



August 7, 2020

Laura J. Duggan  
Senior Manager, Regulatory Affairs  
Siemens Healthcare Diagnostics Inc  
Phone: 302-690-3752  
Email: [laura.j.duggan@siemens-healthineers.com](mailto:laura.j.duggan@siemens-healthineers.com)

Re: EUA201460/S001  
Trade/Device Name: Dimension EXL SARS-CoV-2 Total Antibody Assay (CV2T)  
Supplement Dated: July 19, 2020  
Supplement Received: July 19, 2020

Dear Ms. Duggan:

This is to notify you that your request to incorporate changes in the Instructions for Use (IFU) of the Dimension EXL SARS-CoV-2 Total Antibody Assay (CV2T) regarding: (1) extension of onboard stability of unopened reagents from 14 days to 30 days; (2) Extension of the open well stability from 2 days to 3 days; (3) extension of stability of samples from 4 days to 7 days when stored at 2-8°C; (4) extension of calibration frequency from 7 days to 14 days; (5) correction of precision range description; (6) update the precision data generated from 5 days to 20 days; (7) correct typographic errors in slope goal description in the specimen equivalency section and the title of the EP07 document; and (8) addition of a caution section with steps to follow when using software version 10.4.2 to prevent reagent carryover is granted. Upon review, we concur that the data and information submitted in EUA201460/S001 supports the requested updates for use with the Dimension EXL SARS-CoV-2 Total Antibody Assay (CV2T). 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 Dimension EXL SARS-CoV-2 Total Antibody Assay (CV2T) issued on June 8, 2020.

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