December 9, 2022

Michael J. Wagner, Esq.
Senior Corporate Counsel
Quest Diagnostics Incorporated
33608 Ortega Highway
San Juan Capistrano, CA 92675

Re: EUA220415/S001
Trade/Device Name: Quest Diagnostics Monkeypox Virus Qualitative Real-Time PCR
Dated: October 20, 2022
Received: October 21, 2022

Dear Mr. Wagner:

This is to notify you that your request to update the authorized labeling of the Quest Diagnostics Monkeypox Virus Qualitative Real-Time PCR to; (1) include a specimen stability claim of 24 hours at 18-23°C, 7 days at 2-8°C, 30 days at -20°C, and up to three freeze/thaw cycles at -20°C for lesion swab specimens collected in universal viral transport media (UTM) based on data from a specimen stability study performed to fulfill Condition of Authorization O. in the September 7, 2022 Letter of Authorization, (2) add use of leftover deidentified positive patient specimens as an acceptable positive control material, and (3) make some minor edits for clarification, is granted. Upon review, we concur that the data and information submitted in EUA220415/S001 supports the requested updates for use with the Quest Diagnostics Monkeypox Virus Qualitative Real-Time PCR and fulfills Condition of Authorization O. in the September 7, 2022, letter. 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 Monkeypox Virus Qualitative Real-Time PCR issued on September 7, 2022.

Sincerely yours,

_____

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