



September 18, 2020

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

Re: EUA201779/S001

Trade/Device Name: cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System

Dated: September 14, 2020

Received: September 15, 2020

Dear Ms. Hameister:

This is to notify you that your request to update the cobas Liat System software of the cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System from version 3.2.0 to version 3.3, is granted. Upon review, we concur that the data and information submitted in EUA201779/S001 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. We also concur with the associated updates made to the Quick Reference Instructions to update images throughout to reflect the new graphics/user interface with the new software version. 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 and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health