August 31, 2021

Beth Lingenfelter
Visby Medical, Inc.
3010 N. First Street
San Jose, CA 95134

Device:	Visby Medical COVID-19
EUA Number:	EUA202677
Company:	Visby Medical, Inc.
Indication:	This test is authorized for the following indications for use: For certain authorized laboratories (see below): Qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, anterior nasal, or dual nostril mid-turbinate (mid-turbinate) nasal swabs collected by a healthcare provider[1] (HCP), or anterior nasal or mid-turbinate nasal swabs self-collected (in a healthcare setting) from individuals suspected of COVID-19 by their HCP. For certain authorized laboratories (see below): Qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 5 individual samples from nasopharyngeal, anterior nasal, or mid-turbinate nasal swabs collected by a HCP, or anterior nasal or mid-turbinate nasal swabs self-collected (in a healthcare setting) using individual vials containing transport media. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing of non-pooled specimens 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 or moderate complexity tests. Testing of pooled samples is limited to laboratories certified under CLIA, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Dear Ms. Lingenfelter:

[1] For this EUA, a healthcare provider includes, but is not limited to, physicians, nurses, pharmacists, technologists, laboratory directors, epidemiologists, or any other practitioners or allied health professionals.

On September 16, 2020, based on your[2] request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Visby Medical COVID-19 for the qualitative detection of SARS-CoV-2 RNA in nasopharyngeal, nasal, or mid-turbinate swabs collected by a healthcare provider[1] (HCP) or nasal or mid-turbinate swabs self-collected (in a healthcare setting) from individuals who are 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 laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity tests. Based on your request, FDA granted updates to the Instructions for Use on December 28, 2020.[3]

On July 11, 2021, you requested to further revise your Emergency Use Authorization (EUA). Based on this request and having concluded that revising the September 16, 2020, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act, FDA is reissuing the September 16, 2020, letter in its entirety with the revisions incorporated.[4] 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[5] is now intended for 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.[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

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[2] For ease of reference, this letter will use the term "you" and related terms to refer to Visby Medical, Inc.

[3] On December 28, 2020, your request was granted to update the Instructions for Use (package insert) of the Visby Medical COVID-19 to include FDA Reference Panel testing data.

[4] The revisions to the September 16, 2020, letter and authorized labeling include: (1) updates to the intended use to include testing of pooled samples (in certain authorized laboratories) containing up to 5 individual samples from nasopharyngeal, anterior nasal, or mid-turbinate nasal swabs collected by a HCP, or anterior nasal or mid-turbinate nasal swabs self-collected (in a healthcare setting) using individual vials containing transport media, (2) addition of two manufacturers of VTM, (3) updated *in silico* inclusivity analysis, (4) addition of a limitation statement regarding performance with circulating variants, (5) addition of Conditions R. and S. to evaluate device performance with viral mutations, and (6) addition of Conditions of Authorization related to testing with pooled samples.

[5] For ease of reference, this letter will use the term "your product" to refer to the Visby Medical COVID-19 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*. 85 FR 7316 (February 7, 2020).

Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

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

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[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 (disposable), fully integrated, fast, automated RT-PCR in vitro diagnostic test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, anterior nasal, or dual nostril mid-turbinate (mid-turbinate) nasal swabs collected by a HCP, or anterior nasal or mid-turbinate nasal swabs self-collected (in a healthcare setting) from individuals suspected of COVID-19 by their HCP. Testing of non-pooled specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests.

Your product is also for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 5 individual samples from nasopharyngeal, anterior nasal, or mid-turbinate nasal swabs collected by a HCP, or anterior nasal or mid-turbinate nasal swabs self-collected (in a healthcare setting) using individual vials containing transport media. Negative results from pooled testing should not be treated as definitive. If a patient's clinical signs and symptoms are inconsistent with a negative result or if results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing. For specific patients, whose specimen(s) were the subject of pooling, a notice that pooling was used during testing must be included when reporting the result

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

to the clinician or healthcare provider. Testing of pooled specimens is limited to laboratories certified under CLIA, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

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. The agent detected may not be the definite cause of disease. 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.

To use your product, the nasopharyngeal, anterior nasal or mid-turbinate nasal specimens are first diluted using the sample dilution kit and the diluted sample is loaded into the main test unit. Within the unit, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from nasopharyngeal, anterior nasal or mid-turbinate nasal specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using the Visby Medical COVID-19 test unit. The Visby Medical COVID-19 includes the following materials or other authorized materials: Visby COVID-19 Test unit, and the Visby COVID-19 Dilution Kit.

Your product requires the use of positive and negative external run controls from ZeptoMetrix Corporation which are available separately and are run as outlined in the Instructions for Use.

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition K below), that are processed in the same way as the patient samples and should be tested with each new shipment and new operator or as specified by institutional procedures or laboratory requirements. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Instructions for Use:

- Process Control – 18S rRNA present in all human samples serves the purpose of a process control for the test during normal specimen testing and is included in the test.
- Positive Control – external control from ZeptoMetrix Corporation consisting of intact chemically modified SARS-CoV-2 virus; used to confirm the performance of the assay in the hands of the end-user.
- Negative Control – external control from ZeptoMetrix Corporation consisting of human cells.

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 Instructions for Use.

The labeling entitled "Visby Medical COVID-19 Package Insert" Instructions for Use, the "Visby Medical COVID-19 Quick Reference Guide," and the "Visby Medical COVID-19 Pooling Quick Reference 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 sheets pertaining to the emergency use, is 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
- Fact Sheet for Patients: Visby Medical, Inc. - Visby Medical COVID-19

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

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

Visby Medical, Inc. (You) and Authorized Distributor(s)[8]

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. 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 distributor(s) must include a physical copy of the "Visby Medical COVID-19 Package Insert" Instructions for Use, the "Visby Medical COVID-19 Quick Reference Guide," and the "Visby Medical COVID-19 Pooling Quick Reference Guide" with each shipped product to authorized laboratories.

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, authorized labeling and authorized Fact Sheets.

F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute the test and number of tests 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.

Visby Medical, Inc. (You)

I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

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

J. 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).

K. 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.

L. You must comply with the following requirements under FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

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

N. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

O. You must evaluate the analytical limit of detection and assess traceability[9] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will 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.

P. 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.

Q. You will complete the agreed upon real-time stability study for your product. After submission to and concurrence with the data by FDA, you will 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.

R. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance

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

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.

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

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 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) and you (support@visbymedical.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.

Y. All laboratory personnel using your product must be appropriately trained on the use of the Visby Medical COVID-19 test and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

Z. Authorized laboratories using specimen pooling strategies when testing patient specimens with the Visby Medical COVID Test must include with test result reports for specific patients whose specimen(s) were the subject of pooling, a notice that pooling was used during testing and that "*Patient specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing*."

AA. Authorized laboratories implementing pooling strategies for testing patient specimens

must use the "Specimen Pooling Guidelines" provided in the authorized labeling to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.

BB. Authorized laboratories must keep records of specimen pooling strategies implemented including type of strategy, date implemented, and quantities tested, and test result data generated as part of the Specimen Pooling Implementation and Monitoring Guidelines. For the first 12 months from the date of their creation, such records must be made available to FDA within 48 business hours for inspection upon request and must be made available within a reasonable time after 12 months from the date of their creation.

Visby Medical, Inc. (You), Authorized Distributors and Authorized Laboratories

CC. You, authorized distributors, 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

DD. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) the Act, as applicable, and FDA implementing regulations.

EE. No descriptive printed matter, advertising or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

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

- This product has not been FDA cleared or approved, but has been authorized 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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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure