U.S. FOOD & DRUG ADMINISTRATION

October 25, 2022

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

Re: EUA210568/S002
Trade/Device Name: Atellica IM SARS-CoV-2 Antigen (CoV2Ag)
Dated: May 24, 2022
Received: May 27, 2022

Dear Ms. Kastrup Shah:

This is to notify you that your request to update the Atellica IM SARS-CoV-2 Antigen (CoV2Ag) EUA with the results of the agreed upon specimen stability study in Siemens Healthineers Sample Inactivation Media conducted to fulfill Condition of Authorization U. from the March 11, 2022, Letter of Authorization, is granted. Upon review, we concur that the data and information submitted in EUA210568/S002 for the Atellica IM SARS-CoV-2 Antigen (CoV2Ag) fulfills Condition of Authorization U. from the March 11, 2022, letter of authorization. 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 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