September 21, 2022

Ilia M. Toledo Garcia
President & Director
Laboratorio Clinico Toledo
51 Palma St.
Arecibo PR 00612
Re: Revocation of EUA200207

Dear Ilia M. Toledo Garcia:

This letter is in response to the request from Laboratorio Clinico Toledo, received via email on September 8, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the Laboratorio Clinico Toledo SARS-CoV-2 Assay issued on July 6, 2020, and amended on December 28, 2020, and September 23, 2021. Laboratorio Clinico Toledo indicated in their email and cover letter that they are no longer testing with the Laboratorio Clinico Toledo SARS-CoV-2 Assay and have none of the reagents in stock in their laboratory.

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 (section 564(g)(2)(C) of the Act). Because Laboratorio Clinico Toledo has notified FDA that it has decided to no longer test using the Laboratorio Clinico Toledo SARS-CoV-2 Assay and requested FDA withdraw the EUA for the Laboratorio Clinico Toledo SARS-CoV-2 Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200207 for the Laboratorio Clinico Toledo SARS-CoV-2 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Laboratorio Clinico Toledo SARS-CoV-2 Assay 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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Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration