June 8, 2021

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

Re: EUA202635/S003
Trade/Device Name: cobas SARS-CoV-2 & Influenza A/B
Dated: May 19, 2021
Received: May 20, 2021

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 to: (1) include the additional prospective clinical study data supporting the testing of clinical samples for influenza A and influenza B in the intended use population per Condition P in the EUA LOA dated 9/30/2020 and (2) add relevant regulatory warnings to the product information card, is granted. Upon review, we concur that the data and information submitted in EUA202635/S003 supports the requested updates for use with the cobas SARS-CoV-2 & Influenza A/B. 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 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