June 28, 2021

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

Re: EUA201728/S001
Trade/Device Name: ACON SARS-CoV-2 IgG/IgM Rapid Test
Supplement Dated: May 3, 2021
Supplement Received: May 3, 2021

Dear Qiyi Xie:

This is to notify you that your request to update the Instructions for Use (IFU) of the ACON SARS-CoV-2 IgG/IgM Rapid Test to: increase storage temperature from 9 months at 2-8°C to 12 months at 2-30°C, is granted. Upon review, we concur that the data and information submitted in EUA201728/S001 supports the changes to the IFU. FDA has updated the Instructions for Use to include limitations related to test performance in vaccinated individuals and performance with circulating variants and has updated the Healthcare Provider and Recipient Fact Sheets to reflect more recent authorizations. By submitting this supplement 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 ACON SARS-CoV-2 IgG/IgM Rapid Test issued on December 15, 2020.

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