November 4, 2022

Jumin Oh,
Regulatory Affairs Specialist
Celltrion USA, Inc.
One Evertrust Plaza, Suite 1207
Jersey City, NJ 07302

Re: EUA210501/S014
Trade/Device Name: Celltrion DiaTrust COVID-19 Ag Home Test
Dated: October 20, 2022
Received: October 20, 2022

Dear Jumin Oh:

This is to notify you that your request to update the Celltrion DiaTrust COVID-19 Ag Home Test EUA with the results of the agreed upon clinical study performed to further evaluate the performance of the Celltrion DiaTrust COVID-19 Ag Home Test for the detection of the SARS-CoV-2 omicron variant, conducted to fulfill Condition of Authorization V. from the May 20, 2022, Letter of Authorization, is granted. Upon review, we concur that the data and information submitted in EUA210501/S014 for the Celltrion DiaTrust COVID-19 Ag Home Test fulfills Condition of Authorization V. from the May 20, 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 Celltrion DiaTrust COVID-19 Ag Home Test re-issued on May 20, 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

Cc: Ally Danta, Senior Associate, Parexel International. Correspondent for Celltrion USA, Inc.
Cc: KeeEun Lee, Head of Department of Global Regulatory Affairs, Celltrion, Inc.