



October 12, 2022

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

Re: EUA10639/S009
Trade/Device Name: CLINITEST Rapid COVID-19 Antigen Self-Test
Dated: September 1, 2022
Received: September 1, 2022

Dear Amy Goldberg:

This is to notify you that your request to update the CLINITEST Rapid COVID-19 Antigen Self-Test to extend the shelf-life expiration date to 24 months when stored at 2°C – 30°C, based on the results of your stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210639/S009 support the requested update for the CLINITEST Rapid COVID-19 Antigen Self-Test. By submitting this EUA 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 CLINITEST Rapid COVID-19 Antigen Self-Test re-issued on February 9, 2022.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of Health Technology 7 (OHT7): Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health