January 8, 2021

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

Re: EUA201781/S003
Trade/Device Name: Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay
Dated: December 30, 2020
Received: December 30, 2020

Dear Dr. Kuhnert-Tallman:

This is to notify you that your request to update the Instructions for Use (IFU) of the Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay to; (1) add the Maxwell RSC Viral Total Nucleic Acid Purification Kit used with either the Maxwell CSC 48 or Maxwell RSC 48 Instruments as an authorized extraction option for use with the test, (2) to offer an additional Influenza SARS-CoV-2 Multiplex Assay Primers and Probes Kit and (3) minor updates and other general clarifications, is granted. FDA also concur with the updated manufacturer information for SC2PC reagent used with the Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay. Upon review, we concur that the data and information submitted in EUA201781/S003 supports the requested updates for use with the Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay. FDA made minor updates to the IFU to reflect more recent reporting requirements for 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 Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay issued on July 2, 2020.

Sincerely yours,

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