July 21, 2020

Linda Staswick
Regulatory Affairs Project Manager
Bio-Rad Laboratories
6565 185th Ave NE
Redmond, WA 98052

Re: EUA200571/S002
Trade/Device Name: Platelia SARS-CoV-2 Total Ab
Dated: July 6, 2020
Received: July 6, 2020

Dear Linda Staswick:

This is to notify you that your request to modify the Platelia SARS-CoV-2 Total Ab assay to; (1) update the SARS-CoV-2 antigen used in the detection of the total antibodies (IgM/IgG/IgA) to SARS-CoV-2, and (2) provide the positive and negative controls, included with the assay components, in human serum to meet the Condition of Authorization W, is granted. We also concur with the updates made to the Platelia SARS-CoV-2 Total Ab assay Instructions for Use to summarize the performance with the updated SARS-CoV-2 antigen, update the positive and negative control reagents, and additional minor edits and clarifications. Upon review, we concur that the data and information submitted in EUA200571/A002 supports the requested updates for use with the Platelia SARS-CoV-2 Total Ab assay. The Healthcare Provider and Patient Fact Sheets have 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 Platelia SARS-CoV-2 Total Ab assay issued on April 29, 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