May 18, 2020

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

Re: EUA200518/A001
Trade/Device Name: Quick SARS-CoV-2rRT-PCR Kit
Dated: May 12, 2020
Received: May 12, 2020

Dear Ms. Ogli:

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 additional sample transport and storage conditions, and (2) other minor edits made for clarification, is granted. Upon review, we concur that the data and information submitted in EUA200518/A001 supports the requested updates for use with the Quick SARS-CoV-2rRT-PCR Kit. 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