June 22, 2020

Jacob Richards
Regulatory Affairs Project Manager
Abbott Laboratories Inc.
100 Abbott Laboratories,
Abbott Park, IL 60064 US

Re: EUA200422/A002
Trade/Device Name: SARS-CoV-2 IgG
Amendment Dated: June 03, 2020
Amendment Received: June 03, 2020

Dear Mr. Richards:

This is to notify you that your request to update the Instructions for Use (IFU) of the SARS-CoV-2 IgG assay run on the ARCHITECT i and Alinity i systems to: (1) add endogenous and exogenous interference studies, (2) extend the calibration interval stability from 7 days to 30 days, (3) remove daily maintenance procedures to prevent potential interactions based on a cross-contamination study, and (4) make some additional minor edits and clarifications, is granted. Upon review, we concur that the data and information submitted in EUA200422/A002 supports the requested updates for use with the SARS-CoV-2 IgG assay run on the ARCHITECT i and Alinity i systems. 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 SARS-CoV-2 IgG assay issued on April 26, 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