February 24, 2015

Daniel F. Simpson, RAC (U.S., CAN), ASQ CBA
Sr. Director of Quality and Regulatory Affairs
Corgenix Inc.
11575 Main Street, Suite 400
Broomfield, CO 80020

Dear Mr. Simpson:

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 ReEBOV™ Antigen Rapid Test for the presumptive detection of Ebola viruses[1] 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), pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3). The authorized ReEBOV™ Antigen Rapid 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 ReEBOV™ Antigen Rapid Test is not intended for use for general Ebola virus infection screening, such as airport screening or contact tracing. The ReEBOV™ Antigen Rapid Test is authorized for use in laboratories or facilities adequately equipped, trained, and capable of such testing (including treatment centers and public health clinics).

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.[2] 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 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 21 U.S.C. § 360bbb-3(a).[3]

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[1] This assay is intended for the qualitative detection of antigen from Zaire Ebola virus [detected in the West Africa outbreak in 2014), Sudan Ebola virus, and Bundibugyo Ebola virus; however, it does not distinguish between these different Ebola virus strains.

[2] 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).

[3] 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).

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 ReEBOV™ Antigen Rapid 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 ReEBOV™ Antigen Rapid Test for the presumptive detection of Ebola viruses (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 ReEBOV™ Antigen Rapid 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 ReEBOV™ Antigen Rapid 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 ReEBOV™ Antigen Rapid Test for diagnosing Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection.[4]

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 ReEBOV™ Antigen Rapid Test for the presumptive detection of Ebola Zaire virus (detected in the 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 ReEBOV™ Antigen Rapid 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 ReEBOV™ Antigen Rapid Test is not intended for use for general Ebola infection screening, such as airport screening or contact tracing. The ReEBOV™ Antigen Rapid Test is

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

authorized for use in laboratories or facilities adequately equipped, trained, and capable of such testing (including treatment centers and public health clinics).

The Authorized ReEBOV™ Antigen Rapid Test

The ReEBOV™ Antigen Rapid Test is a chromatographic dipstick-format lateral flow immunoassay for the *in vitro* qualitative detection of VP40 protein from the Ebola Zaire virus (detected in the West Africa outbreak in 2014) in fingerstick (capillary) whole blood, venous whole blood, plasma 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 test procedure consists of a dipstick-format lateral flow immunoassay that is initiated by applying the clinical specimen to the dipstick sample pad followed by insertion of the dipstick into a test tube containing sample buffer which initiates flow within the dipstick device. The test is then incubated for 15-25 minutes before being visually interpreted. The ReEBOV™ Antigen Rapid Test is a point-of-care test.

The ReEBOV™ Antigen Rapid Test consists of a self-contained, disposable dipstick-format lateral flow test that includes an internal process Control Line. Following application of the clinical specimen and insertion into the test tube containing sample buffer the specimen flows through the reagent pads causing the Ebola Zaire virus antigen, VP40 protein, present in the specimen to bind nanoparticles labeled with antigen specific antibodies. As the specimen and nanoparticles flow across the device membrane, immobilized Ebola Zaire virus antigen-specific antibody absorbs the nanoparticle immune-complexes at the Test Line. Antigen dependent deposition of the nanoparticle at the Test Line generates a chromogenic signal relative to the antigen titer. The test is incubated for 15-25 minutes to allow full development of the signal. The test result is determined by visual interpretation of the signal in the Test and Control Lines, with a positive sample resulting in development of a faint pink to dark red signal on the Test Line. Once a clinical specimen is collected and the test is initiated, it takes 15-25 minutes to produce results.

The ReEBOV™ Antigen Rapid Test includes the following internal process Control Line:

- The Process Control Line**,** located following the Test Line on the dipstick, is comprised of Ebola Zaire virus antigen and binds excess or unreacted nanoparticles resulting in a visual pink to red line. A visual signal on the Control Line indicates that the test was performed correctly and that the coated nanoparticles are reactive to the Ebola Zaire virus antigen.

