



July 1, 2025

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

Re: EUA240002/S004  
Trade/Device Name: OSOM Flu SARS-CoV-2 Combo Home 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 Home 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. Upon review, we concur that the data and information submitted in EUA240002/S004 supports the requested update for the OSOM Flu SARS-CoV-2 Combo Home 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 Home Test issued on February 29, 2024.

Sincerely yours,

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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