

August 11, 2022

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

Re: EUA210388/5003 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 SARS-COV-2 Nucleic acid test for use of the cobas SARS-COV-2 Nucleic acid test for use of the cobas SARS-COV-2 Nucleic acid test for use of the cobas SARS-COV-2 Nucleic acid test for use of the cobas SARS-COV-2 Nucleic acid test for use of the cobas SARS-COV-2 Nucleic acid test for use on the cobas SARS-COV-2 Nucleic acid test for use of the cobas SARS-COV-2 Nucleic acid test for use on the cobas SARS-COV-2 Nucleic acid test for use on the cobas SARS-COV-2 Nucleic acid test for use on the cobas SARS-COV-2 Nucleic acid test for use on the cobas SARS-COV-2 Nucleic acid test for use on the cobas SARS-COV-2 Nucleic acid test for use on the cobas SARS-COV-2 Nucleic acid test for use on the cobas Liat System issued on June 17, 2021.

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