



September 19, 2023

Daniel Hsu
Director of QA/QC/RA
Advin Biotech Inc.
10237 Flanders Ct.
San Diego, CA, 92121

Re: EUA220358/S009
Trade/Device Name: Advin COVID-19 Antigen Test @Home
Dated: September 6, 2023
Received: September 6, 2023

Dear Daniel Hsu:

This is to notify you that your request to extend the product shelf-life claim for the Advin COVID-19 Antigen Test @Home from 12-months to 15-months when stored at 2-30°C, based on the results of your ongoing stability studies, is granted. In addition, we acknowledge the data provided for additional simulated summer and winter unopened kit shipping stability studies. Upon review, we concur that the data and information submitted in EUA220358/S009 supports the requested updates for use with the Advin COVID-19 Antigen Test @Home.

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 Advin COVID-19 Antigen Test @Home issued on December 22, 2022.

Sincerely yours,

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