November 22, 2024

Michael J. Wagner, Esq.
Senior Corporate Counsel
Quest Diagnostics Nichols Institute ("Quest Diagnostics")
33608 Ortega Highway
San Juan Capistrano, CA 92675

Re: EUA220415/S003
Trade/Device Name: Quest Diagnostics Mpox Virus Qualitative Real-Time PCR (2-well) Assay
Dated: September 06, 2024
Received: September 06, 2024

Dear Mr. Wagner:

This is to notify you that your request is granted to update the authorized labelling of the Quest Diagnostics Mpox Virus Qualitative Real-Time PCR (2-well) Assay to update language regarding *Orthopoxvirus* infections and include other minor updates. Upon review, we concur that the information submitted in EUA220415/S003 supports the requested updates for use with the Quest Diagnostics Mpox Virus Qualitative Real-Time PCR (2-well) Assay. FDA have updated the Healthcare Provider and Patient Fact Sheets to reflect 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 Quest Diagnostics Mpox Virus Qualitative Real-Time PCR (2-well) Assay re-issued on May 22, 2023.

Sincerely yours,

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Noel J. Gerald, 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