July 14, 2026

Jessica Stahle
Senior Manager Regulatory Affairs
Infectious Disease, Rapid and Molecular Diagnostics
Abbott Diagnostics Scarborough, Inc.
10 Southgate Rd.
Scarborough, ME 04074
Re: Revocation of EUA210517

Dear Jessica Stahle:
This letter is in response to the request from Abbott Diagnostics Scarborough, Inc., in an email dated June 19, 2026, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the ID NOW COVID-19 2.0 issued on May 6, 2022, and amended on June 21, 2022, October 5, 2022, and May 24, 2023. FDA understands that as of the date of this letter there are no viable EUA ID NOW COVID-19 2.0 reagents remaining in distribution in the United States. As of the date of this letter, Abbott Diagnostics Scarborough, Inc. has fully transitioned to the ID NOW COVID-19 2.0 product that was cleared under K221925.

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 Abbott Diagnostics Scarborough, Inc. has requested that FDA revoke the EUA for the ID NOW COVID-19 2.0, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210517 for the ID NOW COVID-19 2.0, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the ID NOW COVID-19 2.0 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,

_____
Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration