June 23, 2022

Amy Goldberg
Director, Regulatory Affairs
Siemens Healthineers
511 Benedict Avenue
Tarrytown, NY 10591

Re: EUA210639/S005
Trade/Device Name: CLINITEST Rapid COVID-19 Antigen Self-Test
Dated: March 29, 2022
Received: March 29, 2022

Dear Amy Goldberg:

This is to notify you that your request to update the CLINITEST Rapid COVID-19 Antigen Self-Test Healthcare Provider Instructions for Use (IFU) and the CLINITEST Rapid COVID-19 Antigen Self-Test Quick Reference Instructions (QRI) with the results of your post authorization clinical evaluation study to further evaluate your product in pediatric individuals <14 years of age, performed to fulfill Condition of Authorization X. in the February 9, 2022 letter, is granted. Upon review, we concur that the data and information submitted in EUA210639/S005 support the requested update for the CLINITEST Rapid COVID-19 Antigen Self-Test and fulfill the Condition of Authorization X. of the February 9, 2022 letter. The Food and Drug Administration (FDA) has also updated the web page links in the Fact Sheet for Healthcare Professionals: Siemens Healthineers - CLINITEST Rapid COVID-19 Antigen Self-Test.

By submitting this EUA revision for review by the FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the CLINITEST Rapid COVID-19 Antigen Self-Test re-issued on February 9, 2022.

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

Enclosure