U.S. FOOD & DRUG ADMINISTRATION

May 12, 2026

Laura Burke
Director of Regulatory Compliance & Quality
SalivaDirect, Inc.
396 Mansfield Street
New Haven, CT 06511
Re: Revocation of EUA210506

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 for use with DTC[1] Kits issued on August 27, 2021, revised and reissued on October 29, 2021, February 23, 2022, and July 1, 2024, and amended on December 14, 2022, and April 21, 2023. 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 for use with DTC Kits, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210506 for SalivaDirect for use with DTC Kits, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SalivaDirect for use with DTC Kits 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

[1] Direct to Consumer