August 27, 2026

Lisa Baumhardt, MT(ASCP), MS, MJ, FRAPS, RAC
Senior Director, Regulatory Affairs
CovarsaDx
Representing:
Osang LLC
625 Fair Oaks Ave. Ste. 360
South Pasadena, CA 91030
Re: Revocation of EUA230042

Dear Lisa Baumhardt:
This letter is in response to your request, on behalf of Osang LLC, in a letter dated August 6, 2026, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the OHC COVID-19/Flu Antigen Test Pro issued on March 21, 2024, and amended on May 21, 2024, and October 18, 2024. FDA understands that as of the date of this letter there are no viable OHC COVID-19/Flu Antigen Test Pro reagents 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 Osang LLC has requested that FDA revoke the EUA for the OHC COVID-19/Flu Antigen Test Pro, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA230042 for the OHC COVID-19/Flu Antigen Test Pro, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the OHC COVID-19/Flu Antigen Test Pro 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