December 10, 2020

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

Re: EUA201779/S003
Trade/Device Name: cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test
Dated: October 1, 2020
Received: October 2, 2020

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 with minor revisions, as well as to include testing of specimens collected in; (1) 0.9% physiological saline solution, (2) Copan Universal Transport Medium without beads, and (3) Thermo Fisher Scientific Remel tube without beads, is granted. Upon review, we concur that the data and information submitted in EUA201779/S003 supports the requested updates for use with the cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test. 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 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