May 12, 2026

Laura Burke
Director of Regulatory Compliance & Quality
SalivaDirect, Inc.
396 Mansfield Street
New Haven, CT 06511
Re: Revocation of EUA202097

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 issued on August 15, 2020, revised and reissued on August 28, 2020, December 16, 2020, April 9, 2021, May 28, 2021, June 3, 2021, October 29, 2021, January 27, 2022, December 14, 2022, and July 1, 2024, and amended on August 25, 2020, September 25, 2020, October 15, 2020, February 5, 2021, March 12, 2021, September 23, 2021, 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, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202097 for SalivaDirect, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SalivaDirect 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