



March 15, 2023

Lisa Baumhardt, MS, MJ, MT (ASCP), RAC, FRAPS  
Senior Medical Device Regulatory Expert  
Hyman, Phelps & McNamara, P.C.  
Representing: OSANG LLC  
215 N. Marengo Ave., 3<sup>rd</sup> Floor  
Pasadena, CA 91101

Re: EUA220037/S008  
Trade/Device Name: OHC COVID-19 Antigen Self Test  
Dated: December 9, 2022  
Received: December 9, 2022

Dear Lisa Baumhardt:

This is to notify you that your request to update the OHC COVID-19 Antigen Self Test to extend the shelf-life expiration date to 18 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 EUA220037/S008 support the requested update for the OHC COVID-19 Antigen Self 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 OHC COVID-19 Antigen Self Test issued on April 6, 2022.

Sincerely yours,

---

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

cc: Seungyeob Lee (Dan Lee), OSANG LLC