



July 13, 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/A004
Trade/Device Name: CDC 2019 Novel Coronavirus (nCoV) Real-Time RT-PCR Diagnostic Panel
Dated: July 3, 2020
Received: July 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 the Promega Maxwell RSC 48 as an authorized extraction option for use with the test, and (2) update of in silico inclusivity analysis summary, is granted. Upon review, we concur that the data and information submitted in EUA200001/A004 supports the requested updates for use with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. 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
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health