



August 3, 2022

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

Re: EUA210401/S005
Trade/Device Name: IntelliSwab COVID-19 Rapid Test Pro
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 Pro* 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 EUA210401/S005 support the requested update 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 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

* The granted shelf-life extension does not include the IntelliSwab COVID-19 Rapid Test Pro Kit Controls, which is sold separately from the IntelliSwab COVID-19 Rapid Test Pro.