July 18, 2023

Stacy Ferguson,
Molecular Diagnostics
Abbott Molecular, Inc.
1300 E Touhy Ave,
Des Plaines, IL 60018

Re: EUA220434/S002
Trade/Device Name: Alinity m MPXV
Dated: April 06, 2023
Received: April 06, 2023

Dear Ms. Ferguson:

This is to notify you that your request to update the authorized labeling of the Alinity m MPXV to (**1**) include data from a clinical validation study evaluating natural clinical lesion swab specimens in viral transport media (VTM) to fulfill Condition of Authorization W listed in the October 7, 2022 Letter of Authorization, and (**2**) provide minor updates, is granted. Upon review, we concur that the data and information submitted in EUA220434/S002 supports the requested updates for use with the Alinity m MPXV AMP Kit Package Insert and fulfills Condition of Authorization W listed in the October 7, 2022, Letter of Authorization. FDA has also updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in 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 Alinity m MPXV issued on October 7, 2022.

Sincerely yours,

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