



October 7, 2021

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

Re: EUA200404/S004
Trade/Device Name: LIAISON SARS-CoV-2 S1/S2 IgG
Dated: June 30, 2021
Received: June 30, 2021

Dear Dr Meyer:

This is to notify you that your request to extend the stability of the LIAISON SARS-CoV-2 S1/S2 IgG to 12 months when stored at 2 -8 °C is granted. Upon review, we concur that the data and information submitted in EUA200404/S004 support the requested updates for the LIAISON SARS-CoV-2 S1/S2 IgG. FDA has updated the Instructions for Use to include limitations related to test performance in vaccinated individuals and performance with circulating variants and to include edits to reflect language used in more recent authorizations, updated the intended use to reflect language used in more recent authorizations, and updated the Healthcare Provider and Recipient Fact Sheets to reflect language used in more recent authorizations. By submitting this information 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 S1/S2 IgG issued on April 24, 2020.

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