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

The above described ReEBOV™ Antigen Rapid 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 ReEBOV™ Antigen Rapid Test Results
- Fact Sheet for Patients: Understanding Results from the ReEBOV™ Antigen Rapid Test

As described in section IV below, Corgenix Inc. is also authorized to make available additional information relating to the emergency use of the authorized ReEBOV™ Antigen Rapid 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 ReEBOV™ Antigen Rapid 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 ReEBOV™ Antigen Rapid 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 ReEBOV™ Antigen Rapid 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 ReEBOV™ Antigen Rapid 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 ReEBOV™ Antigen Rapid 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 ReEBOV™ Antigen Rapid 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 ReEBOV™ Antigen Rapid 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:

Corgenix Inc.

A. Corgenix Inc. will distribute the authorized ReEBOV™ Antigen Rapid Test with the authorized labeling, as may be revised by Corgenix 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. Corgenix Inc. will provide to laboratories and facilities (including treatment centers and public health clinics) adequately equipped, trained, and capable of testing for Ebola infection the authorized ReEBOV™ Antigen Rapid Test Fact Sheet for Health Care Providers and the authorized ReEBOV™ Antigen Rapid Test Fact Sheet for Patients.

C. Corgenix Inc. will make available on its website the ReEBOV™ Antigen Rapid Test Fact Sheet for Health Care Providers and the authorized ReEBOV™ Antigen Rapid Test Fact Sheet for Patients.

D. Corgenix Inc. will inform laboratories, 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. Corgenix Inc. 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 ReEBOV™ Antigen Rapid Test have a process in place for reporting test results to health care professionals and relevant public health authorities, as appropriate.

F. Corgenix Inc. will track adverse events and report to FDA under 21 CFR Part 803.

G. Through a process of inventory control, Corgenix Inc. will maintain records of device usage.

H. Corgenix Inc. 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 Corgenix Inc. becomes aware.

I. Corgenix Inc. is authorized to make available additional information relating to the emergency use of the authorized ReEBOV™ Antigen Rapid Test that is consistent with, and does not exceed, the terms of this letter of authorization.

J. Corgenix Inc. may request changes to the authorized ReEBOV™ Antigen Rapid Test Fact Sheet for Health Care Providers or the authorized ReEBOV™ Antigen Rapid Test Fact Sheet for Patients. Such requests will be made by Corgenix Inc. in consultation with FDA.

K. Corgenix Inc. may request the addition of other specimen types for use with the authorized ReEBOV™ Antigen Rapid Test. Such requests will be made by Corgenix Inc. in consultation with, and require concurrence of, FDA.

L. Corgenix Inc. will notify FDA of any proposed change in its status as exclusive distributor of the ReEBOV™ Antigen Rapid Test, including any proposed authorization of additional distributors.

Laboratories and Facilities Adequately Equipped, Trained, and Capable of Testing for Ebola Infection

M. 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 ReEBOV™ Antigen Rapid 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.

N. 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.

O. 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 Corgenix Inc. any suspected occurrence of false positive or false negative results of which they become aware.

P. All laboratory personnel and personnel from 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 ReEBOV™ Antigen Rapid Test and use appropriate laboratory and personal protective equipment when handling this kit.

Corgenix Inc., Laboratories, and Facilities Adequately Equipped, Trained, and Capable of Testing for Ebola Infection

Q. Corgenix Inc., 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

R. All advertising and promotional descriptive printed matter relating to the use of the authorized ReEBOV™ Antigen Rapid 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.

S. All advertising and promotional descriptive printed matter relating to the use of the authorized ReEBOV™ Antigen Rapid 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 Emergency Use Authorization 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 viruses (including Ebola Zaire virus detected in the West Africa outbreak in 2014); and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of Ebola Zaire 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 ReEBOV™ Antigen Rapid 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 ReEBOV™ Antigen Rapid 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,

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Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

Enclosures