



February 3, 2025

Kaiyu Xiao
Regulatory Affairs Manager
Wondfo USA Co., Ltd.
6720 Cobra Way
San Diego, CA, 92121

Re: EUA240004/S002
Trade/Device Name: WELLlife COVID-19 / Influenza A&B Test
Dated: January 21, 2025
Received: January 21, 2025

Dear Kaiyu Xiao:

This is to notify you that your request to update the WELLlife COVID-19 / Influenza A&B Test to extend the shelf-life expiration date to 10 months when stored at 2°C – 30°C, based on the results of your ongoing stability studies, is granted. In addition, the shelf-life expiration date extension of the external WELLlife COVID-19 / Influenza A&B Test Control Kit, sold separately, to 10 months when stored at 2°C – 30°C is granted based on the results of your ongoing stability studies. Upon review, we concur that the data and information submitted in EUA240004/S002 supports the requested update for the WELLlife COVID-19 / Influenza A&B 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 WELLlife COVID-19 / Influenza A&B Test issued on April 19, 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