July 31, 2015

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

Dear Ms. Miller:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the OraQuick® Ebola Rapid Antigen Test[1] for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014)[2] in venipuncture whole blood or fingerstick whole blood specimens from individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors (including geographic locations with high prevalence of Ebola infection), by laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics), pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3). The OraQuick® Ebola Rapid Antigen Test is intended for circumstances when the use of a rapid Ebola virus test is determined to be more appropriate than the use of an authorized Ebola virus nucleic acid test, which has been demonstrated to be more sensitive in detecting the Ebola Zaire virus. The OraQuick® Ebola Rapid Antigen Test is not intended for use for general Ebola virus infection screening, such as airport screening or contact tracing of individuals without signs and symptoms of Ebola infection.

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 presents a material threat against the United States population sufficient to affect national security.[3] 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 Secretary of the

[1] For purposes of this authorization, the term "OraQuick® Ebola Rapid Antigen Test" includes, in addition to the OraQuick® Ebola Rapid Antigen Test Kit, the OraQuick® Ebola Rapid Antigen Test Kit Controls (quality control reagents intended for use only with the OraQuick® Ebola Rapid Antigen Test) and the OraQuick® Ebola Visual Reference Panel (intended to assist new operators in becoming proficient at reading specimens with antigen levels near the limit of detection of the device). While the OraQuick® Ebola Rapid Antigen Test Kit Controls and OraQuick® Ebola Visual Reference Panel are both sold separately, under this authorization they must be used in conjunction with the OraQuick® Ebola Rapid Antigen Test Kit.

[2] This assay is intended for the qualitative detection of antigens from Zaire Ebola virus (detected in the West Africa outbreak in 2014), but may also detect antigens from Sudan Ebola virus and Bundibugyo Ebola virus; however, it does not distinguish between these different Ebola virus species.

[3] 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).

Department 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(a) of the Act (21 U.S.C. § 360bbb-3(a)).[4]

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the OraQuick® Ebola Rapid Antigen Test (as described in the Scope of Authorization section of this letter (section II)) in individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors (including geographic locations with high prevalence of Ebola infection) (as described in the Scope of Authorization section of this letter (section II)) for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014).

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the OraQuick® Ebola Rapid Antigen Test for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) in the specified population meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The Ebola Zaire virus (detected in the West Africa outbreak in 2014) can cause Ebola virus disease, a serious or life-threatening disease or condition to humans infected with this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the OraQuick® Ebola Rapid Antigen Test may be effective in diagnosing Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection, and that the known and potential benefits of the OraQuick® Ebola Rapid Antigen Test for diagnosing Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the OraQuick® Ebola Rapid Antigen Test for diagnosing Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection.[5]

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 use of the authorized OraQuick® Ebola Rapid Antigen Test by laboratories and facilities adequately equipped, trained, and capable of such testing (including treatment centers and public health clinics) for the presumptive detection of Ebola Zaire virus (detected in the

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

West Africa outbreak in 2014) in individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors (including geographic locations with high prevalence of Ebola infection). The authorized OraQuick® Ebola Rapid Antigen Test is intended for circumstances when use of a rapid Ebola virus test is determined to be more appropriate than use of an authorized Ebola virus nucleic acid test, which has been demonstrated to be more sensitive in detecting the Ebola Zaire virus. The authorized OraQuick® Ebola Rapid Antigen Test is not intended for use for general Ebola infection screening, such as airport screening or contact tracing of individuals without signs and symptoms of Ebola infection.

The Authorized OraQuick® Ebola Rapid Antigen Test

The OraQuick® Ebola Rapid Antigen Test is a rapid single-use chromatographic lateral flow immunoassay contained within a rigid plastic device housing that is intended for the *in vitro* qualitative detection of antigens from the Ebola Zaire virus (detected in the West Africa outbreak 2014) in venipuncture whole blood, fingerstick whole blood, and other authorized specimen types from individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors (including geographic locations with high prevalence of Ebola infection). The OraQuick® Ebola Rapid Antigen Test is a point-of-care test.

The OraQuick® Ebola Rapid Antigen Test utilizes a sandwich capture lateral flow immunoassay method to detect Ebola virus antigens. This lateral flow test is composed of an assay strip with several components: the flat pad, the blocker pad, the conjugate pad, the nitrocellulose membrane (with a Test Line ("T") and a Control ("C") line), and the absorbent pad. The clinical specimen is applied to the device followed by insertion of the device into the developer solution. The execution of the assay occurs as reagents are hydrated and liquid is transported along with the specimen across the strip towards the test zone.

If Ebola viral antigens are present in the patient sample they will be bound by biotinylated anti-Ebola polyclonal antibodies eluting from the blocker pad. These complexed Ebola antigens will then form immunological sandwiches with signal generating colloidal gold labeled Ebola antibodies that are eluting from the conjugate pad. The immunological sandwich complex is subsequently captured through reaction of the biotinylated anti-Ebola antibody with the biotin binding protein streptavidin that is immobilized at the Test Line ("T") of the test strip.

The OraQuick® Ebola Rapid Antigen Test Kit is comprised of an OraQuick® Ebola Rapid Antigen Test device, a filled, capped and labeled Developer Vial, a device stand (used to hold the device during the running of the test following specimen collection), micropipettes, a quick reference guide and the package insert. The test kit has a built-in procedural control that demonstrates assay validity. A purple line in the Control ("C") area of the Result Window indicates that the fluid migrated appropriately through the Test Device. The Control line will appear on all valid tests, whether or not the sample is positive (i.e., reactive) or negative (i.e., non-reactive).

The OraQuick® Ebola Rapid Antigen Test Kit Controls must be used with the OraQuick® Ebola Rapid Antigen Test. The OraQuick® Ebola Rapid Antigen Test Kit Controls contain two vials,

one Ebola positive control vial (orange capped) and one Ebola negative control vial (white capped).

The OraQuick® Ebola Visual Reference Panel is intended to assist new operators in becoming proficient at reading specimens with antigen levels near the limit of detection of the device. It consists of three devices that have been specifically formulated and manufactured to represent positive results near the limit of detection, low positive, and negative test results. New operators must be able to correctly interpret all devices of the OraQuick® Ebola Visual Reference Panel prior to using the OraQuick® Ebola Rapid Antigen Test device with patient samples.

The above described OraQuick® Ebola Rapid Antigen Test, when labeled consistently with the labeling authorized by FDA entitled "OraQuick® Ebola Rapid Antigen Test Instructions for Use" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised by OraSure Technologies, Inc. in consultation with FDA, is authorized to be distributed to laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics), despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described OraQuick® Ebola Rapid Antigen Test is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to health care professionals and patients:

- Fact Sheet for Health Care Providers: Interpreting OraQuick® Ebola Rapid Antigen Test Results

- Fact Sheet for Patients: Understanding Results from the OraQuick® Ebola Rapid Antigen Test

As described in section IV below, OraSure Technologies, Inc. and any authorized distributor(s) are also authorized to make available additional information relating to the emergency use of the authorized OraQuick® Ebola Rapid Antigen Test that is consistent with, and does not exceed, the terms of this letter of authorization.

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 the authorized OraQuick® Ebola Rapid Antigen Test in the specified population, when used for presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014), outweigh the known and potential risks of such a 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 the authorized OraQuick® Ebola Rapid Antigen Test may be effective in the diagnosis of Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection 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 the authorized OraQuick® Ebola Rapid Antigen Test, when used to diagnose Ebola Zaire virus (detected in the West Africa

outbreak in 2014) infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized OraQuick® Ebola Rapid Antigen Test 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 described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the OraQuick® Ebola Rapid Antigen Test described above is authorized to diagnose Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection in individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors (including geographic locations with high prevalence of Ebola infection).

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the OraQuick® Ebola Rapid Antigen Test 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 the OraQuick® Ebola Rapid Antigen Test.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for 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)), any 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).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

OraSure Technologies, Inc. and Any Authorized Distributor(s)

A. OraSure Technologies, Inc. and any authorized distributor(s) will distribute the authorized OraQuick® Ebola Rapid Antigen Test with the authorized labeling, as may be revised by OraSure Technologies, Inc. in consultation with FDA, to laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics).

B. OraSure Technologies, Inc. and any authorized distributor(s) will provide to laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics), the authorized OraQuick® Ebola Rapid Antigen Test Fact Sheet for Health Care Providers and the authorized OraQuick® Ebola Rapid Antigen Test Fact Sheet for Patients.

