



January 14, 2025

Catherine Shi
ACON Laboratories, Inc.
5850 Oberlin Drive, #340
San Diego, CA 92121

Re: EUA240008/S001
Trade/Device Name: Flowflex Plus COVID-19 and Flu A/B Home Test
Dated: December 19, 2024
Received: December 19, 2024

Dear Catherine Shi:

This is to notify you that your request to update the Flowflex Plus COVID-19 and Flu A/B Home Test to extend the shelf-life expiration date to 18 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 EUA240008/S001 supports the requested update for the Flowflex Plus COVID-19 and Flu A/B 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 Flowflex Plus COVID-19 and Flu A/B Home Test issued on July 23, 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