U.S. FOOD & DRUG ADMINISTRATION

February 28, 2022

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

Re: EUA202424/S001
Trade/Device Name: QIAreach Anti-SARS-CoV-2 Total Test
Dated: December 09, 2021
Received: December 09, 2021

Dear Hina Patel:

This is to notify you that your request to **1)** extend the shelf-life stability of the QIAreach Anti-SARS-CoV-2 Total Test to 12 months when stored at 2-30°C, and **2)** provide additional electromagnetic compatibility (EMC) testing data for the QIAreach eHub, is granted. Upon review, we concur that the data and the information provided in EUA202424/S001 support the requested updates. FDA has updated the IFU, Healthcare Provider and Patient Fact Sheets to reflect language used in more recent authorizations. By submitting this supplement for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization S and T stated in the letter authorizing the emergency use of the QIAreach Anti-SARS-CoV-2 Total Test issued on May 11, 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