C. OraSure Technologies, Inc. and any authorized distributor(s) will make available on their websites the authorized OraQuick® Ebola Rapid Antigen Test Fact Sheet for Health Care Providers and the authorized OraQuick® Ebola Rapid Antigen Test Fact Sheet for Patients.

D. OraSure Technologies, Inc. and any authorized distributor(s) will inform laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) and relevant public health authority(ies) of this EUA, including the terms and conditions herein.

E. OraSure Technologies, Inc. and any authorized distributor(s) will ensure that first time users of the OraQuick® Ebola Rapid Antigen Test Kit will be informed about the requirement for use of the control material and the visual reference panel.

F. OraSure Technologies, Inc. and any authorized distributor(s) will ensure that laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) using the authorized OraQuick® Ebola Rapid Antigen Test have a process in place for reporting test results to health care professionals and relevant public health authorities, as appropriate.

G. Through a process of inventory control, OraSure Technologies, Inc. and any authorized distributor(s) will maintain records of device usage.

H. OraSure Technologies, Inc. and any authorized distributor(s) will collect information on the performance of the assay, and report to FDA any suspected occurrence of false positive or false negative results of which OraSure Technologies, Inc. and any authorized distributor(s) become aware.

I. OraSure Technologies, Inc. and any authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized OraQuick® Ebola Rapid Antigen Test that is consistent with, and does not exceed, the terms of this letter of authorization.

OraSure Technologies, Inc.

J. OraSure Technologies, Inc. will notify FDA of any authorized distributor(s) of the OraQuick® Ebola Rapid Antigen Test, including the name, address, and phone number of any authorized distributor(s).

K. OraSure Technologies, Inc. will provide any authorized distributor(s) with a copy of this EUA, and communicate to any authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., fact sheets, instructions for use).

L. OraSure Technologies, Inc. only may request changes to the authorized OraQuick® Ebola Rapid Antigen Test Fact Sheet for Health Care Providers or the authorized OraQuick® Ebola Rapid Antigen Test Fact Sheet for Patients. Such requests will be made only by OraSure Technologies, Inc. in consultation with FDA.

M. OraSure Technologies, Inc. may request the addition of other specimen types for use with the authorized OraQuick® Ebola Rapid Antigen Test. Such requests will be made by OraSure Technologies, Inc. in consultation with, and require concurrence of, FDA.

N. OraSure Technologies, Inc. will track adverse events and report to FDA under 21 CFR Part 803.

Laboratories and Facilities Adequately Equipped, Trained, and Capable of Testing for Ebola Infection (Including Treatment Centers and Public Health Clinics)

O. Laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) will include with reports of the results of the OraQuick® Ebola Rapid Antigen Test the authorized Fact Sheet for Health Care Providers and the authorized Fact Sheet for Patients. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

P. Laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) will have a process in place for reporting test results to health care professionals and relevant public health authorities, as appropriate.

Q. Laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) will collect information on the performance of the assay, and report to OraSure Technologies, Inc. and any authorized distributor(s) any suspected occurrence of false positive or false negative results of which they become aware.

R. All personnel from laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) using the assay will be appropriately trained on the OraQuick® Ebola Rapid Antigen Test and use appropriate laboratory and personal protective equipment when handling this kit.

OraSure Technologies, Inc., Any Authorized Distributor(s), and Laboratories and Facilities Adequately Equipped, Trained, and Capable of Testing for Ebola Infection (Including Treatment Centers and Public Health Clinics)

S. OraSure Technologies, Inc., any authorized distributor(s), and laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Advertising and Promotion

T. All advertising and promotional descriptive printed matter relating to the use of the authorized OraQuick® Ebola Rapid Antigen Test shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

U. All advertising and promotional descriptive printed matter relating to the use of the authorized OraQuick® Ebola Rapid Antigen Test shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics);
- This test has been authorized only for the detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014); and
- This test is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the 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 authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized OraQuick® Ebola Rapid Antigen Test may represent or suggest that this test is safe or effective for the diagnosis of Ebola Zaire virus (detected in the West Africa outbreak in 2014).

The emergency use of the authorized OraQuick® Ebola Rapid Antigen Test 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,

_____
Stephen M. Ostroff, M.D.
Acting Commissioner of Food and Drugs

Enclosures