March 9, 2022

Leslie Musho, Director of Regulatory Affairs and Quality
o/b/o Megna Health Inc.
436 Creamery Way, Suite 200,
Exton, PA 19341 USA

Re: EUA200308-S003
Trade/Device Name: Rapid COVID-19 IgM/IgG Combo Test Kit
Dated: December 08, 2021
Received: December 09, 2021

Dear Leslie Musho:

This is to notify you that your request to (1) update the Rapid COVID-19 IgM/IgG Combo Test Kit authorized labelling (the Instructions for Use (IFU) and Healthcare Provider Fact Sheet) in response to Condition of Authorization (1) in the Viral Mutation Revision Letter dated September 23, 2021, and (2) update the IFU to reflect the correct the antigen targets used in the test validation and update the clinical performance estimates accordingly, is granted. Upon review, we concur that the information provided in EUA200308-S003 supports the requested updates to the authorized labelling for Rapid COVID-19 IgM/IgG Combo Test Kit. FDA has also updated the Factsheet for Healthcare Providers to be consistent with more recent authorizations. By submitting this supplement for review by the FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Rapid COVID-19 IgM/IgG Combo Test Kit reissued on April 22, 2021, and the Viral Mutation Revision Letter issued on September 23, 2021.

Sincerely yours,

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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