December 30, 2020

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

Re: EUA200518/S004
Trade/Device Name: Quick SARS-CoV-2rRT-PCR Kit
Dated: August 26, 2020
Received: September 11, 2020

Dear Mrs. 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) add data from an alternative swab transport media equivalency study, (2) add supplementary data for clinical validation using clinical upper and lower respiratory samples, (3) modify the catalogue numbers for the DNA/RNA Shield Swab Collection Kit and the DNA/RNA Shield Saliva/Sputum Collection Kit, and (4) other minor edits made for correction, is granted. FDA has also updated the intended use and fact sheets to reflect more recent authorizations. By submitting this amendment 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