U.S. FOOD & DRUG ADMINISTRATION

May 18, 2023

Hina Patel
Director, Regulatory Affairs
QIAGEN GmbH
19300 Germantown Road,
Germantown Road, MD 20874

Re: EUA210230/S002
Trade/Device Name: QIAreach SARS-CoV-2 Antigen Test
Dated: November 16, 2022
Received: November 16, 2022

Dear Hina Patel:

This is to notify you that your request to update the authorized labeling of the QIAreach SARS-CoV-2 Antigen Test in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to; (1) revise the authorized use(s) as required and described in Appendix A, and (2) make various updates to the authorized labeling as required and described in Appendix B of the letter, is granted. Upon review, we concur that the information submitted in EUA210230/S002 supports the requested updates for use with the QIAreach SARS-CoV-2 Antigen Test. The Fact Sheet for Healthcare Providers (HCPs) and Fact Sheet for Patients have been updated by FDA consistent with this revision and are included along with this letter. By submitting this supplemental request for review by the Food and Drug Administration (FDA), you have complied with and fulfilled Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022.

Sincerely yours,

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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