



September 2, 2022

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

Re: EUA210494/S016
Trade/Device Name: *Flowflex* COVID-19 Antigen Home Test
Dated: July 21, 2022
Received: July 21, 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 to 19 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/S016 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 June 21, 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