U.S. FOOD & DRUG ADMINISTRATION

May 12, 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 U.S.

Re: EUA200510
Trade/Device Name: Triplex CII-SARS-CoV-2 rRT-PCR Test
Laboratory: Columbia University Laboratory of Personalized Genomic Medicine

Dated: April 23, 2020
Received: April 29, 2020

Dear Dr. Mishra:
This letter is in response to your request that the Food and Drug Administration (FDA) add your test as an authorized test to the March 31, 2020 Emergency Use Authorization (EUA), pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). We have reviewed the EUA submission package and determined that your test meets the criteria for issuance under section 564(c) of the Act because your test is eligible for authorization under the March 31, 2020 EUA for Molecular-based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2 (Molecular LDT COVID-19 Authorized Test). As such, your test is hereby added to Appendix A[1] as an authorized test.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am adding this test to Appendix A as an authorized test, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of the attached letter of authorization[2] for use by the authorized laboratory to detect SARS-CoV-2 in specimens collected from individuals suspected of COVID-19 by their healthcare provider. Accordingly, in addition to this letter, you will receive copies of the FDA Letter of Authorization and the authorized Healthcare Provider and Patient Fact Sheets that must be used in conjunction with your authorized test pursuant to the Conditions of Authorization (Section IV) of the Letter of Authorization.

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

[1] Appendix A is available at, https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations.
[2] The Letter of Authorization is available at, https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations.