April 22, 2021

Daniel Castellanos
Associate Director of Regulatory Affairs and Quality Management
Euroimmun US Inc.
1 Bloomfield Avenue
Mountain Lakes, NJ 07046

Re: EUA201525/S002
Trade/Device Name: EURORealTime SARS-CoV-2
Dated: February 5, 2021
Received: February 6, 2021

Dear Mr. Castellanos:

This is to notify you that your request to update the Instructions for Use (IFU) of the EURORealTime SARS-CoV-2 to; (1) update to include a new extraction method, the Chemagic Viral DNA/RNA 300 Kit H96, (2) update to include a new real-time PCR instrument, the qTOWER^3 (Analytik Jena) (3) revision of the positive control cutoff, (4) update the in silico analysis for inclusivity and (5) other minor clarifications and updates to reflect more recent authorizations, is granted. Upon review, we concur that the data and information submitted in EUA201525/S002 supports the requested updates for use with the EURORealTime SARS-CoV-2 product. In addition, FDA have updated the Fact Sheet for Healthcare Provider and Fact Sheet for Patients to reflect more recent authorizations. 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 EURORealTime SARS-CoV-2 issued on June 8, 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