



September 8, 2025

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

Re: EUA220459/S003

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

Dated: May 14, 2025

Received: May 14, 2025

Dear Tabitha Jackson:

This is to notify you that your request to update the cobas MPXV for use on the cobas 6800/8800 Systems (cobas MPXV) to extend the shelf-life expiration date to 24 months when stored at 2-8°C, is granted. Upon review, we concur that the data and information provided in EUA220459/S003 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,

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