



October 24, 2024

Tabitha Jackson  
Senior Regulatory Affairs Manager  
Roche Molecular Systems, Inc.  
4300 Hacienda Drive  
Pleasanton, CA 94588

Re: EUA220459/S002

Trade/Device Name: cobas MPXV for use on the cobas 6800/8800 Systems (cobas MPXV)

Dated: September 27, 2024

Received: September 27, 2024

Dear Tabitha Jackson:

This is to notify you that your request to update the cobas MPXV Emergency Use Authorization to: (1) update the cobas MPXV Assay Specific Analysis Package (ASAP) to cobas MPXV ASAP v12.2.0, and (2) update the cobas MPXV Instructions for Use to include the current list of authorized distributors, is granted. Upon review, we concur that the data and information provided in EUA220459/S002 supports the requested updates to the authorized labelling for cobas MPXV for use on the cobas 6800/8800 Systems (cobas MPXV). By submitting this supplement for review by the 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,

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Noel J. Gerald, Ph.D.

Deputy 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