May 9, 2020

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

Re: EUA200422/A001
Trade/Device Name: SARS-CoV-2 IgG
Amendment Dated: May 04, 2020
Amendment Received: May 04, 2020

Dear Mr. Richards:

This is to notify you that your request to include the Alinity i instrument platform as an additional authorized instrument for the SARS-CoV-2 IgG assay, is granted. Upon review, we concur that the data and information submitted in EUA200422/A001 supports the addition of the Alinity i system for use with the SARS-CoV-2 IgG assay. 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,

Uwe Scherf -S

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