



June 17, 2025

Yange Wang
Associate Manager, QMS&RA
iHealth Labs, Inc.
880 W Maude Avenue
Sunnyvale, CA 94085

Re: EUA230053/S006
Trade/Device Name: iHealth COVID-19/Flu A&B Rapid Test
Dated: April 23, 2025
Received: April 27, 2025

Dear Yange Wang:

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 20 months when stored at 2°C – 30°C, based on the results of your stability studies, is granted. Upon review, we concur that the data and information submitted in EUA230053/S006 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,

Joseph Briggs, Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health