July 12, 2021

Mari Meyer
Vice President, Regulatory and Clinical Affairs, North America
DiaSorin, Inc.
1951 Northwestern Avenue
Stillwater, MN 55082

Re: EUA202960/S001
Trade/Device Name: LIAISON SARS-CoV-2 Ag
Dated: April 22, 2021
Received: April 23, 2021

Dear Mari Meyer:

This is to notify you that your request to update the Instructions for Use (IFU) of the LIAISON SARS-CoV-2 Ag to; (1) include results of the additional cross-reactivity and microbial interference analysis performed using *Staphylococcus aureus* to fulfill Condition of Authorization S. of the March 26, 2021 letter of authorization, (2) include results of interference testing using Sore Throat Phenol Spray , and (3) include the additional storage claim that unopened vials of the inactivation buffer reagent can be stored for up to eight (8) weeks at 15-25 °C, is granted. Upon review, we concur that the data and information submitted in EUA202029/S001 supports the requested updates for use with the LIAISON SARS-CoV-2 Ag. In addition, we concur with the results of the fresh versus frozen study provided as part of Condition of Authorization S. of the March 26, 2021 letter of authorization. FDA have also updated the webpage links in the HCP Fact Sheet. 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 LIAISON SARS-CoV-2 Ag issued on March 26, 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