



December 27, 2022

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

Re: EUA210536/S001
Trade/Device Name: iHealth COVID-19 Antigen Rapid Test Pro
Dated: October 14, 2022
Received: October 14, 2022

Dear Jack Feng:

This is to notify you that your request to update the iHealth COVID-19 Antigen Rapid Test Pro to extend the shelf-life expiration date to 15 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 EUA10536/S001 support the requested update for the iHealth COVID-19 Antigen Rapid Test Pro. 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 Pro issued on January 14, 2022.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of Health Technology 7 (OHT7): Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health