August 3, 2020

Brian Yang
Chief Executive Officer
Beijing Tongze Medical Technology Co. Ltd.
Representing: Biohit Healthcare (Hefei) Co. Ltd.
Suite 0617, 6th Floor, Building 1 Guoyingyuan
Xicheng District
Beijing, 100035 China

Re: EUA200192/S001
Trade/Device Name: Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit
Dated: June 29, 2020
Received: June 29, 2020

Dear Mr. Yang:

This is to notify you that your request pertaining to revise the distribution list for three additional authorized distributors e.g., MP Biomedicals Diagnostics Division, ADS Biotec Inc, and Avrio Genetics to market the Biohit Healthcare (Hefei) Co. Ltd.'s EUA authorized Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit (EUA200192) is granted. Further, your request to update the Instructions for Use (IFU) of the Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit to reflect the availability of external controls with separate labeling per Condition "Y" of the June 18, 2020 Letter of Authorization is also granted. Upon review, we concur that the data and information submitted in EUA200192/S001 supports the requested updates for use with the Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit. By submitting these revisions 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 Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit issued on June 18, 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