May 14, 2026

Estela Raychaudhuri
President
InBios International, Inc.
307 Westlake Avenue N, Suite 300
Seattle, WA 98109
Re: Revocation of EUA210368

Dear Estela Raychaudhuri:
This letter is in response to the request from InBios International, Inc., in an email dated April 30, 2026, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the SCoV-2 *Detect* IgG Rapid Test issued on August 24, 2021. FDA understands that as of the date of this letter there are no viable SCoV-2 *Detect* IgG Rapid 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 InBios International, Inc. has requested that FDA revoke the EUA for the SCoV-2 *Detect* IgG Rapid Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210368 for the SCoV-2 *Detect* IgG Rapid Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SCoV-2 *Detect* IgG Rapid 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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Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration