



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