



November 15, 2023

Dimitris Demirtzoglou
Director, Regulatory Affairs
SEKISUI Diagnostics, LLC
One Wall Street
Burlington, MA 01803

Re: EUA210448/S005
Trade/Device Name: OSOM COVID-19 Antigen Rapid Test
Dated: October 9, 2023
Received: October 9, 2023

Dear Dimitris Demirtzoglou:

This is to notify you that your request to update the OSOM COVID-19 Antigen Rapid Test to extend the shelf-life expiration date to 24 months, when stored at 15°C – 30°C, based on the results of your stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210448/S005 support the requested update for the OSOM COVID-19 Antigen 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 OSOM COVID-19 Antigen Rapid Test re-issued on June 9, 2023.

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