April 4, 2022

Jack Feng
iHealth Labs, Inc.
120 San Lucar Ct.
Sunnyvale, CA 94086

Re: EUA210470/S003 and S004
Trade/Device Name: iHealth COVID-19 Antigen Rapid Test
Dated: January 10, 2022 and January 17, 2022
Received: January 12, 2022 and January 19, 2022

Dear Mr. Feng:

This is to notify you that your request to; (1) distribute the iHealth COVID-19 Antigen Rapid Test under the brand name "GoToKnow COVID-19 Antigen Rapid Test," (2) update the iHealth COVID-19 Test Application (App) to fulfill Condition of Authorization S. in the December 22, 2021 letter, and (3) fulfill Condition of Authorization T. in the December 22, 2021 letter with the results summarized in your 90-day report, is granted. Upon review, we concur that the data and information submitted in EUA210470/S003 and S004 support the requested update for the iHealth COVID-19 Antigen 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 Antigen Rapid Test re-issued on December 22, 2021.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health