



September 26, 2023

Tamasha Parsons
Sr. Regulatory Affairs Specialist
OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015

Re: EUA210401/S011
Trade/Device Name: IntelliSwab COVID-19 Rapid Test Pro
Dated: September 15, 2023
Received: September 15, 2023

Dear Tamasha Parsons:

This is to notify you that your request to update the IntelliSwab COVID-19 Rapid Test Pro to extend the shelf-life expiration date to 24 months when stored at 2°C – 30°C,¹ based on the results of your stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210401/S011 support the requested updates for the IntelliSwab COVID-19 Rapid Test Pro. 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 Pro reissued on January 27, 2022.

Sincerely yours,

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

¹ The shelf-life of the IntelliSwab COVID-19 Rapid Test Pro Kit Controls remains at 11 months when stored at 2°C – 8°C as granted by FDA on August 22, 2023.