January 3, 2023

Vincent Jacquemin
Associate Director of Quality
ChromaCode Inc.
2330 Faraday Avenue Suite 100
Carlsbad, CA 92008

Re: Revocation of EUA200707

Dear Mr. Jacquemin:

This letter is in response to the request from ChromaCode Inc., received via email on December 2, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the HDPCR SARS-CoV-2 Assay issued on June 9, 2020, amended on September 12, 2020, and September 23, 2021, and reissued on February 14, 2022. ChromaCode Inc. indicated that they are discontinuing the HDPCR SARS-CoV-2 Assay and requested that the EUA be revoked. FDA understands that as of the date of this letter there will no longer be any viable HDPCR SARS-CoV-2 Assay reagents remaining 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 ChromaCode Inc. has requested FDA revoke the EUA for the HDPCR SARS-CoV-2 Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200707 for the HDPCR SARS-CoV-2 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the HDPCR SARS-CoV-2 Assay 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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Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration