December 9, 2020

George DeLaRosa
Manager II, Regulatory Affairs
Digital Biology Group (DBG)
Bio-Rad Laboratories
5731 W. Las Positas Blvd
Pleasanton, CA 94588

Re: EUA200440/S003
Trade/Device Name: Bio-Rad SARS-CoV-2 ddPCR Kit
Dated: October 25, 2020
Received: October 26, 2020

Dear Mr. DeLaRosa:

This is to notify you that your request to update the Instructions for Use (IFU) of the Bio-Rad SARS-CoV-2 ddPCR Kit to: (1) add the use of the automated KingFisher Flex System as a new extraction method, (2) add the QX Manager 1.1 Software for acquisition and analysis, and (3) update the IFU to reflect the additional automated extraction platform and software acquisition/analysis program, is granted. Upon review, we concur that the data and information submitted in EUA200440/S003 supports the requested updates for use with the Bio-Rad SARS-CoV-2 ddPCR Kit. 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 Bio-Rad SARS-CoV-2 ddPCR Kit issued on September 18, 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