



August 24, 2022

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

Re: EUA202698/S005
Trade/Device Name: Elecsys Anti-SARS-CoV-2 S
Dated: July 28, 2022
Received: August 3, 2022

Dear Cynthia Aker:

This is to notify you that your request to 1) extend shelf-life claims for the Elecsys Anti-SARS-CoV-2 S reagents and CalSet Anti-SARS-CoV-2 S calibrators to 18 months when stored at 2-8°C, and 2) extend the in-use stability claims for the PreciControl Anti-SARS-CoV-2 S control material to 8 weeks when stored at 2-8°C after opening, is granted. Upon review, we concur that the data and information submitted in EUA202698/S005 support the requested updates for use with the Elecsys Anti-SARS-CoV-2 S and to the authorized labelling. 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.

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