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

**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 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 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.

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:**

E-mail: 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.