August 25, 2025

Marlene A. Hanna, RAC
Senior Director, Regulatory Affairs
Ortho Clinical Diagnostics, Inc. (QuidelOrtho)
100 Indigo Creek Drive
Rochester, NY 14626

Re: Revocation of EUA210355

Dear Marlene Hanna:

This letter is in response to the request from Ortho Clinical Diagnostics, Inc. (QuidelOrtho), in an email dated June 10, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators issued on July 22, 2021 and amended on September 21, 2023. FDA understands that as of the date of this letter there is no viable VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators 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 Ortho Clinical Diagnostics, Inc. (QuidelOrtho) has requested that FDA revoke the EUA for the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210355 for the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators 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