

February 24, 2026

Estela Raychaudhuri  
President  
InBios International, Inc.  
307 Westlake Avenue N, Suite 300  
Seattle, WA 98109

**Re: Revocation of EUA210540**

Dear Estela Raychaudhuri:

This letter is in response to the request from InBios International, Inc., in an email dated February 16, 2026, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the SCoV-2 *Detect* Neutralizing Ab ELISA issued on October 22, 2021. FDA understands that as of the date of this letter there is no viable SCoV-2 *Detect* Neutralizing Ab ELISA 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 InBios International, Inc. has requested that FDA revoke the EUA for the SCoV-2 *Detect* Neutralizing Ab ELISA, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210540 for the SCoV-2 *Detect* Neutralizing Ab ELISA, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SCoV-2 *Detect* Neutralizing Ab ELISA 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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Ellen J. Flannery, J.D.  
Deputy Center Director for Policy  
Director, Office of Policy  
Center for Devices and Radiological Health  
Food and Drug Administration