



March 2, 2023

Ally Danta
Senior Associate
Parexel International
Representing:
Celltrion USA, Inc.
One Evertrust Plaza, Suite 1207
Jersey City, NJ 07302

Re: EUA210501/S012
Trade/Device Name: Celltrion DiaTrust COVID-19 Ag Home Test
Dated: September 19, 2022
Received: September 19, 2022

Dear Ally Danta:

This is to notify you that your request to update the Celltrion DiaTrust COVID-19 Ag Home Test to (1) extend the shelf-life expiration date to 24 months when stored at 2°C – 30°C, based on the results of your completed stability studies, provided to fulfill Condition of Authorization Z in the May 20, 2022 Letter of Authorization, and (2) update the labeling to include minor changes related to the shelf-life expiration dating, is granted. Upon review, we concur that the data and information submitted in EUA210501/S012 support the requested updates for the Celltrion DiaTrust COVID-19 Ag Home Test and fulfill Condition of Authorization Z in the May 20, 2022 letter. 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,

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