



July 22, 2022

Beth Lingenfelter  
Vice President Regulatory and Clinical Affairs  
Visby Medical, Inc.  
3010 N. First Street  
San Jose, CA 95134

Device: Visby Medical COVID-19 Point of Care Test  
EUA Number: EUA203089  
Company: Visby Medical, Inc.  
Indication: Qualitative detection of SARS-CoV-2 nucleic acid in nasopharyngeal, anterior nasal, or mid-turbinate swabs collected by a health care provider (HCP) or anterior nasal (nasal) or mid-turbinate swabs self-collected (by individuals 18 years of age or older, under the supervision of an HCP) from individuals suspected of COVID-19 by their HCP.  
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 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 Ms. Lingenfelter:

On February 8, 2021, based on your<sup>1</sup> request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the Visby Medical COVID-19 Point of Care 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.<sup>2</sup> In addition, FDA

<sup>1</sup> For ease of reference, this letter will use the term “you” and related terms to refer to Visby Medical, Inc.

<sup>2</sup> The February 8, 2021, letter authorized the Visby Medical COVID-19 Point of Care Test for the qualitative detection of SARS-CoV-2 nucleic acid in nasopharyngeal, anterior nasal, or mid-turbinate swabs collected by a health care provider (HCP) or anterior nasal or mid-turbinate swabs self-collected (by individuals 18 years of age or older, under the supervision of an HCP) from individuals suspected of COVID-19 by their HCP. Emergency use of this test was limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that met the requirements to perform moderate, high or waived complexity tests. This test was 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.

established additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.<sup>3</sup>

On September 30, 2021, and March 22, 2022, FDA received requests from you to amend the EUA. In response to those requests, and having concluded that revising the February 8, 2021, 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 February 8, 2021, letter in its entirety with the amendments incorporated<sup>4</sup> to authorize the emergency use of your product.<sup>5</sup> Pursuant to section 564 of the Act, Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product is now intended for the indication 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.<sup>6</sup>

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 “Visby Medical COVID-19 Point of Care Package Insert” (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

<sup>3</sup> The Viral Mutation Revision Letter – September 23, 2021, can be accessed at:

<https://www.fda.gov/oc/152406/download>.

<sup>4</sup> The revisions to the February 8, 2021, letter and authorized labeling include: (1) update the intended use to remove “*Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with different authorized or cleared molecular tests,*” (2) update the authorized labeling to fulfill Condition of Authorization (1) in the Viral Mutation Revision Letter – September 23, 2021, (3) incorporate Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (Q. and R. below), (4) update the performance to include results of latest *in silico* inclusivity analyses, (5) update the performance to include results of the post-authorization clinical study performed to satisfy Condition of Authorization Q. from the February 8, 2021 letter and therefore delete Condition of Authorization Q. from the letter as fulfilled, and (6) update the letter and fact sheets to reflect the updated intended use and for consistency with language used in more recent authorizations.

<sup>5</sup> For ease of reference, this letter will use the term “your product” to refer to the Visby Medical COVID-19 Point of Care Test used for the indication identified above.

<sup>6</sup> U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing 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.<sup>7</sup>

## 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 (disposable), fully-integrated, fast, automated RT-PCR in vitro diagnostic test intended for the qualitative detection of SARS-CoV-2 nucleic acid in nasopharyngeal, anterior nasal (nasal), or mid-turbinate swabs collected by a health care provider (HCP) or anterior nasal or mid-turbinate swabs self-collected (by individuals 18 years of age or older, under the supervision of an HCP) from individuals suspected of COVID-19 by their HCP. 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. The 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.

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 infected 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 nasopharyngeal, anterior nasal or mid-turbinate swab specimens are tested with your product according to the “Visby Medical COVID-19 Point of Care Package Insert” and the “Visby Medical COVID-19 Point of Care Test Quick Reference Guide.” The Visby Medical COVID-19 Point of Care Test includes the materials or other authorized materials (as may be requested under Condition L. below), necessary to process and test nasopharyngeal, anterior nasal or mid-

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<sup>7</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

turbinate swab specimens as described in the “Visby Medical COVID-19 Point of Care Package Insert” and the “Visby Medical COVID-19 Point of Care Test Quick Reference Guide.”

Your product requires the use of control materials, or other authorized control materials (as may be requested under Condition L. below), that are processed as outlined in the “Visby Medical COVID-19 Point of Care Package Insert.”

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 Package Insert.

The labeling entitled “Visby Medical COVID-19 Point of Care Package Insert” is available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>, “Visby Medical COVID-19 Point of Care Test Quick Reference Guide”, “Visby Medical COVID-19 Point of Care Test Dual Nostril Anterior Nasal Specimen Collection Instructions”, “Visby Medical COVID-19 Point of Care Test Nasopharyngeal Specimen Collection Instructions”, “Visby Medical COVID-19 Point of Care Test Mid-Turbinate Dual Nostril Specimen Collection Instructions”, 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: Visby Medical, Inc. - Visby Medical COVID-19 Point of Care Test
- Fact Sheet for Patients: Visby Medical, Inc. - Visby Medical COVID-19 Point of Care 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:

#### Visby Medical, Inc. (You) and Authorized Distributor(s)

- A. Your product must comply with the following labeling requirements pursuant to FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 355(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 distributor(s) must include a physical copy of the “Visby Medical COVID-19 Point of Care Package Insert,” “Visby Medical COVID-19 Point of Care Test Quick Reference Guide”, “Visby Medical COVID-19 Point of Care Test Dual Nostril Anterior Nasal Specimen Collection Instructions”, “Visby Medical COVID-19 Point of Care Test Nasopharyngeal Specimen Collection Instructions”, and “Visby Medical COVID-19 Point of Care Test Mid-Turbinate Dual Nostril Specimen Collection Instructions”, with each shipped product to authorized laboratories.

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<sup>8</sup> “Authorized Distributor(s)” are identified by you, Visby Medical, Inc., in your EUA submission as an entity allowed to distribute your product.

- E. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.
- F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute your product and number they distribute.
- G. You and authorized distributor(s) must collect information on the performance of your product. You will report to FDA any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware.
- H. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.
- I. You and authorized distributor(s) must make available the control material, SARS-CoV-2 Positive and A549 Cells Negative External Control (Ctubes) by Microbiologics, or other authorized control materials (as may be requested under Condition L. below), at the same time as your product.

**Visby Medical, 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 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.
- M. 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).

- N. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that your product released for distribution has 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<sup>9</sup> 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-OIR/OPEQ/CDRH.
- Q. 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](mailto: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 will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- S. You must have a process in place to track adverse events, including any occurrence of false results with your product and report to FDA in accordance with 21 CFR Part 803.

#### Authorized Laboratories

- T. 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.
- U. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized

<sup>9</sup> Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

materials required to use your product are not permitted.

- V. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- W. 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.
- X. 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](mailto:CDRH-EUA-Reporting@fda.hhs.gov)) and you ([support@visbymedical.com](mailto:support@visbymedical.com)) any suspected occurrence of false positive or false negative results and significant deviation from the established performance characteristics of your product of which they become aware.
- Y. All laboratory personnel using your product must be appropriately trained in the use of the Visby Medical COVID-19 Point of Care Test and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

**Visby Medical, Inc. (You), Authorized Distributor(s), and Authorized Laboratories**

- Z. 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**

- AA. 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.
- BB. 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.
- CC. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:
  - This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
  - This product has been authorized only for 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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Jacqueline A. O'Shaughnessy, Ph.D.  
Acting Chief Scientist  
Food and Drug Administration

Enclosure

**REVOKED**