December 14, 2022

Michael Lynch
Manager, Regulatory Affairs
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588

Re: EUA220459/S001
Trade/Device Name: cobas MPXV for use on the cobas 6800/8800 Systems (cobas MPXV)
Dated: November 29, 2022
Received: November 29, 2022

Dear Mr. Lynch:

This is to notify you that your request to update the cobas MPXV for use on the cobas 6800/8800 Systems (cobas MPXV) Emergency Use Authorization to include information concerning Roche Molecular Systems, Inc.'s current quality system, provided to fulfill Condition of Authorization V. in the November 15, 2022, Letter of Authorization, is granted. Upon review, we concur that the information submitted in EUA220459/S001 fulfills Condition of Authorization V. in the November 15, 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 cobas MPXV for use on the cobas 6800/8800 Systems (cobas MPXV) issued on November 15, 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