



January 11, 2023

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

Re: EUA210470/S015  
Trade/Device Name: iHealth COVID-19 Antigen Rapid Test  
Dated: September 26, 2022  
Received: September 26, 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 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 EUA210470/S015 support the requested update for the iHealth COVID-19 Antigen Rapid Test. The authorized labeling has been updated to include the 15-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,

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

Enclosure