January 17, 2024

Glenn Neuman
RADx Regulatory Consultant
New World Regulatory Solutions, Inc.
Representing:
Tangen Biosciences, Inc.
20 Commercial Street
Branford, CT 06405
**Re: Revocation of EUA230015**

Dear Mr. Neuman:

This letter is in response to the request from Tangen Biosciences, Inc., in a letter dated January 10, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the TangenDx SARS-CoV-2 Molecular Test, that includes use of the GeneSpark instrument, issued on September 29, 2023. Tangen Biosciences, Inc. indicated that they have ceased manufacturing of the TangenDx SARS-CoV-2 Molecular Test and the GeneSpark instrument and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no TangenDx SARS-CoV-2 Molecular Test reagents or GeneSpark instruments in distribution in the United States.

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 Tangen Biosciences, Inc. has requested that FDA revoke the EUA for the TangenDx SARS-CoV-2 Molecular Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA230015 for the TangenDx SARS-CoV-2 Molecular Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the TangenDx SARS-CoV-2 Molecular Test 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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Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration