



May 12, 2026

Laura Burke  
Director of Regulatory Compliance & Quality  
SalivaDirect, Inc.  
396 Mansfield Street  
New Haven, CT 06511  
**Re: Revocation of EUA210243**

Dear Laura Burke:

This letter is in response to the request from SalivaDirect, Inc., in an email dated March 23, 2026, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the SalivaDirect At-Home Collection Kit issued on April 9, 2021, revised and reissued on March 1, 2022, and July 1, 2024, and amended on May 6, 2021, July 8, 2022, and December 1, 2022. FDA understands that as of the date of this letter, SalivaDirect, Inc. will have ceased operations.

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 SalivaDirect, Inc. has requested that FDA withdraw the EUA for SalivaDirect At-Home Collection Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210243 for SalivaDirect At-Home Collection Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SalivaDirect At-Home Collection Kit 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