March 01, 2022

Kruti Shah
Regulatory Affairs Manager
EUROIMMUN US Inc.
1 Bloomfield Avenue
Mountain Lakes, NJ 07046

Re: EUA210347/S001
Trade/Device Name: EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG)
Dated: February 9, 2022
Received: February 9, 2022

Dear Kruti Shah:

This is to notify you that your request to update the Instructions for Use (IFU) of the EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) to: (1) add minor updates to authorized trade names of the instruments, (2) specify in-use stability of the EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) to 3 months at 2-8°C, (3) remove instrument setting information and add edits for clarification, and (4) remove redundant information and add minor edits to clarify the interference study description, is granted. Upon review, we concur the information provided in EUA210347/S001 supports the requested updates to the IFU. FDA has updated the Healthcare Provider and Patient Fact Sheets to reflect language used in more recent authorizations. By submitting this supplement 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 EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) issued on October 4th, 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