



January 9, 2023

Jonathan Maa
Chief Operating Officer
Maxim Biomedical, Inc.
1500 East Gude Drive, Suite A
Rockville, MD 20850

Re: EUA210663/S008
Trade/Device Name: MaximBio ClearDetect COVID-19 Antigen Home Test
Dated: August 26, 2022
Received: August 26, 2022

Dear Jonathan Maa:

This is to notify you that your request to update the MaximBio ClearDetect COVID-19 Antigen Home Test to extend the shelf-life expiration date to 12 months, when stored at 4°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 EUA210663/S008 support the requested update for the MaximBio ClearDetect COVID-19 Antigen Home 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 MaximBio ClearDetect COVID-19 Antigen Home Test issued on January 19, 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