June 2, 2020

Renlin Li
Marketing Manager
Maccura Biotechnology (USA) LLC
11300 Rockville Pike, Suite 715
Rockville, MD 20852

Re: EUA200065/A001
Trade/Device Name: SARS-CoV-2 Fluorescent PCR Kit
Dated: May 21, 2020
Received: May 21, 2020

Dear Mr. Li:

This is to notify you that your request to update the Instructions for Use (IFU) of the SARS-CoV-2 Fluorescent PCR Kit to; (1) add the QIAGEN QIAamp Viral RNA Mini Kit as an additional authorized extraction method, and (2) make some minor clarifications and edits, is granted. Upon review, we concur that the data and information submitted in EUA200065/A001 supports the requested updates for use with the SARS-CoV-2 Fluorescent PCR Kit, and we have also updated the Healthcare Provider and Patient Fact Sheets. 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 SARS-CoV-2 Fluorescent PCR Kit issued on April 15, 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