June 1, 2020

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

Re: EUA200387/A001
Trade/Device Name: UTHSC/UCH SARS-CoV-2-RT-PCR Assay
Dated: May 21, 2020
Received: May 21, 2020

Dear Mr. Hodge:

This is to notify you that your request to update the Instructions for Use (IFU) of the UTHSC/UCH SARS-CoV-2-RT-PCR Assay to; (1) remove the Trizol/Chloroform for the RNA viral inactivation and replace with a heat inactivation methodology, at 56^{o}C for 30 minutes, and (2) make some minor edits and clarifications, is granted. Upon review, we concur that the data and information submitted in EUA200338/A001 supports the requested updates for use with the UTHSC/UCH SARS-CoV-2-RT-PCR Assay. FDA also made some minor updates to the EUA Summary. 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 1, 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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov