August 6, 2021

Dr. Katie Bessette
Sr. Director, Regulatory Affairs
Guardant Health, Inc.
505 Penobscot Drive
Redwood City, CA 94063

Re: Revocation of EUA201847

Dear Dr. Bessette,

This letter is in response to Guardant Health Inc.'s (Guardant) request, dated August 2, 2021, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA201847) for Guardant-19 issued on August 21, 2020 and amended on December 28, 2020. In its August 2 letter, Guardant requested revocation of the Guardant-19 effective July 16, 2021.

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 Guardant has requested that FDA revoke the authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201847 for Guardant-19, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Guardant-19 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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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration