U.S. FOOD & DRUG ADMINISTRATION

September 18, 2020

Jacob Richards
Regulatory Affairs Project Manager
Abbott Diagnostics Division
Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064

Re: EUA200422/S003
Trade/Device Name: ARCHITECT i SARS-CoV-2 IgG and Alinity i SARS-CoV-2 IgG
Supplement Dated: August 7, 2020
Supplement Received: September 10, 2020

Dear Mr. Richards:

This is to notify you that your request to 1) replace the detergent formulation in the calibrator and positive control of the ARCHITECT and Alinity SARS-CoV-2 IgG tests to comply with European REACH regulations, 2) transfer the bulk manufacturing, filling and labeling of the calibrator and controls to the Ireland facility, and 3) add stability studies for the calibrator and positive control with the new detergent formulation to the ongoing stability study outlined in EUA200422, is granted. Upon review, we concur that the data and information submitted in EUA200422/S003 supports the change in detergent for the calibrator and positive control of the SARS-CoV-2 IgG assay for ARCHITECT and Alinity systems. The intended use has also been updated to reflect more recent authorizations. 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 ARCHITECT SARS-CoV-2 IgG assay issued on April 26, 2020, and the Alinity i SARS-CoV-2 IgG assay issued on May 9, 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