July 21, 2026

Tiffany Miller
Vice President Regulatory Affairs
OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015

Device:	OraQuick Ebola 2.0 Rapid Antigen Test
EUA Number:	EUA260001
Company:	OraSure Technologies, Inc.
Indication:	This test is authorized for the presumptive qualitative detection of antigens from viruses within the *Orthoebolavirus*[1] genus (such as *Orthoebolavirus zairense, Orthoebolavirus bundibugyoense, Orthoebolavirus sudanense* and *Orthoebolavirus taiense*[2]) in: • Venipuncture whole blood and fingerstick whole blood specimens as an aid in the diagnosis of Ebola disease in patients suspected of and with signs and symptoms consistent with Ebola disease and who have epidemiological risk factors for *Orthoebolavirus* exposure. • Cadaveric oral fluid collected from recently deceased individuals with epidemiological risk factors who are suspected to have had Ebola disease at the time of death. The test is intended as an aid in determining Ebola disease at the time of death to inform decisions regarding the safe handling of cadavers to prevent disease transmission. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high complexity tests,

[1] The nomenclature of the family *Filoviridae*, including the viruses that cause Ebola disease, has changed over time. Recently, the genus name *Ebolavirus* was changed to *Orthoebolavirus*, and the species name Zaire ebolavirus (including the strain of Ebola virus detected in the 2014 West African outbreak) was changed to *Orthoebolavirus zairense*. Refer to: *Biedenkopf N., et al, Renaming of genera Ebolavirus and Marburgvirus to Orthoebolavirus and Orthomarburgvirus, respectively, and introduction of binomial species names within family Filoviridae. Arch Virol., 2023 Aug 3;168(8):220. doi: 10.1007/s00705-023-05834-2. PMID: 37537381*, and https://ictv.global/report/chapter/filoviridae/filoviridae/orthoebolavirus.

[2] This assay may detect antigens from *Orthoebolavirus zairense* (including the strain detected in the 2014 West African outbreak), *Orthoebolavirus bundibugyoense, Orthoebolavirus sudanense,* and *Orthoebolavirus taiense*; however, it does not distinguish among these different *Orthoebolavirus* species.

or in similarly qualified non-U.S. laboratories and facilities adequately equipped, trained, and capable of testing for *Orthoebolavirus* infection, by experienced personnel who have received specific training on the use of the OraQuick Ebola 2.0 Rapid Antigen Test, training in the correct use of recommended personal protective equipment (PPE), and expertise in infectious disease diagnostic testing, including the safe handling of clinical specimens potentially containing *Orthoebolavirus.*

Dear Tiffany Miller:

This letter is in response to your[3] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[4] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On September 22, 2006, then-Secretary of the Department of Homeland Security (DHS), Michael Chertoff, determined, pursuant to section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. § 247d-6b), that the Ebola virus[5] presents a material threat against the United States population sufficient to affect national security.[6] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the then-Secretary of Health and Human Services (HHS) declared on August 5, 2014, that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection of Ebola virus, subject to the terms of any authorization issued under section 564 (21 U.S.C. § 360bbb-3).[7]

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 authorized test for the qualitative detection of antigens from viruses within the *Orthoebolavirus*[8] genus, but this is not an adequate and available alternative to your product.[9]

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the

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[3] For ease of reference, this letter will use the term "you" and related terms to refer to the OraSure Technologies, Inc.

[4] For ease of reference, this letter will use the term "your product" to refer to the OraQuick Ebola 2.0 Rapid Antigen Test used for the indication identified above.

[5] See footnote 1 above.

[6] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), the HHS Secretary's declaration that supports EUA issuance must be based on one of four determinations, including the identification by the DHS Secretary of a material threat pursuant to section 319F-2 of the PHS Act sufficient to affect national security or the health and security of United States citizens living abroad (section 564(b)(1)(D) of the Act).

[7] U.S. Department of Health and Human Services. *Declaration Regarding Emergency Use of In Vitro Diagnostics for Detection of Ebola Virus*. 79 Fed. Reg. 47141 (August 12, 2014).

