Fact Sheet for Ebola Response Teams: Interpreting Results from the OraQuick® Ebola Rapid Antigen Test for use with Cadaveric Oral Fluid

March 4, 2016

Dear Response Team:

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to authorize the use of the OraQuick® Ebola Rapid Antigen Test for the qualitative detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) in cadaveric oral fluid swab specimens from individuals with epidemiological risk factors for Ebola virus infection and suspected to have died of Ebola. This test is intended to aid in diagnosing Ebola Zaire virus infection as the cause of death in order to inform decisions on safe and dignified burial procedures to prevent transmission of Ebola virus in the community. The OraQuick® Ebola Rapid Antigen Test for cadaveric oral fluid may be used with direct testing or in conjunction with recommended swabs in viral transport media.

FDA issued this EUA based on data submitted by OraSure Technologies, Inc. to FDA and on the U.S. Secretary of Health and Human Services' (HHS) declaration that circumstances exist to justify the emergency use of *in vitro* diagnostic tests for the detection of Ebola virus. This EUA will terminate when the HHS Secretary's declaration terminates, unless FDA revokes it sooner.

The authorized OraQuick® Ebola Rapid Antigen Test for use with cadaveric oral fluid is not intended for use as a diagnostic test for oral fluid swabs of living individuals. The OraQuick® Ebola Rapid Antigen Test is authorized for use by personnel who are adequately equipped, trained, and capable of testing for Ebola infection, in laboratories, facilities, and in field surveillance and response teams acting under the direction of public health authorities.

The information in this Fact Sheet is necessary to inform you of the significant known and potential risks and benefits of the emergency use of the OraQuick® Ebola Rapid Antigen Test. For more information on this EUA, please see FDA's website at **http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm#ebola**.

Why is this test needed at this time?

At this time, no FDA-approved/cleared tests that can detect Ebola Zaire virus (detected in the West Africa outbreak in 2014) in cadaveric oral fluid clinical specimens are available. OraSure Technologies, Inc. has developed the OraQuick® Ebola Rapid Antigen Test to detect Ebola Zaire virus (detected in the West Africa outbreak in 2014) infections in individuals who are suspected to have died of Ebola virus infection.

If infection with Ebola Zaire virus (detected in the West Africa outbreak in 2014) is suspected based on current clinical and epidemiological criteria recommended by public health authorities, the OraQuick® Ebola Rapid Antigen Test should be used in the specified population to inform decisions on safe and dignified burial procedures in order to prevent transmission of the Ebola Zaire virus in the community. This test is authorized for use with cadaveric oral fluid swab specimens.

Specimens should be collected with appropriate infection control precautions for Ebola viruses, according to instructions for the specimen collection device.

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected to have died from Ebola Zaire virus infection. The OraQuick® Ebola Rapid Antigen Test should be used only by trained personnel who have received specific training on the use of the OraQuick® Ebola Rapid Antigen Test.

Current information about safe and dignified burial procedures is available in the guideline, *How to conduct safe and dignified burial of a patient who has died from suspected or confirmed Ebola virus disease,* developed by the World Health Organization (WHO) and found at http://apps.who.int/iris/bitstream/10665/137379/1/WHO_EVD_GUIDANCE_Burials_14.2_eng.pdf.
Current information about surveillance is available in the guidelines, *Surveillance strategy during Phase 3 of the Ebola response* developed by the WHO and found at http://apps.who.int/iris/bitstream/10665/192997/1/WHO_EVD_Guidance_Sur_15.1_eng.pdf.
Current information about Ebola virus disease for health care workers, including case definitions and infection control, is available in the manual, *Infection Control for Viral Hemorrhagic Fevers in the African Health Care Setting*, developed by the U.S. Centers for Disease Control and Prevention (CDC) in conjunction with the WHO and found at http://www.cdc.gov/vhf/abroad/healthcare-workers.html.

All information and guidelines, including those on Ebola Zaire virus laboratory testing, may change as we continue to learn more about this virus. Please check the CDC Ebola Hemorrhagic Fever website regularly for the most current information (http://www.cdc.gov/vhf/ebola/index.html).

What does it mean if the specimen tests positive for Ebola virus?

A positive test result from the OraQuick® Ebola Rapid Antigen Test indicates that the tested cadaver was very likely infected with Ebola Zaire virus (detected in the West Africa outbreak in 2014).
In accordance with CDC and WHO recommendations, cadavers with a positive result should be subjected to safe and dignified burial procedures and contacts of an Ebola positive cadaver should be identified and followed up. Contact testing should be conducted in accordance with, *EMERGENCY GUIDELINE Implementation and management of contact tracing for Ebola virus disease,* developed by the WHO and the CDC and found at **http://apps.who.int/iris/bitstream/10665/185258/1/WHO_EVD_Guidance_Contact_15.1_eng.pdf?ua=1**

What does it mean if the specimen tests negative for Ebola Zaire virus?

A negative test indicates that Ebola virus (including Ebola Zaire virus detected in the West Africa outbreak in 2014) was not present at the detection level of the assay. However, negative results do not preclude Ebola virus infection. The possibility of a false negative result should especially be considered if the deceased individual's recent exposures or clinical presentation indicate that Ebola virus infection was likely.

Reporting Adverse Events

Any adverse events should be sent to the following website/email address:
customercare@orasure.com

Give Relatives or Caregivers the *Fact Sheet for Relatives and Caregivers: Understanding Results from the OraQuick® Ebola Rapid Antigen Test*

Contact Information for Technical Assistance for the OraQuick® Ebola Rapid Antigen Test:

EMail: customercare@orasure.com

OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015

Telephone: 1-800-672-7873

Health care providers, public health authorities, and stakeholders working with such public health authorities will be contacted by OraSure Technologies, Inc. in the event of any significant new findings that negatively impact the performance of the test and that are observed during the course of the emergency use of the OraQuick® Ebola Rapid Antigen Test when used with cadaveric oral fluid.