May 13, 2020

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

Re: EUA200009/A002
     Trade/Device Name: cobas SARS-CoV-2
     Dated: May 5, 2020
     Received: May 5, 2020

Dear Ms. Hoady:

This is to notify you that your request to update the Assay Specific Analysis Package (ASAP) software associated with the cobas 6800/8800 Systems performing the cobas SARS-CoV-2 test to; (1) allow use of the cobas PCR Media tube as the primary tube for processing without the need to remove the swab, (2) adjust liquid handling parameters to reduce dispense clot rates, and (3) adjust the PCR fluorescence curve analysis algorithm, is granted. In addition, the request to update the Instructions for Use (IFU) of the cobas SARS-CoV-2 test to; (1) add instructions for the cobas PCR Media primary tube processing, (2) add limit of detection study in copies/mL using the SeraCare AccuPlex material, (3) revise the Results Interpretation table by removing the need for retesting of presumptive positives based on real world data, (4) updated the Nasal swab collection pictogram, (5) corrections to confidence intervals in Table 15, and (6) other minor edits made for clarification and/or requested by FDA, is granted. Upon review, we concur that the data and information submitted in EUA200009/A002 supports the requested updates for use with the cobas SARS-CoV-2 test. As part of this amendment request, FDA also made revisions to the Healthcare Provider and Patient Fact Sheets to reflect recent updates. By submitting this amendment 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 test issued on March 12, 2020.

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