July 21, 2020

Tammy Dean
Manager, Regulatory Affairs
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250

Re: EUA200514/A002
Trade/Device Name: Elecsys Anti-SARS-CoV-2
Dated: May 26, 2020
Received: May 26, 2020

Dear Ms. Dean:

This is to notify you that your request to update the Instructions for Use (IFU) of the Elecsys Anti-SARS-CoV-2 to; (1) revise the assay labeling to reflect the availability of external controls with separate labeling per Condition "S" of the May 2 Letter of Authorization, (2) revise the labeling to incorporate new or additional data for cross-reactivity, reagent stability, endogenous interference, reagent kit calibration frequency, lot calibration frequency, assay precision, hook effect, clinical specificity and sensitivity, is granted. Upon review, we concur that the data and information submitted in EUA200514/A002 supports the requested updates for use with the Elecsys Anti-SARS-CoV-2. 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 Elecsys Anti-SARS-CoV-2 issued on May 2, 2020.

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