Date: 06/10/2022

Shelf-life Extension of the Clarity COVID-19 Antigen Rapid Test Cassettes

The purpose of this letter is to inform users of the Clarity COVID-19 Antigen Rapid Test Cassettes (CLA-COV19AG-VIS) regarding the extension of the current product's expiration date.

As per US FDA Emergency Use Authorization (EUA) requirement, Salofa Oy 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 **21 months**, when the products are stored at 35.6°F – 86°F (2°C— 30°C), has been granted.

Therefore, all products will have an expiration date that is **9 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 (12 Month Shelf-life)	Extended Expiration Date (21 Month Shelf-life)
August 2022	May 2023
September 2022	June 2023
October 2022	July 2023
November 2022	August 2023
December 2022	September 2023
January 2023	October 2023
February 2023	November 2023
March 2023	December 2023

If you have a test kit with an expiry dating that is not mentioned in the above table, please add 9 months to the Expiration Date mentioned on the box and or test pouch to estimate the Extended Expiration Date.

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

June 9, 2022

Christoffer Riska
Vice President Regulatory Affairs, Quality Assurance
Salofa Oy
Örninkatu 15
Salo, Finland 24100

Re: EUA210062/S002
Trade/Device Name: Sienna-Clarity COVID-19 Antigen Rapid Test Cassette
Dated: May 4, 2022
Received: May 4, 2022

Dear Christoffer Riska:

This is to notify you that your request to update the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette to extend the shelf-life expiration date to 21 months, when stored at 2°C – 30°C, based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210062/S002 support the requested update for the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette. 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 Sienna-Clarity COVID-19 Antigen Rapid Test Cassette issued on May 20, 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