June 24, 2021

Kaitlyn Hameister
Senior Regulatory Affairs Specialist 1
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588

Re: EUA201779/S005
Trade/Device Name: cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System
Dated: April 20, 2021
Received: May 5, 2021

Dear Kaitlyn Hameister:

This is to notify you that your request to implement an assay script software update to address performance issues for the cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System is granted. Upon review, we concur that the data and information submitted in EUA201779/S005 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. FDA has updated the Healthcare Provider and Patient Fact Sheets 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 and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health