



March 2, 2026

Tammy Dean
Senior Regulatory Affairs Manager
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
Re: Revocation of EUA200514

Dear Tammy Dean:

This letter is in response to the request from Roche Diagnostics, in an email dated February 6, 2026, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Elecsys Anti-SARS-CoV-2 issued on May 2, 2020, revised and reissued on May 19, 2021, and amended on June 4, 2020, July 21, 2020, October 23, 2020, July 13, 2021, September 23, 2021, and December 17, 2021. FDA understands that as of the date of this letter there are no viable EUA Elecsys Anti-SARS-CoV-2 reagents remaining in distribution in the United States. As of the date of this letter, Roche Diagnostics has fully transitioned to the Elecsys Anti-SARS-CoV-2 product that was cleared under K250768.

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 Roche Diagnostics has requested that FDA revoke the EUA for the Elecsys Anti-SARS-CoV-2, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200514 for the Elecsys Anti-SARS-CoV-2, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Elecsys Anti-SARS-CoV-2 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