



August 16, 2023

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Device: Visby Medical Respiratory Health Test
EUA Number: EUA220437
Company: Visby Medical, Inc.
Indication: This test is authorized for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B viral RNA in healthcare provider-collected nasopharyngeal and anterior nasal swab specimens, and healthcare provider-instructed self-collected anterior nasal swab specimens (collected on site) from individuals with signs and symptoms of respiratory tract infection consistent with COVID-19.

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 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 Dr. Albrecht:

On December 23, 2022, based on your¹ request, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the Visby Medical Respiratory Health 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 Based on your

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

² The Visby Medical Respiratory Health Test was authorized for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B viral RNA in nasopharyngeal swab specimens from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider. 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, moderate, or waived complexity tests. This test was

subsequent request, FDA revised and reissued the letter in its entirety on March 22, 2023, with revisions incorporated.³

On July 24, 2023, FDA received a request from you to amend your EUA. In response to this request, and having concluded that revising the March 22, 2023, 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 March 22, 2023, 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, and 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 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). There is an FDA approved/cleared test for the qualitative detection and identification of SARS-CoV-2, influenza A virus, and influenza B virus along with some other organism types and subtypes not targeted

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.

³ On March 22, 2023, the revisions to the December 23, 2022, letter and authorized labeling included: (1) addition of healthcare provider-collected anterior nasal swab specimens and healthcare provider-instructed self-collected anterior nasal swab specimens (collected on site) as acceptable for use with this assay, (2) addition of analytical and clinical performance data using anterior nasal swab specimens, (3) addition of instructions for healthcare provider collection of anterior nasal swab specimens and for self-collection of anterior nasal swab specimens to the authorized labeling, (4) modification of the Intended Use population from “individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider” to “individuals with signs and symptoms of respiratory tract infection consistent with COVID-19,” and (5) provide minor updates.

⁴ The revisions to the March 22, 2023, letter and authorized labeling include: (1) removal of presumptive negative SARS-CoV-2 and presumptive negative influenza A claims from the intended use, based on results of additional prospective clinical study data, (2) removal of the limitation language regarding presumptive negative SARS-CoV-2 or presumptive negative influenza A results, and (3) update the “Expected Values” and “Performance Characteristics” sections of the Instructions For Use to include additional prospective clinical study results.

⁵ For ease of reference, this letter will use the term “your product” to refer to the Visby Medical Respiratory Health 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”).

by your product, but this is not an adequate and available alternative to your product. Respiratory viral infections caused by the influenza A and B viruses and SARS-CoV-2 can have similar clinical presentation and diagnostic considerations. Thus, to differentially detect SARS-CoV-2, information from a test that detects and differentiates the virus that causes COVID-19 and the common influenza viruses that cause seasonal epidemics of flu is needed.

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, through the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A, and/or influenza B viral RNA, 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, rapid, automated RT-PCR in vitro diagnostic test intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B viral RNA in healthcare provider-collected nasopharyngeal and anterior nasal swab specimens, and healthcare provider-instructed self-collected anterior nasal swab specimens (collected on site) from individuals with signs and symptoms of respiratory tract infection consistent with COVID-19. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

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

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

(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 simultaneous detection and differentiation of SARS-CoV-2, influenza A, and influenza B viral RNA in clinical specimens and is not intended to detect influenza C virus. SARS-CoV-2, influenza A, and influenza B viral RNA are generally detectable in nasopharyngeal and anterior nasal swab specimens during the acute phase of infection.

Positive results are indicative of the presence of SARS-CoV-2, influenza A, and/or influenza B nucleic acid, but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. The agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Negative results for influenza B are presumptive and should be confirmed with an alternative molecular FDA-cleared or authorized assay, if necessary for patient management. Negative results do not preclude SARS-CoV-2, influenza A, and/or influenza B 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.

To use your product, nasopharyngeal swab specimens are first processed in buffer and the specimen is transferred to the sample port of the device using a fixed volume pipette. Within the device, SARS-CoV-2, influenza A, and/or influenza B RNA present are first lysed from cells and then reverse transcribed into cDNA followed by PCR amplification and detection within the same authorized device. Your product includes the materials (or other authorized materials and authorized ancillary reagents as may be requested under Condition L. below) described in the Instructions for Use.

Your product requires use of the “Respiratory Health Control Swabs” (not provided with your product), or other authorized control materials (as may be requested under Condition L. below) which are not included with your product but are available from you with the “Instructions for Use” for the Respiratory Health Control Swabs, to be run as outlined in the Instructions for Use for your product.

The labeling entitled “Visby Medical Respiratory Health: Instructions for Use,” “Visby Medical Respiratory Health: Quick Reference Guide,” “Instructions for Use” for the Respiratory Health Control Swabs, “Visby Medical Recommended Health Care Provider Collection Instructions: Nasopharyngeal Specimen,” “Visby Medical Recommended Health Care Provider Collection Instructions: Dual Nostril Anterior Nasal Specimen,” “Visby Medical Recommended Self-Collection Instructions in Health Care Settings: Dual Nostril Anterior Nasal Specimen”, (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, are required to be made available as set forth in the Conditions of Authorization (Section III), and are collectively referred to as “authorized labeling:”

- Fact Sheet for Healthcare Providers: Visby Medical, Inc. – Visby Medical Respiratory Health Test
- Fact Sheet for Patients: Visby Medical, Inc. - Visby Medical Respiratory Health Test

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section III), 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 III). 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. 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: 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

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

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 at least one physical copy of the “Visby Medical Respiratory Health: Quick Reference Guide”, “Visby Medical Recommended Health Care Provider Collection Instructions: Nasopharyngeal Specimen”, “Visby Medical Recommended Health Care Provider Collection Instructions: Dual Nostril Anterior Nasal Specimen”, and “Visby Medical Recommended Self-Collection Instructions in Health Care Settings: Dual Nostril Anterior Nasal Specimen” with each shipped product to authorized laboratories, and must make the authorized “Visby Medical Respiratory Health: Instructions for Use” 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 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 your product is distributed and the number of your product distributed to each authorized laboratory.
- 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 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 DMD/OHT7/OPEQ/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, Respiratory Health Control Swabs with the “Instructions for Use” for the Respiratory Health Control Swabs, 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/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 maintain records of 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.
- N. Within three months of the date of this letter, you must establish and maintain a quality system that is appropriate for your product's design and manufacture, and that meets the requirements of 21 CFR Part 820. If requested by FDA, you must submit associated documents or records related to your quality system for FDA review within 48 hours of the request.
- O. 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.
- P. 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.
- Q. You must evaluate the analytical limit of detection and assess traceability⁹ 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.

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

- R. You must further evaluate the clinical performance of your product as authorized in an FDA agreed upon post authorization clinical evaluation study within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update authorized 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 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).
- T. 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.

Authorized Laboratories

- U. 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.
- V. 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.
- W. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- X. 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.
- Y. 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 (support@visby.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.
- Z. 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.

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

AA. 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

BB. 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.

CC. 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.

DD. 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 and differentiation of nucleic acid from SARS-CoV-2, influenza A, and influenza B, 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.

IV. 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,

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure