August 24, 2022

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

Re: EUA203142/S001
Trade/Device Name: BioCode CoV-2 Flu Plus Assay
Dated: February 11, 2022
Received: February 11, 2022

Dear Dr. Aye:

This is to notify you that your request to update the Instructions for Use (IFU) of the BioCode CoV-2 Flu Plus Assay to; (1) include results of the additional LoD testing using contemporary influenza strains, performed to fulfill Condition of Authorization P. from the December 15, 2021 Letter of Authorization, (2) include results of the additional potential competitive interference study performed to fulfill Condition of Authorization Q. from the December 15, 2021 Letter of Authorization, (3) include an updated inclusivity *in silico* analysis, and (4) other minor updates for clarification, is granted. Upon review, we concur that the data and information submitted in EUA203142/S001 supports the requested updates for use with the BioCode CoV-2 Flu Plus Assay and fulfills Conditions of Authorization P. and Q. from the December 15, 2021, letter. 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 CoV-2 Flu Plus Assay issued on December 15, 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