



December 8, 2021

Chris Andry, MPhil, Ph.D.
Professor and Chair
Department of Pathology & Laboratory Medicine
Boston University School of Medicine
Chief of Pathology & Laboratory Medicine
Boston Medical Center
670 Albany Street, 7th Floor, Room 736
Boston, MA 02118
Re: Revocation of EUA201811

Dear Dr. Andry:

This letter is in response to Boston Medical Center's request received October 4, 2021, and reconfirmed December 6, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA201811) for the BMC-CReM COVID-19 Test issued on July 10, 2020, and amended on September 25, 2020, and September 23, 2021. Boston Medical Center confirmed that the BMC-CReM COVID-19 Test is no longer performed pursuant to the EUA.

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 Boston Medical Center has notified FDA that the BMC-CReM COVID-19 Test is no longer performed pursuant to the EUA and requests FDA withdraw the authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201811 for the BMC-CReM COVID-19 Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the BMC-CReM COVID-19 Test 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,

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration