



July 13, 2021

Tammy Dean
Manager, Regulatory Affairs
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250 USA
Phone: (317) 521-3978
Email: tammy.dean@roche.com

Re: EUA200514/S005
Trade/Device Name: Elecsys Anti-SARS-CoV-2
Dated: June 03, 2021
Received: June 04, 2021

Dear Tammy Dean:

This is to notify you that your request to extend the shelf-life stability claim for (1) Elecsys Anti-SARS-CoV-2 Assay reagent pack, and (2) PreciControl Anti-SARS-CoV-2 from 2 months to 4 months when stored at 2-8°C, and (3) updating of the Instructions for Use (IFU) to remove instructions for the extra (optional) wash step is granted. Upon review, we conclude the information provided in EUA200514/S005 supports the requested updates for use with the Elecsys Anti-SARS-CoV-2. FDA has updated the Healthcare Provider and Patient Fact Sheets to reflect language used in more recent authorizations. By submitting this supplement for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization T stated in the letter authorizing the emergency use of the Elecsys Anti-SARS-CoV-2 re-issued on May 19, 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