



February 8, 2023

Caroline Sobek
Sr. Regulatory Specialist I
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, California 94588-0900

Re: EUA200009/S010
Trade/Device Name: cobas SARS-CoV-2
Dated: January 19, 2023
Received: January 19, 2023

Dear Ms. Sobek:

This is to notify you that your request to extend the shelf life stability to 18 months for the cobas SARS-CoV-2, is granted. Upon review, we concur that the data and information submitted in EUA200009/S010 supports the requested updates for use with the cobas SARS-CoV-2. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in more recent authorizations. 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 reissued letter authorizing the emergency use of the cobas SARS-CoV-2 issued on April 21, 2021.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health