March 31, 2020

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

Re: EUA200009/A001
Trade/Device Name: cobas SARS-CoV-2
Dated: March 27, 2020
Received: March 28, 2020

Dear Ms. Hoady:

This is to notify you that your request to update the Instructions for Use (IFU) of the cobas SARS-CoV-2 test to: (1) include in the intended use the testing of "*clinician-instructed self-collected (collected on Site) and clinician-collected nasal swab specimens*", (2) addition of the cobas PCR Media provided in both the cobas PCR Media Uni Swab Sample Kit and the cobas PCR Media Dual Swab Sample Kit, and 0.9% Physiological Saline, as acceptable collection and transport media, (3) expand the claimed specimen types to include nasal, nasopharyngeal and oropharyngeal specimens collected according to standard collection technique using flocked or polyester-tipped swabs and immediately placed in 3 mL of Copan Universal Transport Medium (UTM-RT) or BD Universal Viral Transport (UVT), (4) expand the claimed specimen types to include nasal swab specimens collected using the cobas PCR Media Uni Swab Sample Kit (P/N 07958030190) or the cobas PCR Media Dual Swab Sample Kit (P/N 07958021190), (5) expand the claimed specimen types to include nasal swab specimens collected according to standard collection technique using flocked or polyester-tipped swabs immediately placed in 3 mL of 0.9% physiological saline, (6) add the specific instructions for collecting nasal swab specimens using either the cobas PCR Media Dual Swab Kit or the cobas PCR Media Uni Swab Kit, and (7) make some other minor revisions that are of a correction and improving or further clarification nature and are consistent with the IFU under the original EUA (EUA200009), have been granted. Upon review, we concur that the data submitted in EUA200009/A001 supports the requested updates for use with the cobas SARS-CoV-2 test. We also concur with the related changes to the Instructions for Use test that reflect the requested updates and have also updated the Healthcare Provider Fact Sheet for the cobas SARS-CoV-2 test accordingly. 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.
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