



December 17, 2021

Jon Nakamoto
Amazon.com Services LLC
c/o Amazon Legal Dept
410 Terry Ave. N.
Seattle, WA 98109

Re: EUA202760/S006
Trade/Device Name: Amazon Real-Time RT-PCR Test for Detecting SARS-CoV-2 ("Amazon Test")
Dated: November 22, 2021
Received: November 25, 2021

Dear Dr. Nakamoto:

This is to notify you that your request to update the EUA Summary of the Amazon Real-Time RT-PCR Test for Detecting SARS-CoV-2 to; (1) add alternative packing companies for collection kit assembly and (2) add alternative suppliers for collection kit components, is granted. Upon review, we concur that the information submitted in EUA202760/S006 supports the requested updates for use with the Amazon Real-Time RT-PCR Test for Detecting SARS-CoV-2. 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 Amazon Real-Time RT-PCR Test for Detecting SARS-CoV-2 re-issued on May 28, 2021.

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