July 19, 2022

Jon Nakamoto
Amazon.com Services LLC
c/o Amazon Legal Dept
410 Terry Ave. N.
Seattle, WA 98109
Re: Revocation of EUA210481

Dear Jon Nakamoto:

This letter is in response to a request from STS Lab Holdco (a subsidiary of Amazon.com Services LLC), received July 11, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test issued on August 11, 2021, and amended on December 17, 2021, and January 26, 2022. FDA understands there is no viable (non-expired) Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test remaining in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety. Because STS Lab Holdco (a subsidiary of Amazon.com Services LLC) has notified FDA that there is no viable (non-expired) Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test remaining in distribution in the United States and requested FDA revoke the authorization of the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210481 for the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Amazon Multi-Target SARS-CoV-2 Real-Time RT-PCR Test is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

cc: Kenneth Bedsted, Director, Amazon Labs