U.S. FOOD & DRUG ADMINISTRATION

April 21, 2022

John D. Roback
Emory Medical Laboratories,
Emory University Hospital,
1364 Clifton Road NE,
Atlanta, GA 30322

Re: EUA201663/S001
Trade/Device Name: SARS-CoV-2 RBD IgG.
Dated: October 2, 2020
Received: October 2, 2020

Dear John Roback:

This is to notify you that your request to update; (1) the Standard Operating Procedure (SOP) of the Emory Medical Laboratories, SARS-CoV-2 RBD IgG to include the limitation "*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*", and (2) the Fact Sheet for Healthcare Providers of the Emory Medical Laboratories, SARS-CoV-2 RBD IgG to include the statement "*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,*" is granted. Upon review, we concur the information provided in EUA201663/S001 supports the requested updates to the SOP and fact sheet. FDA has also updated the SOP, Fact Sheet for Healthcare Providers, Fact Sheets for Recipients, and EUA Summary to reflect language used in more recent authorizations and to address Condition of Authorization (1) in the Viral Mutation Revision Letter dated September 23, 2021. By submitting this supplement 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 Emory Medical Laboratories, SARS-CoV-2 RBD IgG on 16 June 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
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