March 27, 2023

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

Re: EUA202357/S003
Trade/Device Name: Sampinute COVID-19 Antigen MIA
Dated: November 21, 2022
Received: November 21, 2022

Dear Ally Danta:

This is to notify you that your request to update the authorized labeling of the Sampinute COVID-19 Antigen MIA in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to; (1) revise the authorized use(s) as required and described in Appendix A, and (2) make various updates to the authorized labeling as required and described in Appendix B of the letter, is granted. Upon review, we concur that the information submitted in EUA202357/S003 supports the requested updates for use with the Sampinute COVID-19 Antigen MIA. 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.

Sincerely yours,

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Kristian Roth, Ph.D.
Deputy Director, Division of Microbiology
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Cc: Jumin Oh, Regulatory Affairs Specialist, Global Regulatory Affairs Team, Celltrion USA, Inc.