. below), at the same time as your product.

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

M. You must comply with the following requirements in accordance with 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).

N. 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.

O. 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.

P. You must evaluate the analytical limit of detection and assess traceability[15] of your product with any FDA-recommended reference material(s). After submission to FDA and FDA's review and concurrence with the data, you must update labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

Q. You must evaluate the impact of SARS-CoV-2 viral mutations and all other target analytes 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).

R. 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 must be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

Authorized Laboratories

S. 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.

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

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

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

V. 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.

W. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (via email: techsupport@thermofisher.com) 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.

X. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

Mesa Biotech Inc. (You), Authorized Distributor(s) and Authorized Laboratories

Y. 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 must be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

Z. 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 regulations.

AA. 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.

BB. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This test 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 test 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 test 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 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