March 29, 2023

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: November 17, 2022
Received: November 17, 2022

Dear Mr. Riska:

This is to notify you that your request to update the authorized labeling of the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette; (1) in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to revise the authorized use(s) as required and described in Appendix A, and make various updates to the authorized labeling as required and described in Appendix B of the letter, and (2) include results of additional reactivity studies, is granted. We also concur with the equivalent updates made to the authorized distributor brand name labeling for; (1) Sienna COVID-19 Antigen Rapid Test Cassette, (2) Clarity COVID-19 Antigen Rapid Test Cassette, (3) OVIOS COVID-19 Antigen Rapid Test Cassette, (4) Spring Health COVID-19 Antigen Rapid Test, and (5) Salocor COVID-19 Antigen Rapid Test Cassette. Upon review, we concur that the information submitted in EUA210062/S002 supports the requested updates for use with the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette and the authorized distributor brand names and fulfills Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022. The Fact Sheet for Healthcare Providers (HCPs) and Fact Sheet for Patients have been updated by FDA consistent with this revision and are included along with this letter.

By submitting this supplemental request for review by the Food and Drug Administration (FDA), you have complied with and fulfilled Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022, and 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.
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