July 28, 2022

Sally McFall, PhD
Chief Scientific Officer
Minute Molecular Diagnostics, Inc.
1800 Sherman Avenue, Suite 504
Evanston, IL 60201

Re: EUA210603/S001
Trade/Device Name: DASH SARS-CoV-2/S Test
Dated: April 26, 2022
Received: April 26, 2022

Dear Dr. McFall:

This is to notify you that your request to; (1) update the Instructions for Use and Quick Reference Guide of the DASH SARS-CoV-2/S Test to indicate that direct anterior nasal swab specimens are stable when stored at room temperature (15-30°C) for up to 48 hours until testing is performed on a Minute Molecular Diagnostics DASH analyzer, and (2) update the DASH SARS-CoV-2/S Test submission with Flex study data and information to fulfill Condition of Authorization Q. from the March 15, 2022 Letter of Authorization, is granted. Upon review, we concur that the data and information submitted in EUA210603/S001 supports the requested updates for use with the DASH SARS-CoV-2/S Test and fulfills Condition of Authorization Q. from the March 15, 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 DASH SARS-CoV-2/S Test issued on March 15, 2022.

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