U.S. FOOD & DRUG ADMINISTRATION

February 25, 2022

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

Re: EUA200512/S004
Trade/Device Name: Platelia SARS-CoV-2 Total Ab
Dated: December 15, 2021
Received: December 16, 2021

Dear Linda Staswick:

This is to notify you that your request to (1) update the Platelia SARS-CoV-2 Total Ab authorized labelling (the Instructions for Use (IFU) and Healthcare Provider Fact Sheet) in response to Condition of Authorization (1) in the Viral Mutation Revision Letter dated September 23, 2021, and (2) update the IFU to reflect changes to the kit components and to provide more concise language for the instructions, is granted. Upon review, we concur that the information provided in EUA200512/S004 supports the requested updates to the authorized labelling for Platelia SARS-CoV-2 Total Ab. FDA has also updated the Factsheet for Healthcare Providers and Factsheet for Patients to be consistent with more recent authorizations. By submitting this supplement for review by the 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 and the Viral Mutation Revision Letter issued on September 23, 2021.

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

CC: Frank Lou, Director, Azure Biotech, Inc.