



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,

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