



June 13, 2022

Han-bum Park  
RA Manager  
GenBody Inc.  
3-18, Eopseong 2-gil, Seobuk-gu, Cheonan-si,  
Chungcheongnam-do, 31077 Republic of Korea

Re: EUA210249/S006  
Trade/Device Name: GenBody COVID-19 Ag  
Dated: May 17, 2022  
Received: May 17, 2022

Dear Han-bum Park:

This is to notify you that your request to update the GenBody COVID-19 Ag test to extend the shelf-life expiration date to 21 months, when stored at 2°C – 30°C, based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210249/S006 support the requested update for the GenBody COVID-19 Ag test. 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 GenBody COVID-19 Ag re-issued on November 17, 2021.

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