October 26, 2022

Khushvanreep Singh M.S.
Regulatory Affairs Specialist
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588

Re: EUA201779/S010/A001
Trade/Device Name: cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System
Dated: July 12, 2022 and August 4, 2022
Received: July 13, 2022 and August 4, 2022

Dear Khushvanreep Singh:

This is to notify you that your request to extend the shelf life for the cobas SARS-CoV-2 & Influenza A/B and cobas SARS-CoV-2 & Influenza A/B Quality Control Kit reagents to 18 months at 2-8°C, based on the results of a real-time stability study preformed to fulfill Condition of Authorization Q in the September 14, 2020 Letter of Authorization, is granted. Upon review, we concur that the data and information submitted in EUA201779/S010/A001 support the requested updates for the cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System and fulfills Condition of Authorization Q in the September 14, 2020 Letter of Authorization. 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 SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System issued on September 14, 2020.

Sincerely yours,

_____

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