



January 26, 2022

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

Re: EUA202760/S007
Trade/Device Name: Amazon Real-Time RT-PCR Test for Detecting SARS-CoV-2 ("Amazon Test")
Dated: January 24, 2022
Received: January 24, 2022

Dear Dr. Nakamoto:

This is to notify you that your request to update the standard operating procedure "*Amazon Real-Time RT-PCR Test for Detecting SARS-CoV-2 (Rx only) and Amazon Real-Time RT-PCR DTC Test for Detecting SARS-CoV-2 Laboratory Protocol*", is granted. Upon review, we concur that the information submitted in EUA202760/S007 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