U.S. FOOD & DRUG ADMINISTRATION

October 22, 2020

Tara Viviani, RAC
Director Regulatory and Clinical Affairs
Applied BioCode, Inc.
12130 Mora Drive, Unit 2
Santa Fe Springs, CA 90670

Re: EUA200433/S002
Trade/Device Name: BioCode SARS-CoV-2 Assay
Dated: August 6, 2020
Received: September 8, 2020

Dear Ms. Viviani:

This is to notify you that your request to update the Instructions for Use (IFU) of the BioCode SARS-CoV-2 Assay to include; (1) clinical data from a post-authorization clinical evaluation study and (2) results from testing the FDA Reference Panel, is granted. Upon review, we concur that the data and information submitted in EUA200433/S002 supports the requested updates for use with the BioCode SARS-CoV-2 Assay. FDA has also updated the Intended Use to reflect more recent policy. 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 issued on June 15, 2020.

Sincerely yours,

Uwe Scherf -S

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health