



July 8, 2022

Jack Feng
iHealth Labs, Inc.
120 San Lucar Ct.
Sunnyvale, CA 94086

Re: EUA210470/S010
Trade/Device Name: iHealth COVID-19 Antigen Rapid Test
Dated: June 20, 2022
Received: June 20, 2022

Dear Mr. Feng:

This is to notify you that your request to update the iHealth COVID-19 Antigen Rapid Test to extend the shelf-life expiration date of the iHealth COVID-19 Antigen Rapid Test to 12 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 EUA210470/S010 support the requested update for the iHealth COVID-19 Antigen Rapid Test. The authorized labeling has been updated to include the 12-month shelf-life. 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 iHealth COVID-19 Antigen Rapid Test re-issued on December 22, 2021.

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

Enclosure