



February 1, 2019

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

Re: EUA160001/A004  
Trade/Device Name: OraQuick Ebola Rapid Antigen Test For Use With Cadaveric Oral Fluid  
Dated: September 26, 2018  
Received: September 27, 2018

Dear Mrs. Miller:

This is to notify you that your request to modify the Instructions for Use of the OraQuick Ebola Rapid Antigen Test to include new data on (1) Clinical Performance, (2) Cross Reactivity and (3) Reproducibility of the device has been granted.

Upon review, we concur that the data submitted in EUA160001/A004 supports the proposed modification to the Instructions for Use. By submitting this amendment for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the OraQuick Ebola Rapid Antigen Test issued on March 4, 2016.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.  
Director  
Division of Microbiology Devices  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health