May 3, 2023

Sara Kastrup Shah
Siemens Healthcare Diagnostics Inc.
511 Benedict Ave.
Tarrytown, NY 10591

Re: EUA210568/S003
Trade/Device Name: Atellica IM SARS-CoV-2 Antigen (CoV2Ag)
Dated: November 16, 2022
Received: November 16, 2022

Dear Sara Kastrup Shah:

This is to notify you that your request to update the authorized labeling of the Atellica IM SARS-CoV-2 Antigen (CoV2Ag); (1) in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to revise the authorized use(s) as required and described in Appendix A, and make various updates to the authorized labeling as required and described in Appendix B of the letter, and (2) include results of additional reactivity studies, is granted. Upon review, we concur that the information submitted in EUA210568/S003 supports the requested updates for use with the Atellica IM SARS-CoV-2 Antigen (CoV2Ag) and fulfills Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022. The Fact Sheet for Healthcare Providers (HCPs) and Fact Sheet for Patients have been updated by FDA consistent with this revision and are included along with this letter.

By submitting this supplemental request for review by the Food and Drug Administration (FDA), you have complied with and fulfilled Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022, and complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Atellica IM SARS-CoV-2 Antigen (CoV2Ag) issued on March 11, 2022.

Sincerely yours,

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