

April 14, 2023

Sarai Meyer  
Principal Regulatory Affairs Specialist  
Detect, Inc.  
530 Old Whitfield St.  
Guilford, CT 06437

**Re: Revocation of EUA210534**

Dear Sarai Meyer:

This letter is in response to the request from Detect, Inc., in a letter received March 16, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Detect Covid-19 Test issued on October 28, 2021, reissued April 11, 2022, and revised on January 12, 2022, and August 17, 2022. FDA understands that as of the date of this letter there are no viable Detect Covid-19 Test reagents remaining 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 Detect, Inc. has requested FDA revoke the EUA for Detect Covid-19 Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210534 for the Detect Covid-19 Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Detect Covid-19 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