



August 3, 2022

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

Re: EUA210378/S007  
Trade/Device Name: IntelliSwab COVID-19 Rapid Test  
Dated: June 1, 2022  
Received: June 2, 2022

Dear Tiffany Miller:

This is to notify you that your request to update the IntelliSwab COVID-19 Rapid Test to extend the shelf-life expiration date to 12 months, when stored at 2°C – 30°C, based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210378/S007 support the requested update for the IntelliSwab COVID-19 Rapid Test. By submitting this EUA revision 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 IntelliSwab COVID-19 Rapid Test re-issued on January 27, 2022.

Sincerely yours,

---

Uwe Scherf, M.Sc., Ph.D.  
Director, Division of Microbiology Devices  
OHT7: Office of In Vitro Diagnostics and Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health