



June 17, 2025

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

Re: EUA240005/S005  
Trade/Device Name: iHealth COVID-19/Flu A&B Rapid Test Pro  
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 Pro 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 EUA240005/S005 supports the requested update for the iHealth COVID-19/Flu A&B 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/Flu A&B Rapid Test Pro issued on May 31, 2024.

Sincerely yours,

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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

Technical Correction November 10, 2025: Footnote 1 was deleted from the letter as the sponsor had data to support a 20-month shelf-life for the positive and negative controls included in the iHealth COVID-19/Flu A&B Rapid Test Pro kit and therefore also the iHealth COVID-19/Flu A&B Rapid Test Pro Control Kit when stored at 2°C – 30°C.”