February 1, 2023

Myriam Battistutta
Head of Regulatory
Ellume Limited
57 Didsbury Street
East Brisbane QLD 4169
Australia

Re: EUA210340/S001
Trade/Device Name: ellume.lab COVID Antigen
Dated: November 15, 2022
Received: November 15, 2022

Dear Myriam Battistutta:

This is to notify you that your request to update the authorized labeling of the ellume.lab COVID Antigen 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 make various updates to the authorized labeling as required and described in Appendix B of the letter, and (2) include the results of additional reactivity studies, is granted. Upon review, we concur that the information submitted in EUA210340/S001 supports the requested updates for use with the ellume.lab COVID Antigen and fulfills Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022. 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, and complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the ellume.lab COVID Antigen issued on July 8, 2021.

Sincerely yours,

Uwe Scherf -S

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