March 22, 2023

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

Re: EUA200338/S005 and EUA200338/S006
Trade/Device Name: UTHSC/UCH SARS-CoV-2-RT-PCR Assay
Dated: December 17, 2021 and January 26, 2022
Received: December 17, 2021 and January 26, 2022

Dear Mr. Hodge:

This is to notify you that your request to update the EUA Summary and the laboratory SOP of the UTHSC/UCH SARS-CoV-2-RT-PCR Assay to; (1) update the Limitations section to fulfill Conditions of Authorization included in the September 23, 2021 Viral Mutation Revision Letter, and (2) allow additional reagent options for your authorized primer set, is granted. Upon review, we concur that the data and information submitted in EUA200338/S005 and EUA200338/S006 supports the requested updates for use with the UTHSC/UCH SARS-CoV-2-RT-PCR Assay. 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 reissued letter authorizing the emergency use of the UTHSC/UCH SARS-CoV-2-RT-PCR Assay issued on November 15, 2021.

Sincerely yours,

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Kristian Roth, Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health