February 9, 2022

Cynthia Aker
Principal, U.S. Regulatory Affairs
Roche Diagnostics, Inc.
9115 Hague Road
Indianapolis, IN 46250

Re: EUA202698/S004
Trade/Device Name: Elecsys Anti-SARS-CoV-2 S
Dated: November 22, 2021
Received: November 23, 2021

Dear Cynthia Aker:

This is to notify you that your request to- (1) update the authorized labeling to address Condition of Authorization (1) in the Viral Mutation Revision Letter dated September 23, 2021, (2) to extend the reagent on-board stability to 28 days on the cobas e 411, cobas e 601, and cobas e 602 analyzers, and to 16 weeks on the cobas e 801 analyzer, (3) to extend sample stability to 14 days at 15-25°C, and (4) to extend shelf-life claims for the Elecsys Anti-SARS-CoV-2 S reagent and CalSet Anti-SARS-CoV-2 S calibrators to 12 months, and PreciControl Anti-SARS-CoV-2 S control material to 10 months when stored at 2-8ºC, is granted. Upon review, we concur that the data and information submitted in EUA202698/S004 support the requested updates. FDA also updated the Healthcare Provider Fact Sheet and Recipient Fact Sheet to reflect language used in more recent authorizations. By submitting this information for review by the FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of Elecsys Anti-SARS-CoV-2 S issued on November 25, 2020 and the Viral Mutation Revision Letter issued on September 23, 2021.

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