December 1, 2020

Jacob Richards, Ph.D.
Associate Director of Regulatory Affairs
Abbott Laboratories, Inc.
100 Abbott Laboratories
Abbott Park, IL 60064 USA

Re: EUA200422/S004
Device Name (Authorized): Abbott SARS-CoV-2 IgG assay
Authorization Date: April 26, 2020
Supplement Received: October 7, 2020

Dear Dr. Richards:

This is to notify you that your request to update the Fact Sheet for Healthcare Providers of the Abbott SARS-CoV-2 IgG, to include a limitation, is granted. Upon review, for the Abbott SARS-CoV-2 IgG, we concur with the additional statement to the Fact Sheet for Health Care Providers: "*Due to the risk of false positive results, confirmation of positive results should be considered – using a second, different antibody assay that detects the same type of antibodies.*" FDA also made minor updates to the IFU, the Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients to reflect more recent authorizations.

By submitting this revision 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 Abbott SARS-CoV-2 IgG issued on April 26, 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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov