August 11, 2022

Bomin Kim,
Team Leader, Global Regulatory Affairs Team
Celltrion USA, Inc.
One Evertrust Plaza, Suite 1207
Jersey City, NJ 07302

Re: EUA210190/S011
Trade/Device Name: Celltrion DiaTrust COVID-19 Ag Rapid Test
Dated: May 30, 2022
Received: May 30, 2022

Dear Bomin Kim:

This is to notify you that your request to offer the Celltrion DiaTrust COVID-19 Ag Rapid Test under the brand name/trade name of Humasis COVID-19 Ag Test, is granted. Upon review, we concur that the information and Humasis COVID-19 Ag Test labeling submitted in EUA210190/S011 is consistent with and supports the requested update. 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 Rapid Test re-issued on May 16, 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, Parexel International. Correspondent for Celltrion USA, Inc.