March 30, 2022

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

Re: EUA210663/S005
Trade/Device MaximBio ClearDetect COVID-19 Antigen Home Test
Dated: March 18, 2022
Received: March 18, 2022

Dear Johnathan Maa:

This is to notify you that your request to update the MaximBio ClearDetect COVID-19 Antigen Home Test, to include an alternative swab for use with your test, is granted. Upon review, we concur that the data and information submitted in EUA210663/S005 support the requested updates 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