February 14, 2023

Jane Hughie
Director, QA/RA
Babson Diagnostics
1205 Sheldon Cove, Suite 2-J
Austin, TX 78753

Re: Revocation of EUA200682

Dear Jane Hughie:

This letter is in response to the request from Babson Diagnostics, Inc., received via email on February 7, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Babson Diagnostics aC19G1 issued on June 23, 2020, and amended on September 23, 2021. Babson Diagnostics, Inc., indicated that they no longer offer the Babson Diagnostics aC19G1 and requested that the EUA be revoked.

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 Babson Diagnostics, Inc. has requested FDA revoke the EUA for the Babson Diagnostics aC19G1, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200682 for the Babson Diagnostics aC19G1, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Babson Diagnostics aC19G1 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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Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration