June 12, 2020

Wendi Kuhnert-Tallman, Ph.D.
EOC Laboratory Task Force Lead
CDC COVID-19 Response
Centers for Disease Control and Prevention
1600 Clifton Rd. NE, MS H24-12
Atlanta, GA 30333

Re: EUA200001/A003
Trade/Device Name: CDC 2019 Novel Coronavirus (nCoV) Real-Time RT-PCR Diagnostic Panel
Dated: May 3, 2020
Received: May 3, 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 MagNA Pure 24 as an authorized extraction option for use with the test, (2) add alternative Roche external Lysis buffer product options, (3) add an alternative QIAGEN Buffer AVL product, (4) add a heat treatment method when used in combination with the Quantabio UltraPlex 1-Step ToughMix (4X) enzyme mix as an alternative to extraction in certain situations, and (5) make minor clarifications and corrections, is granted. Upon review, we concur that the data and information submitted in EUA200001/A003 supports the requested updates for use with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. FDA have also updated the Healthcare Provider and Patient Fact Sheets. 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,

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Uwe Scherf, M.Sc., Ph.D.
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