July 21, 2021

James P. Canner Ph.D.
VP, Regulatory, Clinical, and Research Programs
Gravity Diagnostics, LLC
632 Russell Street
Covington, KY 41011
Re: Revocation of EUA200031

Dear Dr. Canner:

This letter is in response to Gravity Diagnostics, LLC's (Gravity's) email request originally received March 11, 2021, and reconfirmed July 12, 2021, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA200031) for the Gravity Diagnostics COVID-19 Assay issued on June 1, 2020, and amended on June 30, 2020, and September 21, 2020. Gravity confirmed that it is no longer using the Gravity Diagnostics COVID-19 Assay at Gravity's laboratory, having transitioned to another EUA-authorized test.

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 Gravity has notified FDA that it is longer using the Gravity Diagnostics COVID-19 Assay and requests 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 EUA200031 for the Gravity Diagnostics COVID-19 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Gravity Diagnostics COVID-19 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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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration