July 19, 2022

Jon Nakamoto
Amazon.com Services LLC
c/o Amazon Legal Dept
410 Terry Ave. N.
Seattle, WA 98109
Re: Revocation of EUA210308

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 Real-Time RT-PCR DTC Test for Detecting SARS-CoV-2 issued on May 28, 2021, re-issued on January 26, 2022, and amended on December 17, 2021. FDA understands there is no viable (non-expired) Amazon Real-Time RT-PCR DTC Test for Detecting SARS-CoV-2 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 Real-Time RT-PCR DTC Test for Detecting SARS-CoV-2 remaining in distribution in the United States and requested FDA revoke the authorization of the Amazon Real-Time RT-PCR DTC Test for Detecting SARS-CoV-2, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210308 for the Amazon Real-Time RT-PCR DTC Test for Detecting SARS-CoV-2, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Amazon Real-Time RT-PCR DTC Test for Detecting SARS-CoV-2 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