



April 15, 2021

Sarah O. Kalil
SK Consulting
Representing: Quanterix Corporation
900 Middlesex Turnpike, Building 1
Billerica, MA 01821

Re: EUA201648/S001 and EUA201648/S002
Trade/Device Name: Quanterix COVID-19 IgG Antibody Test
Dated: February 6, 2021
Received: February 16, 2021

Dear Sarah Kalil:

This is to notify you that your request to (1) provide electromagnetic compatibility (EMC) testing for the Quanterix HD-X analyzer and (2) provide interference data for biotin and protein, update the Interfering Substances sections of the Instructions for Use (IFU) and include additional limitations regarding biotin and protein interference in the IFU is granted. Upon review, we concur the information provided in EUA201648/S001 regarding the EMC testing is complete and acceptable and that the information submitted in EUA201648/S002 regarding biotin and protein interference testing support the requested updates to the IFU for the Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody Test. Minor modifications were also requested by you and incorporated into the IFU. FDA has included additional limitations in the IFU of the Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody Test related to performance for vaccinated individuals and performance with circulating variants and has updated the Healthcare Provider and Patient Fact Sheets to include information related to vaccinated individuals and updated the Healthcare Provider Fact Sheet for information related to circulating variants. FDA has also made a minor update to the intended use to reflect more recent authorizations.

By submitting this information for review by FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Quanterix COVID-19 IgG Antibody Test issued on December 23, 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