September 14, 2020

Nischay Mishra, Ph.D.
Assistant Professor, Center for Infection and Immunity
Columbia University Laboratory of Personalized Genomic Medicine
630 W 168th Street, VP&S11-453.
New York, NY, 10032

Re: EUA200510/S001
Trade/Device Name: Triplex CII-SARS-CoV-2 rRT-PCR Test
Dated: August 5, 2020
Received: August 5, 2020

Dear Dr. Mishra:

This is to notify you that your request to update the Instructions for Use (IFU) of the Triplex CII-SARS-CoV-2 rRT-PCR Test to add the QIAcube HT automated extraction system to the list of authorized extraction methods is granted. Upon review, we concur that the data and information submitted in EUA200510/S001 supports the requested updates for use with the Triplex CII-SARS-CoV-2 rRT-PCR Test. FDA also requested some minor updates to the intended use to reflect more recent authorizations and reporting recommendations. 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 March 31, 2020 Letter Of Authorization for Molecular-based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2 (Molecular LDT COVID-19 Authorized Test), for which the Triplex CII-SARS-CoV-2 rRT-PCR Test was added to Appendix A as an authorized test on May 12, 2020

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