March 20, 2025

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

Re: EUA240005/S003
Trade/Device Name: iHealth COVID-19/Flu A&B Rapid Test Pro
Dated: March 6, 2025
Received: March 6, 2025

Dear Yange Wang:

This is to notify you that your request to update the iHealth COVID-19/Flu A&B Rapid Test Pro[1] 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 EUA240005/S003 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

[1] Note the shelf-life for the iHealth COVID-19/Flu A&B Rapid Test Pro Control Kit was not evaluated as part of this study and remains at 3 months when stored at 2°C – 30°C.