July 22, 2020

Tim Hodge
Director of Operations
UTMG Pathology, LLC
930 Madison Avenue, Suite 500
Memphis, TN 38163

Re: EUA200338/A002
Trade/Device Name: UTHSC/UCH SARS-CoV-2-RT-PCR Assay
Dated: June 10, 2020
Received: June 10, 2020

Dear Mr. Hodge:

This is to notify you that your request to update the UTHSC/UCH SARS-CoV-2-RT-PCR Assay to include a laboratory developed viral RNA extraction protocol in combination with the Applied Biosystems 7900HT Real-Time PCR Thermocycler to generate an additional high-throughput testing option, is granted. Upon review, we concur that the data and information submitted in EUA200338/A002 supports the requested updates for use with the UTHSC/UCH SARS-CoV-2-RT-PCR Assay. FDA concurs with the additional laboratory instructions for use "UTHSC/UCH SARS-CoV-2 RT-PCR Assay Instructions for Use – High Throughput Option" and the associated updates to the EUA summary to include additional analytical and clinical performance data. FDA also requested some minor updates to the original laboratory UTHSC/UCH SARS-CoV-2 RT-PCR Assay - Instructions For Use protocol and concur with the final updated authorized labeling. By submitting this amendment for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in 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), for which the UTHSC/UCH SARS-CoV-2-RT-PCR Assay was added to Appendix A as an authorized test on May 3, 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

----------INTERNAL ONLY – DELETE PRIOR TO SIGNING LETTER----------

Final Amendment Package Review and Concurrence Table	
DMD EUA Team Lead	07/21/2020 – Kim Sapsford (DMD/OHT7-OIR/OPEQ/CDRH): Reviewed, concurred and prepared the final amendment package for Division. Note: requested changes are covered under Conditions M and N in the EUA Letter of Authorization - Laboratories Who Have Developed a Molecular-Based Test (LDTs) for Coronavirus Disease 2019 (COVID-19)
Branch Review/Concurrence	N/A - LDT submissions go straight to Division Review.
Division Review Review/Concurrence	07/22/2020 – Uwe Scherf (DMD/OHT7-OIR/OPEQ/CDRH)
Office of Counter Terrorism and Emerging Threats (OCET)/OCS/OC Review/Concurrence	N/A

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