August 11, 2022

Aradhana Karthikeyan
Manager, Regulatory Affairs
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588

Re: EUA210388/S003
Trade/Device Name: cobas SARS-COV-2 Nucleic acid test for use on the cobas Liat System
Dated: August 1, 2022
Received: August 1, 2022

Dear Aradhana Karthikeyan:

This is to notify you that your request to; (1) update the Instructions for Use (IFU) and box labeling of the cobas SARS-COV-2 Nucleic acid test for use on the cobas Liat System to include a description and/or information about the new pipette packaging format, and (2) update the IFU with some minor updates and clarifications, is granted. Upon review, we concur that the information submitted in EUA210388/S003 supports the requested updates for use with the cobas SARS-COV-2 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 Nucleic acid test for use on the cobas Liat System issued on June 17, 2021.

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