



December 17, 2021

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

Re: EUA210308/S002

Trade/Device Name: Amazon Real-Time RT-PCR DTC Test for Detecting SARS-CoV-2 (“Amazon DTC 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 DTC 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 EUA210308/S002 supports the requested updates for use with the Amazon Real-Time RT-PCR DTC 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 DTC Test for Detecting SARS-CoV-2 re-issued on August 9, 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