



March 30, 2020

Wendi Kuhnert-Tallman, Ph.D.
Associate Deputy Incident Manager
CDC 2019-nCoV Response
Centers for Disease Control And Prevention (CDC)
1600 Clifton Road NE,
Atlanta, GA 30333 US

Re: EUA200001/A002
Trade/Device Name: CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR
Diagnostic Panel
Dated: March 27, 2020
Received: March 28, 2020

Dear Dr. Kuhnert-Tallman:

This is to notify you that your request to update the Instructions for Use (IFU) of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel to; (1) add the acceptable RT-PCR master mix options - Quantabio qScript XLT One-Step RT-qPCR ToughMix, Quantabio UltraPlex 1-Step ToughMix (4X), and Promega GoTaq Probe 1- Step RT-qPCR System, and (2) add two minor clarifications, has been granted. Upon review, we concur that the data submitted in EUA200001/A002 supports the additional enzyme master mixes for use with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. We also concur with the related updates of the Instructions for Use for the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel that reflect the requested updates. By submitting this amendment 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 CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel re-issued on March 15, 2020.

Sincerely yours,

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