January 6, 2022

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

Re: EUA201779/S008
Trade/Device Name: cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System
Dated: November 12, 2021
Received: November 15, 2021

Dear Ms. Hameister:

This is to notify you that your request to update the Instructions for Use (IFU) of the cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System to; (1) include additional clinical performance data collected to fulfill Condition P. of the September 14, 2020 letter, (2) remove references to the outdated software version 3.2, (3) add variant language in accordance with the Conditions of Authorization included in the September 23, 2021 Viral Mutation Revision Letter, and (4) include minor edits, is granted. Upon review, we concur that the data and information submitted in EUA201779/S008 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. 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