



October 18, 2024

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., 3rd Floor
Pasadena, CA 91101

Re: EUA230042/S003
Trade/Device Name: OHC COVID-19/Flu Antigen Test Pro
Dated: October 7, 2024
Received: October 7, 2024

Dear Lisa Baumhardt:

This is to notify you that your request to update the OHC COVID-19/Flu Antigen Test Pro¹ to extend the shelf-life expiration date to 18 months when stored at 2°C – 30°C, based on the results of your stability studies, is granted. Upon review, we concur that the data and information submitted in EUA230042/S003 supports the requested update for the OHC COVID-19/Flu Antigen Test Pro. 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/Flu Antigen Test Pro issued on March 21, 2024.

Sincerely yours,

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

¹ Note the shelf-life for the OHC COVID-19/Flu Control Swab Kit was not evaluated as part of this study and remains at 6 months when stored at 2°C – 30°C.
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov