February 14, 2022

Julie Ogi
Quality Assurance and Regulatory Officer
Zymo Research Corporation
17062 Murphy Ave.
Irvine, CA 92614

Re: EUA200518/S005/S006/S007
Trade/Device Name: Quick SARS-CoV-2rRT-PCR Kit
Dated: S005-October 13, 2021; S006-November 10, 2021; S007-February 7, 2022
Received: S005-October 13, 2021; S006-November 12, 2021; S007-February 7, 2022

Dear Julie Ogi:

This is to notify you that your request to update the Instructions for Use (IFU) of the Quick SARS-CoV-2rRT-PCR Kit to; (1) update the Limitations section to fulfill Conditions of Authorization included in the September 23, 2021 Viral Mutation Revision Letter, and (2) provide minor updates, is granted. 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 Quick SARS-CoV-2rRT-PCR Kit issued on May 7, 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