October 30, 2020

Laura J. Duggan
Siemens Healthcare Diagnostics
500 GBC Drive
Newark, DE 19714 USA

Re: EUA201460/S002
Device Name (Authorized): Dimension EXL SARS-CoV-2 Total antibody assay (CV2T)
Authorization Date: June 8, 2020
Supplement Received: October 2, 2020

Dear Ms. Laura J. Duggan:

This is to notify you that your request to update the Instructions for Use (IFU) of the Dimension EXL SARS-CoV-2 Total antibody assay (CV2T), to include a limitation, is granted. Upon review, for the Dimension EXL SARS-CoV-2 Total antibody assay (CV2T), we concur with the additional limitation to the IFU: "*A positive result may not indicate previous SARS-CoV-2 infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.*" FDA also made minor updates to the IFU, the Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients to reflect more recent authorizations.

By submitting this revision 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,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
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