

December 17, 2021

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

Re: EUA210481/S001

Trade/Device Name: Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test. ("Amazon Multi-Target 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 Multi-Target SARS-CoV-2 Real-Time RT-PCR Test to; (1) add alternative packing companies for sollection kit assembly and (2) add alternative suppliers for collection kit components, is granted. Upon review, we concur that the information submitted in EUA210481/S001 supports the requested updates for use with the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test. 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 Multi-Target SARS-CoV-2 Real-Time RT-PCR Test issued on August 11, 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

