March 17, 2022

Dr. Florian Vogel
Chief Process Officer
CENTOGENE GmbH
Am Strande 7
18055 Rostock
Germany

Re: Revocation of EUA201018

Dear Dr. Vogel:

This letter is in response to the request from CENTOGENE US, LLC. ("Centogene"), received on March 14, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the CentoFast-SARS-CoV-2 RT-PCR Assay issued on July 1, 2020, and amended on August 13, 2021, and September 23, 2021. Centogene indicated that it does not offer this test anymore. FDA understands Centogene has notified all associated laboratories to also stop using this 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 Centogene has notified FDA that it does not offer the CentoFast-SARS-CoV-2 RT-PCR Assay anymore and requested FDA revoke the EUA for the CentoFast-SARS-CoV-2 RT-PCR Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201018 for the CentoFast-SARS-CoV-2 RT-PCR Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the CentoFast-SARS-CoV-2 RT-PCR 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

Cc: Justin Bingham, CENTOGENE US, LLC.