[8] See footnote 1 above.

[9] The OraQuick Ebola Rapid Antigen Test has a granted De Novo (Product Code: QID; DEN190025). To date, the OraQuick Ebola Rapid Antigen Test is available in the United States for the detection of antigens from viruses within the *Orthoebolavirus* [then known as *Ebolavirus*] genus without differentiating among these viruses. Available information indicates that there is currently a need in the United States for additional diagnostic testing for the viruses that cause Ebola disease (including the strain detected in the 2014 West African outbreak) to control the spread of contagious infection.

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. Orthoebolaviruses (including the strain of Ebola virus detected in the 2014 West African outbreak) can cause Ebola disease, a serious or life-threatening disease or condition to humans infected with these viruses;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in detecting *Orthoebolavirus* as an aid in the diagnosis of Ebola disease and as an aid in determining Ebola disease at the time of death to prevent disease transmission, and that the known and potential benefits of your product when used for detecting *Orthoebolavirus* (including the strain of Ebola virus detected in the 2014 West African outbreak), 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.[10]

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 indications above.

Authorized Product Details

Your product is an *in vitro* diagnostic single-use immunoassay intended for the presumptive qualitative detection of antigens from viruses within the *Orthoebolavirus* genus (such as *Orthoebolavirus zairense*, *Orthoebolavirus bundibugyoense*, *Orthoebolavirus sudanense*, and *Orthoebolavirus taiense*); it does not, however, differentiate among these viruses. Use of your product is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high complexity tests, or in similarly qualified non-U.S. laboratories and facilities adequately equipped, trained, and capable of testing for *Orthoebolavirus* infection. The test is intended for use by experienced personnel who have received specific training on the use of your product, training in the correct use of recommended personal protective equipment (PPE), and expertise in infectious disease diagnostic testing, including the safe handling of clinical specimens potentially containing *Orthoebolavirus*. Testing for Ebola disease must be performed in accordance with current guidelines provided by the appropriate public health authorities that address appropriate biosafety conditions, interpretation of test results, and coordination of testing, results, and patient management.

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

Your product is intended for use in:

- Venipuncture whole blood and fingerstick whole blood specimens as an aid in the diagnosis of Ebola disease in patients suspected of and with signs and symptoms consistent with Ebola disease and who have epidemiological risk factors for Orthoebolavirus exposure.
- Cadaveric oral fluid collected from recently deceased individuals with epidemiological risk factors who are suspected to have had Ebola disease at the time of death. The test is intended as an aid in determining Ebola disease at the time of death to inform decisions regarding the safe handling of cadavers to prevent disease transmission.

The test results are presumptive. Definitive identification of Ebola disease requires additional testing and confirmation procedures in consultation with public health and/or other appropriate authorities to whom reporting is required. The diagnosis of Ebola disease must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification of *Orthoebolavirus*.

Positive results indicate the presence of *Orthoebolavirus* antigens; clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results do not preclude *Orthoebolavirus* infection and should not be used as the sole basis for treatment of patient management decisions. Negative results should be considered in the context of history, signs, symptoms, and exposure likelihood.

Your product is not intended for general *Orthoebolavirus* infection screening, such as airport screening or contact tracing of individuals at risk of exposure without signs or symptoms of infection. Your product is not intended for use as a diagnostic test for oral fluid samples of living individuals.

Specimens are tested with your product according to the "OraQuick Ebola 2.0 Rapid Antigen Test Instructions for Use," the "Whole Blood Quick Reference Guide OraQuick Ebola 2.0 Rapid Antigen," and the "Cadaveric Oral Fluid Quick Reference Guide OraQuick Ebola 2.0 Rapid Antigen." Your product includes the materials, or other authorized materials (as may be requested under Condition P. below), necessary to process and test venipuncture whole blood, fingerstick whole blood, and cadaveric oral fluid specimens as described in the "OraQuick Ebola 2.0 Rapid Antigen Test Instructions for Use," the "Whole Blood Quick Reference Guide OraQuick Ebola 2.0 Rapid Antigen," and the "Cadaveric Oral Fluid Quick Reference Guide OraQuick Ebola 2.0 Rapid Antigen."

Your product requires various types of quality control, including the procedural internal control that is built into the control line region "C" of the test device and the external quality controls, available from you separately as the "OraQuick Ebola 2.0 Rapid Antigen Test Kit Controls" with the "OraQuick Ebola 2.0 Rapid Antigen Test Kit Controls" instructions for use, or other

authorized control materials (as may be requested under Condition P. below), to be run as outlined in the "OraQuick Ebola 2.0 Rapid Antigen Test Instructions for Use." 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 of Use described below.

The labeling entitled "OraQuick Ebola 2.0 Rapid Antigen Test Instructions for Use," the "Whole Blood Quick Reference Guide OraQuick Ebola 2.0 Rapid Antigen," the "Cadaveric Oral Fluid Quick Reference Guide OraQuick Ebola 2.0 Rapid Antigen," the "OraQuick Ebola 2.0 Rapid Antigen Test Kit Controls" instructions for use, the "OraQuick Ebola 2.0 Rapid Antigen Test Positive Test Results Visual Reference Card," (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices#ebola), and the following fact sheets pertaining to the emergency use, which are required to be made available as set forth in the Conditions of Authorization (Section IV) are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers: OraSure Technologies, Inc. – OraQuick Ebola 2.0 Rapid Antigen Test
- Fact Sheet for Patients: OraSure Technologies, Inc. – OraQuick Ebola 2.0 Rapid Antigen Test
- Fact Sheet for Response Teams: OraSure Technologies, Inc. – OraQuick Ebola 2.0 Rapid Antigen Test
- Fact Sheet for Relatives and Caregivers: OraSure Technologies, Inc. – OraQuick Ebola 2.0 Rapid Antigen Test

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 used by the 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 detecting *Orthoebolavirus* 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 DHS'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 management system requirements under 21 CFR Part 820, which incorporates by reference ISO 13485:2016, with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding those parts of 21 CFR Part 820 which incorporates by reference ISO 13485:2016 that relate to acceptance activities, nonconforming product, statistical techniques, and complaint files, including, but not limited to ISO 13485:2016 Clauses 7.5.8, 8.2.2, 8.2.6, 8.3 and 21 CFR 820.35.

IV. Conditions of Authorization

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

OraSure Technologies, Inc. (You) and Authorized Distributor(s)[11]

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. Your product must comply with those parts of 21 CFR Part 820, which incorporates by reference ISO 13485:2016, that relate to acceptance activities, nonconforming product, statistical techniques, and complaint files, including, but not limited to: ISO 13485:2016 Clauses 7.5.8, 8.2.2, 8.2.6, 8.3 and 21 CFR 820.35.

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

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

E. You and authorized distributor(s) must include a physical copy of the authorized "OraQuick Ebola 2.0 Rapid Antigen Test Instructions for Use," the "Whole Blood

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

Quick Reference Guide OraQuick Ebola 2.0 Rapid Antigen," the "Cadaveric Oral Fluid Quick Reference Guide OraQuick Ebola 2.0 Rapid Antigen," the "OraQuick Ebola 2.0 Rapid Antigen Test Kit Controls" instructions for use, the "OraQuick Ebola 2.0 Rapid Antigen Test Positive Test Results Visual Reference Card," with each shipped product to authorized laboratories.

F. 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.

G. 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.

H. You and authorized distributor(s) must collect information on the performance of your product. You must report any significant deviations from the established performance characteristics of your product of which you become aware 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-EUA-Reporting@fda.hhs.gov).

I. 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.

J. You and authorized distributor(s) must make available the control material "the "OraQuick Ebola 2.0 Rapid Antigen Test Kit Controls" with the the "OraQuick Ebola 2.0 Rapid Antigen Test Kit Controls" instructions for use or other authorized control materials (as may be requested under Condition P. below), at the same time as your product.

OraSure Technologies, Inc. (You)

K. You must register and list consistent with 21 CFR Part 807 within one month of this letter.

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

M. You must have a signed agreement with each authorized distributor that distribution of the authorized product must be consistent with this Letter of Authorization.

N. If requested by FDA, you must submit associated documents and records related to your quality management system for FDA review within 48 hours of the request.

O. 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).

P. You may request modifications 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 modification to this EUA should be submitted to DMD/OHT7/OPEQ/CDRH and require appropriate authorization from FDA.

Q. 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.

R. 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. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

S. You must evaluate the analytical limit of detection and assess traceability of your product with any FDA-recommended reference material(s) if requested by FDA.[12] 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.

T. You must have a process in place to track adverse events and report to FDA pursuant to 21 CFR Part 803.

U. You must evaluate the impact of *Orthoebolavirus* 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).

V. If requested by FDA, you must update your labeling within seven (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.

[12] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study in the event that we receive reports of adverse events concerning your product.

W. You must submit to DMD/OHT7/OPEQ/CDRH within 3 months of the date of this letter your plan and anticipated timeline to establish and maintain a quality management system that is appropriate for your product's design and manufacture, and that meets the requirements of 21 CFR Part 820 (which incorporates by reference ISO 13485:2016).

X. You must further evaluate the clinical performance of your product using fresh natural clinical specimens of venipuncture whole blood, fingerstick whole blood, and cadaveric oral fluid in an FDA agreed upon post authorization clinical evaluation study. After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

Y. You must further evaluate whole blood specimen stability when used with your product using negative clinical specimens in an FDA agreed upon post-authorization study. After submission to and concurrence with the data by FDA, you must update the authorized labeling, if applicable, to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

Z. You must further evaluate the analytical limit of detection (LoD) of your product using *Orthoebolavirus sudanense* in an FDA agreed upon post-authorization LoD confirmatory study. After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

AA. You must evaluate microbial interference with your product in an FDA agreed upon post-authorization study. After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

BB. You must further evaluate the sample incubation time for your product using positive spiked samples in an FDA agreed upon post-authorization study. After submission to and concurrence with the data by FDA, you must update the authorized labeling, if applicable, to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

CC. You must further evaluate the effect of operational temperature and relative humidity conditions using whole blood specimens on your product in an FDA agreed upon post authorization study. After submission to and concurrence with the data by FDA, you must update the authorized labeling, if applicable, to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

DD. To extend the shelf-life of your product, you must submit study data from an FDA agreed upon real-time stability study to DMD/OHT7/OPEQ/CDRH for review and concurrence.

Authorized Laboratories

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

FF. 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.

GG. 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.

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

II. Authorized laboratories must have a process in place to track adverse events and report to you (For customers within the US phone: (800)ORASURE (800-672-7873). For customers outside the US, phone: +(001)610-882-1820 or go to www.OraSure.com) and to FDA pursuant to 21 CFR Part 803.

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

OraSure Technologies, Inc. (You), Authorized Distributor(s) and Authorized Laboratories

KK. You, authorized distributor(s), and authorized laboratories must collect information on the performance of your product and must report any significant deviations from the established performance characteristics of your product of which they become aware to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) In addition, authorized distributor(s) and authorized laboratories report to you (For customers within the US phone: (800)ORASURE (800-672-7873). For customers outside the US, phone: +(001)610-882-1820 or go to www.OraSure.com).

LL. 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

MM. 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.

NN. 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 *Orthoebolavirus* infection.

OO. 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 the authorized laboratory; and
- This product has been authorized only for the detection of antigens from orthoebolaviruses including *Orthoebolavirus zairense, Orthoebolavirus bundibugyoense, Orthoebolavirus sudanense,* and *Orthoebolavirus taiense,* 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 of Ebola virus 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 of Ebola virus 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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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
Technical Correction: July 22, 2026