October 15, 2021

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

Re: EUA210494/S001
Trade/Device Name: Flow*flex* COVID-19 Antigen Home Test
Dated: October 8, 2021
Received: October 12, 2021

Dear Qiyi Xie:

This is to notify you that your request to update the Flow*flex* COVID-19 Antigen Home Test labeling to; (1) offer a 25 kits/box configuration, (2) update the kit box dimensions (for the 1 and 2 kit/box configurations) and kit box design to incorporate a built-in tube holder, (3) add use of shorter individually wrapped swabs for certain box configurations, and (4) update the Extraction Buffer Tube option that uses a foil seal, is granted. Upon review, we concur that the data, information and updated instructions for use submitted in EUA210494/S001 supports the requested updates for use with the Flow*flex* 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 Flow*flex* COVID-19 Antigen Home Test issued on October 4, 2021.

Sincerely yours,

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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