March 21, 2023

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

Re: EUA210663/S010
Trade/Device Name: MaximBio ClearDetect COVID-19 Antigen Home Test
Dated: January 11, 2023
Received: January 11, 2023

Dear Jonathan Maa:

This is to notify you that your request to update authorized labeling of the MaximBio ClearDetect COVID-19 Antigen Home Test to include details of an optional web-based reporting mechanism to address Condition of Authorization S. in the January 19, 2022 Letter of Authorization, is granted. Upon review, we concur that the information submitted in EUA210663/S010 support the requested updates for the MaximBio ClearDetect COVID-19 Antigen Home Test and fulfill Condition of Authorization S. in the January 19, 2022 letter. 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,

_____

Kristian Roth, Ph.D.
Deputy Director, Division of Microbiology
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health