December 16, 2022

Taylor Edwards, MSc, Ph.D.
Associate Staff Scientist, Clinical Laboratory Manager
University of Arizona Genetics Core for Clinical Services
Keating Bioresearch Building
1657 E. Helen Street Room 111H
Tucson, AZ 85721

Re: Revocation of EUA201116

Dear Dr. Edwards:

This letter is in response to the request from the University of Arizona Genetics Core for Clinical Services, received via email on December 14, 2022, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the COVID-19 ELISA pan-Ig Antibody Test issued on August 31, 2020, and amended September 23, 2021. The University of Arizona Genetics Core for Clinical Services indicated that they are no longer offering this as a clinical test service, and it has been removed from their activity menu.

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 the University of Arizona Genetics Core for Clinical Services has requested FDA withdraw the EUA for the COVID-19 ELISA pan-Ig Antibody Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201116 for the COVID-19 ELISA pan-Ig Antibody Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the COVID-19 ELISA pan-Ig Antibody 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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Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration