U.S. FOOD & DRUG ADMINISTRATION

September 12, 2024

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

Re: EUA240005/S002
Trade/Device Name: iHealth COVID-19/Flu A&B Rapid Test Pro
Dated: September 3, 2024
Received: September 3, 2024

Dear Tianyang Liu:

This is to notify you that your request to update the iHealth COVID-19/Flu A&B Rapid Test Pro with data evaluating additional inclusivity of the product to fulfill Condition of Authorization S. of the May 31, 2024, Letter of Authorization is granted. Upon review, we concur that the data and information submitted in EUA240005/S002 supports the requested update for the iHealth COVID-19/Flu A&B Rapid Test Pro and fulfills Condition of Authorization S. of the May 31, 2024, Letter. 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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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