Bethany Hills
Morrison & Foerster LLP
Representing: PlexBio Co., Ltd.
250 West 55th Street
New York, NY 10019

February 3, 2021

Re: EUA201563/S001
Trade/Device Name: IntelliPlex SARS-CoV-2 Detection Kit
Dated: September 7, 2020
Received: September 9, 2020

Dear Ms. Hills:

This is to notify you that your request to update the Instructions for Use (IFU) of the IntelliPlex SARS-CoV-2 Detection Kit to; (1) add an additional automated extraction platform manufactured by PlexBio, (2) add analytical data to support use of the new automated extraction platform, (3) add clinical validation data from a post-authorization study, and (4) include testing results of the FDA Reference Panel, is granted. Upon review, we concur that the data and information submitted in EUA201563/S001 supports the requested updates for use with the IntelliPlex SARS-CoV-2 Detection Kit. The IntelliPrep Nucleic Acid Extraction Kit User Manual and IntelliPrep Automated Nucleic Acid Extraction System User Manual have been included in the authorized labeling for the IntelliPlex SARS-CoV-2 Detection Kit and will be available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

In addition, FDA is granting you a 3-month extension, based on the date of the granting letter, to obtain and test additional low positive clinical samples. After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, you will update authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

FDA has updated the Intended Use, the Fact Sheet for Healthcare Providers, and the Fact Sheet for Patients for the IntelliPlex SARS-CoV-2 Detection Kit to reflect more recent policy and 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 IntelliPlex SARS-CoV-2 Detection Kit issued on June 25, 2020.

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

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