February 16, 2023

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

Re: EUA201779/S012
Trade/Device Name: cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System
Dated: February 03, 2023
Received: February 06, 2023

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 24 months at 2-8°C, based on the results of a real-time stability study performed 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/S012 supports the requested updates for use with 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. FDA has 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 cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System issued on September 14, 2020.

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