June 3, 2025

Estela Raychaudhuri
President
InBios International, Inc.
307 Westlake Avenue N, Suite 300
Seattle, WA 98109
Re: Revocation of EUA210234

Dear Estela Raychaudhuri:
This letter is in response to the request from InBios International, Inc., in an email dated May 9, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the SCoV-2 Ag *Detect* Rapid Test issued on May 6, 2021, revised and reissued on September 3, 2021, and amended on March 3, 2022, May 26, 2022, November 1, 2022, and December 23, 2022. InBios International, Inc. indicated that the last distributed lot of EUA labeled SCoV-2 Ag *Detect* Rapid Test has expired and requested that the EUA be revoked. As of the date of this letter, InBios International, Inc. has fully transitioned to the SCoV-2 Ag *Detect* Rapid Test product that was cleared under K233358.

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 Ag *Detect* Rapid Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210234 for the SCoV-2 Ag *Detect* Rapid Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SCoV-2 Ag *Detect* 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