Date: 03/05/2025

Shelf-life Extension of the WELLlife COVID-19 / Influenza A&B Test

The purpose of this letter is to inform users of the WELLlife COVID-19 / Influenza A&B Test cassettes (CLA-COVFLAB25) regarding the extension of the current product's expiration date.

As per US FDA Emergency Use Authorization (EUA) requirement, Wondfo USA Co. had submitted the real-time stability data to support the extension of the product's shelf-life. Upon FDA's review, a shelf-life of **10 months**, when the products are stored at 35.6°F – 86°F (2°C— 30°C), has been granted.

Therefore, the lot below will have an expiration date that is **4 months beyond the expiration date printed on the product label**. Please refer to the table below for the new expiration dates:

Expiration Date on Label (WV01409001)	**Extended Expiration Date (10 Month Shelf-life)**
March 2025	July 2025

A letter from the USFDA regarding Shelf-Life Extension is attached for your review and records. If you have any questions/ concerns, please don't hesitate to contact us.

Regards,

Ashish Parikh
Director of Product and Business Development
Clarity Diagnostics LLC
Cell: (224) 360-7669
Email : ashish.parikh@claritydiagnostics.com

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,

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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