March 29, 2021

Bethany Hills, Partner
Morrison & Foerster
Representing: BGI Genomics Co. Ltd.
250 West 55th Street,
New York, NY 10019

Re: EUA200034/S004
Trade/Device Name: Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2
Dated: February 18, 2021
Received: February 19, 2021

Dear Ms. Hills:

This is to notify you that your request to update the Instructions for Use (IFU) of the Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 to include appendices with RUO instrument qualification protocol and RUO label, is granted. Upon review, we concur that the information submitted in EUA200034/S004 supports the requested updates for use with the Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2. In addition, FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect more recent authorizations. 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 Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 reissued on January 28, 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