May 14, 2021

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

Re: EUA200009/S006
Trade/Device Name: cobas SARS-CoV-2
Dated: May 11, 2021
Received: May 12, 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 to include additional clinical validation data in a screening population to fulfil a Condition of Authorization, is granted. Upon review, we concur that the data and information submitted in EUA200009/S006 supports the requested update for use with the 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 reissued on April 12, 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