



July 5, 2023

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

Re: EUA210663/S012  
Trade/Device Name: MaximBio ClearDetect COVID-19 Antigen Home Test  
Dated: May 26, 2023  
Received: May 26, 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 18 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/S012 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,

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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