October 30, 2020

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

Re: EUA200512/S003
Device Name (Authorized): Platelia SARS-CoV-2 Total Ab
Authorization Date: April 29, 2020
Supplement Received: October 3, 2020

Dear Ms. Linda Staswick:

This is to notify you that your request to update the Instructions for Use (IFU) of the Platelia SARS-CoV-2 Total Ab, to include a limitation, is granted. Upon review, for the Platelia SARS-CoV-2 Total Ab, we concur with the additional limitation to the IFU: "*A positive result may not indicate previous SARS-CoV-2 infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response*." 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 Platelia SARS-CoV-2 Total Ab issued on April 29, 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