May 28, 2020

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

Re: EUA200518/A002
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 catalog numbers to reflect larger kit sizes: R3011-1K and R3011-10K, (2) modify the product name for the *DNA/RNA Shield Saliva Collection Kit* to *DNA/RNA Shield Saliva/Sputum Collection Kit,* and (3) other minor edits made for clarification, is granted. 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