



April 24, 2020

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

Re: EUA200034/A001
Trade/Device Name: Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2
Dated: April 13, 2020
Received: April 17, 2020

Dear Ms. Hills:

This is to notify you that your request to update the Instructions for Use (IFU) labeling for the Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV to; (1) revise the name of the device to Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2, (2) add the MGIEasy Nucleic Acid Extraction Kit for specimen processing, including the option for automation using the MGISP-960RS High-throughput Automated Sample Preparation System, (3) add additional Real-Time PCR instruments, Applied Biosystems 7500 Fast Real-Time PCR System, QuantStudio 5 Real-Time PCR System and the LightCycler 480 System, (4) add nasopharyngeal swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal washes, nasal aspirates to the intended use and associated limitation, (5) correct grammatical and typographical errors and (5) include other minor edits in the IFU for clarification, is granted. Upon review, we concur that the data and information submitted in EUA200034/A001 supports the requested updates for use with the Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2 (updated device name). We also concur with the associated updates made to the Healthcare Provider and Patient Fact Sheets and device labels. By submitting this amendment 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 (updated device name) issued on March 26, 2020.

Sincerely yours,

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