November 20, 2020

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/S002
Trade/Device Name: Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay
Dated: October 31, 2020
Received: November 2, 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 Roche MagNA Pure Compact, QIAGEN QIAcube HT, ThermoFisher KingFisher Flex Purification System, and bioMérieux NucliSENS easyMAG extraction methods as authorized extraction options for use with the test, (2) to offer the Influenza SARS-CoV-2 Multiplex Assay reagents either as the original full kit (Catalog # Flu-SC2-EUA) or split into two separate kits: one that contains the primers and probes entitled Influenza SARS-CoV-2 Multiplex Assay Primer and Probe Kit (Catalog # Flu-SC2PP-EUA) and one that contains the positive controls entitled Influenza SARS-CoV-2 Multiplex Assay Positive Controls Kit (Catalog # Flu-SC2PC-EUA), and (3) minor updates to advise use of the JOE filter instead of the VIC filter when using the alternative filter calibrations option and other general clarifications, is granted. Upon review, we concur that the data and information submitted in EUA201781/S002 supports the requested updates for use with the Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay. 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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