



June 13, 2025

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

Re: EUA240004/S003  
Trade/Device Name: WELLlife COVID-19 / Influenza A&B Test  
Dated: April 22, 2025  
Received: April 22, 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 12 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 12 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/S003 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,

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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