March 10, 2022

Anna Rolda, MS
Sr. Manager, Quality & Regulatory Affairs
BillionToOne, Inc.
1035 O'Brien Drive
Menlo Park, CA 94025
Re: Revocation of EUA201022

Dear Ms. Rolda:

This letter is in response to the request from BillionToOne, Inc., received via email on February 25, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the qSanger-COVID-19 Assay issued on September 4, 2020, and amended on June 23, 2021, and September 23, 2021. BillionToOne, Inc. indicated that it has decided to discontinue distribution of the qSanger-COVID-19 Assay and there is not any viable/non-expired product remaining in distribution.

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 BillionToOne, Inc. has notified FDA that it has decided to discontinue distribution of the qSanger-COVID-19 Assay and requested FDA revoke the EUA for the qSanger-COVID-19 Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201022 for the qSanger-COVID-19 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the qSanger-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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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration