



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