

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,

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