



October 31, 2020

Delemir Delev  
International Business Development Director  
Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.  
31 Kexueyuan Road  
Changping District, Beijing, China 201106

Re: EUA202599/S001  
Trade/Device Name: Wantai SARS-CoV-2 RT-PCR Kit  
Dated: October 13, 2020  
Received: October 14, 2020

Dear Delemir Delev:

This is to notify you that your request to update the Instructions for Use (IFU) of the Wantai SARS-CoV-2 RT-PCR Kit to; (1) add two alternate automated nucleic acid extraction platforms to be used with the Wantai Nucleic Acid Extracting Reagent, and (2) correct minor informalities, is granted. Upon review, we concur that the data and information submitted in EUA202599/S001 supports the requested updates for use with the Wantai SARS-CoV-2 RT-PCR 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 Wantai SARS-CoV-2 RT-PCR Kit issued on September 9, 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