March 14, 2023

Kenneth Bramwell
Senior Vice President of In Vitro Diagnostics
Co-Diagnostics, Inc.
2401 Foothill Drive, Suite D
Salt Lake City, UT 84109

Re: EUA200049/S004
Trade/Device Name: Logix Smart Coronavirus Disease 2019 (COVID-19) Kit
Dated: December 09, 2021
Received: December 10, 2021

Dear Mr. Bramwell:

This is to notify you that your request to update the Instructions for Use of the Logix Smart Coronavirus Disease 2019 (COVID-19) Kit to; (1) update the Limitations section to fulfill Conditions of Authorization included in the September 23, 2021 Viral Mutation Revision Letter, (2) update and add inclusivity study data, (3) update the contact email and website information, and (4) provide minor edits, is granted. Upon review, we concur that the data and information submitted in EUA200049/S004 supports the requested updates for use with the Logix Smart Coronavirus Disease 2019 (COVID-19) Kit. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients 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 Logix Smart Coronavirus Disease 2019 (COVID-19) Kit issued on April 3, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health