U.S. FOOD & DRUG ADMINISTRATION

April 2, 2021

Laura J. Duggan, Ph.D., RAC
Senior Manager Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
500 GBC Drive, Mailstop 514
P.O. Box 6101
Newark, DE 19714

Re: EUA202112/S001
Trade/Device Name: Dimension EXL SARS-CoV-2 IgG (CV2G) Assay
Dated: February 1, 2021
Received: February 2, 2021

Dear Dr. Duggan:

This is to notify you that your request to update the interference section of the Instructions for Use (IFU) for the Dimension EXL SARS-CoV-2 IgG (CV2G) Assay is granted. Upon review, we concur that the data and information submitted in EUA202112/S001 support the requested updates to the Instructions for Use for the Dimension EXL SARS-CoV-2 IgG (CV2G) Assay. FDA has included additional limitations in the IFU related to performance for vaccinated individuals and performance with circulating variants and added minor updates to the Intended Use, the Instructions for Use and the Healthcare Provider and Patient Fact Sheets for the Dimension EXL SARS-CoV-2 IgG (COV2G) Assay to reflect more recent authorizations. By submitting this supplement for review by FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Dimension EXL SARS-CoV-2 IgG (CV2G) Assay issued on January 8, 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