



April 20, 2022

Qiyi Xie
ACON Laboratories, Inc.
5850 Oberlin Drive, #340
San Diego, CA 92121

Re: EUA210494/S009
Trade/Device Name: *Flowflex* COVID-19 Antigen Home Test
Dated: March 3, 2022
Received: March 3, 2022

Dear Qiyi Xie:

This is to notify you that your request to update the *Flowflex* COVID-19 Antigen Home Test to extend the shelf-life expiration date of the *Flowflex* COVID-19 Antigen Home Test to 16 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 EUA210494/S009 support the requested update for the *Flowflex* COVID-19 Antigen 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* COVID-19 Antigen Home Test re-issued on February 18, 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

**ACON Laboratories, Inc: Flowflex COVID-19 Antigen Home Test
19-month to 21-month self-life extension granted by the FDA on November 18, 2022**

Lot Number	Tests with this printed expiration date	Now have this extended expiration date
COV1100041 – COV1100088	October 2022	July 2023
COV1110071 – COV1110266	November 2022	August 2023
COV1120041 – COV1125011	December 2022	September 2023
COV2010001 – COV2010100	January 2023	October 2023
COV2020003 – COV2030010	February 2023	November 2023
COV2030011 – COV2030023	March 2023	December 2023