August 7, 2020

Laura J. Duggan
Senior Manager, Regulatory Affairs
Siemens Healthcare Diagnostics, Inc
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Re: EUA201459/S001
Trade/Device Name: Dimension Vista SARS-CoV-2 Total Antibody Assay (COV2T)
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 Vista SARS-CoV-2 Total Antibody Assay (COV2T) 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 3.9.2 to prevent reagent carryover is granted. Upon review, we concur that the data and information submitted in EUA201459/S001 supports the requested updates for use with the Dimension Vista SARS-CoV-2 Total Antibody Assay (COV2T). 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 Vista SARS-CoV-2 Total Antibody Assay (COV2T) 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