



JUNE 8, 2021

Michael Aye
Chief Scientific Officer
Applied BioCode, Inc.
12130 Mora Dr. Unit 2
Santa Fe Springs, CA 90670

Re: EUA200433/S003
Trade/Device Name: BioCode SARS-CoV-2 Assay
Dated: April 16, 2021
Received: April 19, 2021

Dear Michael Aye:

This is to notify you that your request to update the Instructions for Use (IFU) of the BioCode SARS-CoV-2 Assay to include data supporting the pooling claim, is granted. Upon review, we concur that the data and information submitted in EUA200433/S003 supports the requested updates for use with the BioCode SARS-CoV-2 Assay. FDA has updated the IFU to include an additional limitation related to performance with circulating variants and has updated the intended use and the Healthcare Provider and Patient Fact Sheets to reflect language used in more recent authorizations. By submitting this EUA 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 BioCode SARS-CoV-2 Assay reissued on December 7, 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