July 16, 2021

Varsha Odiyanda
Quality Systems Specialist
Enzo Life Sciences, Inc.
10 Executive Blvd.
Farmingdale, NY 11735

Re: EUA200260/S003 and S004/A001
Trade/Device Name: AMPIPROBE SARS-CoV-2 Test System
Dated: January 21, 2021 and June 8, 2021
Received: January 21, 2021 and June 9, 2921

Dear Varsha Odiyanda:

This is to notify you that your request to update the Instructions for Use (IFU) of the AMPIPROBE SARS-CoV-2 Test System to; (1) modify the extraction procedure for your existing proprietary extraction kit, AMPIXTRACT SARS-CoV-2 Extraction kit, (2) include results of the additional post-authorization study to further evaluate the 5-specimen pooling clinical performance completed to fulfill Condition of Authorization Q. of the December 30, 2020 letter of authorization, and (3) include instructions to apply an Emergency Use Only (EUO) label on the authorized Research Use Only ThermoFisher QuantStudio 5 Real-Time PCR System to fulfill Condition of Authorization P. of the December 30, 2020 letter of authorization, is granted. Upon review, we concur that the data and information submitted in EUA200260/S003 and S004/A001 supports the requested updates for use with the AMPIPROBE SARS-CoV-2 Test System. In addition, FDA have updated the Healthcare Provider and Patient Fact Sheets to reflect 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 AMPIPROBE SARS-CoV-2 Test System re-issued on December 30, 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