February 1, 2023

Alex Kim
Chief Operating Officer
Standard BioTools Inc.
2 Tower Place Suite 2000
South San Francisco, CA 94080

Re: Revocation of EUA210664

Dear Alex Kim:

This letter is in response to the request from Standard BioTools Inc., received via email on January 30, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the Advanta Dx COVID-19 EASE Assay issued on February 7, 2022, and reissued on June 14, 2022. Standard BioTools Inc. indicated that they have discontinued the Advanta Dx COVID-19 EASE Assay and are no longer selling this EUA product. FDA understands that as of the date of this letter there will no longer be any viable Advanta Dx COVID-19 EASE Assay reagents 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 (section 564(g)(2)(C) of the Act). Because Standard BioTools Inc. has requested FDA withdraw the EUA for the Advanta Dx COVID-19 EASE Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210664 for the Advanta Dx COVID-19 EASE Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Advanta Dx COVID-19 EASE 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