U.S. FOOD & DRUG ADMINISTRATION

May 3, 2023

Sharmini Muralitharan, PhD., RAC
Director Regulatory Affairs
Qorvo Biotechnologies, LLC
14505 21st Ave, Suite 212
Plymouth, MN 55447

Re: EUA203121/S004
Trade/Device Name: Omnia SARS-CoV-2 Antigen Test
Dated: December 28, 2022
Received: December 28, 2022

Dear Dr. Muralitharan:

This is to notify you that your request to update the Omnia SARS-CoV-2 Antigen Test to extend the shelf-life expiration date to 12 months when stored at 2°C – 8°C, based on the results of your completed stability studies, is granted*. Upon review, we concur that the data and information submitted in EUA203121/S004 support the requested update for the Omnia SARS-CoV-2 Antigen 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 Omnia SARS-CoV-2 Antigen Test reissued on July 29, 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

* The granted shelf-life extension does not apply to the Qorvo Omnia SARS-CoV-2 Antigen Positive Control, which is sold separately from the Omnia SARS-CoV-2 Antigen Test.