



July 1, 2025

Penny White, B.Sc.
Associate Director, Regulatory Affairs
SEKISUI Diagnostics, LLC
6659 Top Gun Street
San Diego, CA 92121

Re: EUA230045/S003
Trade/Device Name: OSOM Flu SARS-CoV-2 Combo Test
Dated: May 5, 2025
Received: May 5, 2025

Dear Penny White:

This is to notify you that your request is granted to update the OSOM Flu SARS-CoV-2 Combo Test to extend the shelf-life expiration date to 20 months when stored at 15°C – 30°C, based on the results of your stability studies. In addition, the shelf-life expiration date extension of the external OSOM Flu SARS-CoV-2 Combo Control Kit, sold separately, to 20 months when stored at 15°C – 30°C is granted based on the results of your ongoing stability studies. Upon review, we concur that the data and information submitted in EUA230045/S003 supports the requested update for the OSOM Flu SARS-CoV-2 Combo 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 Flu SARS-CoV-2 Combo Test issued on February 29, 2024.

Sincerely yours,

Joseph Briggs, Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health