



June 14, 2023

Rachel Lee, Ph.D.
Microbiological Sciences Branch Manager
Texas Department of State Health Services, Laboratory Services Section
1100 W. 49th Street
Austin, TX 78756

Re: EUA200536/S002
Trade/Device Name: Texas Department of State Health Services (DSHS) SARS-CoV-2 Assay
Dated: October 26, 2020
Received: October 26, 2020

Dear Dr. Lee:

This is to notify you that your request to update the EUA Summary of the Texas Department of State Health Services (DSHS) SARS-CoV-2 Assay to; (1) include additional clinical performance data testing real clinical specimens, collected to fulfill Condition S. of the August 21, 2020, letter of authorization, (2) remove clinical performance data that resulted from testing contrived samples, given the new clinical performance data provided, and (3) provide minor edits, is granted. Upon review, we concur that the data and information submitted in EUA200536/S002 supports the requested updates for use with the Texas Department of State Health Services (DSHS) SARS-CoV-2. 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 letter authorizing the emergency use of the Texas Department of State Health Services (DSHS) SARS-CoV-2 Assay issued on August 21, 2020.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health