March 17, 2022

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

Re: Revocation of EUA202546

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 CentoSure SARS-CoV-2 RT-PCR Assay issued on September 29, 2020, and amended on August 13, 2021, and September 23, 2021. Centogene indicated that it does not offer this test anymore. FDA understands Centogene and has notified 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 CentoSure SARS-CoV-2 RT-PCR Assay anymore and requested FDA revoke the EUA for the CentoSure 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 EUA202546 for the CentoSure SARS-CoV-2 RT-PCR Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the CentoSure 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.