July 8, 2024

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

Re: EUA210663/S014
Trade/Device Name: MaximBio ClearDetect COVID-19 Antigen Home Test
Dated: June 5, 2024
Received: June 5, 2024

Dear Jessica Maa:

This is to notify you that your request to update the MaximBio ClearDetect COVID-19 Antigen Home Test to; (1) update the formatting of the outer package label to improve readability, (2) provide an optional instruction video to improve accessibility, (3) update the MaximBio website to include a link to the optional web-based reporting mechanism, and (4) add a QR code to the outer package label to facilitate access to the instruction video and to the web-based reporting mechanism, is granted. Upon review, we concur that the information submitted in EUA210663/S014 supports the requested updates for use with 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