



October 9, 2024

Tianyang Liu
Director of Regulatory and Policy
iHealth Labs, Inc.
880 W Maude Avenue
Sunnyvale, CA 94085

Re: EUA230053/S003
Trade/Device Name: iHealth COVID-19/Flu A&B Rapid Test
Dated: September 14, 2024
Received: September 14, 2024

Dear Tianyang Liu:

This is to notify you that your request to update the iHealth COVID-19/Flu A&B Rapid Test to extend the shelf-life expiration date to 17 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 EUA230053/S003 supports the requested update for the iHealth COVID-19/Flu A&B Rapid 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 iHealth COVID-19/Flu A&B Rapid Test issued on May 7, 2024.

Sincerely yours,

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