



September 27, 2024

Riazur Rahman, MS
Regulatory Affairs Manager
Healgen Scientific, LLC
3818 Fuqua Street
Houston, TX 77047

Re: EUA240010/S001
Trade/Device Name: Healgen COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab)
Dated: September 9, 2024
Received: September 9, 2024

Dear Riazur Rahman:

This is to notify you that your request to update the Healgen COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab)¹ 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 EUA240010/S001 supports the requested update for the Healgen COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab). 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 Healgen COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) issued on June 10, 2024.

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

¹ Note the shelf-life for the External Controls Healgen COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) was not evaluated as part of this study and remains at 15 months when stored at 2°C – 30°C.