



October 26, 2023

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

Re: EUA210663/S013
Trade/Device Name: MaximBio ClearDetect COVID-19 Antigen Home Test
Dated: September 29, 2023
Received: September 29, 2023

Dear Jessica 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 24 months, when stored at 4°C – 30°C, based on the results of your stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210663/S013 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
Office of Product Evaluation and Quality
Center for Devices and Radiological Health