October 20, 2026

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/S002
Trade/Device Name: CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A(H7) [Eurasian Lineage] Assay
Dated: July 2, 2026
Received: July 2, 2026

Dear Melissa Ivey:

This is to notify you that your request to update the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A(H7) [Eurasian Lineage] Assay to extend the shelf-life expiration date of the kit to January 9, 2028 for Lot# 241201 when stored at - 20°C, is granted. Upon review, we concur that the data and information submitted in EUA140003/S002 supports the requested update for the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A(H7) [Eurasian Lineage] 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 CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A(H7) [Eurasian Lineage] Assay reissued on March 27, 2018.

Sincerely yours,

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Joseph Briggs, 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