July 12, 2021

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

Re: EUA201039/S002
Trade/Device Name: Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test Cassette
Dated: May 19, 2021
Received: May 19, 2021

Dear Christoffer Riska:

This is to notify you that your request to revise the Instructions for Use (IFU) of the Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test Cassette to (1) extend the Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test Cassette reagent shelf-life stability from 3 months to 12 months when stored at 2-8°C and 12 months stored at 27−33°C, and (2) to provide data to extend the transportation stability from 3 months to 12 months after three freeze-thaw cycles, storage at -20°C for 72 hours, and storage at 55°C for 72 hours is granted. Upon review, we concur the information provided in EUA201039/S002 support the requested updates to the IFU for the Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test Cassette. FDA included additional limitations in the IFU of the Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test Cassette related to performance for vaccinated individuals performance with circulating variants and updated the FDA web page link in the Conditions of Authorization for the Laboratory. FDA also updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients to include information related to vaccinated individuals and other edits to reflect language used in more recent authorizations, and updated the Healthcare Provider Fact Sheet for information related to performance with circulating variants. By submitting these revisions 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 COVIBLOCK COVID-19 IgG/IgM Rapid Test Cassette issued on January 5, 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

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