



May 18, 2023

Alicja Stradomska, Ph.D.
Regulatory Affairs Project Manager
Roche Molecular Systems
4300 Hacienda Drive
Pleasanton, CA 94588

Re: EUA210388/S005

Trade/Device Name: cobas SARS-CoV-2 Nucleic acid test for use on the cobas Liat System (cobas SARS-CoV-2)

Dated: May 09, 2023

Received: May 11, 2023

Dear Dr. Stradomska:

This is to notify you that your request to extend the shelf-life expiration date for the cobas SARS-CoV-2 Nucleic acid test for use on the cobas Liat System (cobas SARS-CoV-2) assay tubes to 18 months when stored at 2–8°C, based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210388/S005 supports the requested updates for use with the cobas SARS-CoV-2 Nucleic acid test for use on the cobas Liat System (cobas SARS-CoV-2). 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 (cobas SARS-CoV-2) issued on June 17, 2021.

Sincerely yours,

Kristian Roth, Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health