December 15, 2020

Rita Hoady, MS, RAC, CCRA
Senior Manager, Regulatory Affairs
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588-0900, US

Re: EUA202635/S002
Trade/Device Name: cobas SARS-CoV-2 & Influenza A/B Assay
Dated: December 9, 2020
Received: December 9, 2020

Dear Ms. Hoady:

This is to notify you that your request to update the Instructions for Use (IFU) of the cobas SARS-CoV-2 & Influenza A/B Assay to; (1) include a new warning/limitation statement further addressing the potential risk of erroneous influenza results when using the EUA authorized cobas SARS-CoV-2 & Influenza A/B for use on the cobas 6800/8800 Systems, and (2) correct the performance data table for the internal precision study, is granted. Upon review, we concur that the data and information submitted in EUA202635/S002 supports the requested updates for use with the cobas SARS-CoV-2 & Influenza A/B Assay. We also concur with the associated updates made to the Healthcare Provider Fact Sheet. 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 Assay issued on September 3, 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