



July 25, 2025

Melissa Ivey
Regulatory Affairs Specialist,
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd,
Atlanta, GA 30329

Re: EUA140003/S001

Trade/Device Name: CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A(H7) [Eurasian Lineage] Assay

Dated: April 21, 2025

Received: April 21, 2025

Dear Melissa Ivey:

This is to notify you that your request is granted to update the authorized labeling of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A(H7) [Eurasian Lineage] Assay to; (1) add QIAGEN as a qualified manufacturer of the kit reagents, (2) update the positive control material, (3) remove the Roche MagNA Pure LC platform as an authorized nucleic acid extraction method, and (4) update the analytical reactivity (inclusivity) to include an *in-silico* analysis summary. Upon review, we concur that the data and information submitted in EUA140003/S001 supports the requested updates for use with the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A(H7) [Eurasian Lineage] Assay. We also concur with the updates made to the Healthcare Provider and Patient Fact Sheets to reflect more recent information and for consistency with more recent authorizations. 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 CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A(H7) [Eurasian Lineage] Assay reissued on March 27, 2018.

Sincerely yours,

Joseph Briggs, M.Sc., Ph.D.,
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health