



May 04, 2021

Jamie Ferguson
Principal, Regulatory Affairs
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250

Re: EUA202698/S001
Trade/Device Name: Elecsys Anti-SARS-CoV-2 S
Dated: February 17, 2021
Received: February 17, 2021

Dear Jamie Ferguson:

This is to notify you that your request to revise the Instructions for Use (IFU) of the Elecsys Anti-SARS-CoV-2 S Antibody Assay to (1) extend the Elecsys Anti-SARS-CoV-2 S Antibody Assay reagent shelf-life stability from 4 weeks to 12 weeks when stored at 2-8°C, (2) extend the storage of samples at 2-8°C from 7 days to up to 14 days and from 28 days to up to 3 months at -20°C (\pm 5°C), (3) increase the number of freeze/thaw cycles of serum and plasma samples from one cycle to 3 cycles, (4) include additional information on interference testing, (5) include additional information on analytical specificity, and (6) extend the claimed dilution range up to 1:100 is granted. Upon review, we concur the information provided in EUA202698/S001 support the requested updates to the IFU for the Elecsys Anti-SARS-CoV-2 S Antibody Assay. FDA has made minor edits to the intended use to reflect more recent authorizations, included additional limitations in the IFU of the Elecsys Anti-SARS-CoV-2 S Antibody Assay related to performance for vaccinated individuals and performance with circulating variants, updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients to include information related to vaccinated individuals and updated the Healthcare Provider Fact Sheet for information related to circulating variants and other edits to reflect more recent authorizations. By submitting these revisions 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 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

Technical Correction May 6, 2021: All mentions of the name of the assay are corrected to read "Elecsys Anti-SARS-CoV-2 S"