July 3, 2024

Aradhana Karthikeyan
Senior Manager Regulatory Affairs
RA Functional Partner, molecular PoC
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588

Re: Revocation of EUA201779

Dear Aradhana Karthikeyan:

This letter is in response to the request from Roche Molecular Systems, Inc., in a letter dated June 21, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the cobas SARS-CoV-2 & Influenza A/B nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV-2 & Influenza A/B Quality Control Kit, issued on September 14, 2020, and revised on September 18, 2020, November 19, 2020, December 10, 2020, May 7, 2021, May 14, 2021, June 24, 2021, September 23, 2021, January 6, 2022, March 25, 2022, August 11, 2022, October 26, 2022, February 16, 2023 and June 16, 2023.

Roche Molecular Systems, Inc. indicated that they have ceased the manufacture and distribution of the cobas SARS-CoV-2 & Influenza A/B nucleic acid test for use on the cobas Liat System reagents for the EUA labeled product, that includes the cobas SARS-CoV-2 & Influenza A/B Quality Control Kit, and requested that the EUA be revoked. As of the date of this letter Roche Molecular Systems, Inc., has fully transitioned to the cobas SARS-CoV-2 & Influenza A/B Nucleic acid test for use on the cobas Liat System product that was cleared under K223591.

FDA understands that as of the date of this letter Roche Molecular Systems, Inc. has ceased the manufacture and distribution of the cobas SARS-CoV-2 & Influenza A/B nucleic acid test for use on the cobas Liat System reagents, that also includes the cobas SARS-CoV-2 & Influenza A/B Quality Control Kit, for the EUA labeled product, but that there remains some viable EUA labeled product 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 Roche Molecular Systems, Inc. has requested that FDA revoke the EUA for the cobas SARS-CoV-2 & Influenza A/B nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV-2 & Influenza A/B Quality Control Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201779 for the cobas SARS-CoV-2 & Influenza A/B nucleic acid test for use on the cobas Liat System, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the cobas SARS-CoV-2 & Influenza A/B

nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV-2 & Influenza A/B Quality Control Kit, is no longer authorized for emergency use by FDA.

As discussed, FDA does not have concerns with the use of any remaining viable inventory of the cobas SARS-CoV-2 & Influenza A/B nucleic acid test for use on the cobas Liat System, that includes the cobas SARS-CoV-2 & Influenza A/B Quality Control Kit, that is the EUA labeled product and that was distributed prior to revocation of the EUA, when such product is used in conjunction with the cleared package insert/manufacturer instructions for use cleared as part of the July 27, 2023 510(k) cleared cobas SARS-CoV-2 & Influenza A/B Nucleic acid test for use on the cobas Liat System . Importantly, the cobas SARS-CoV-2 & Influenza A/B Nucleic acid test for use on the cobas Liat System product for which FDA had issued an EUA and the product for which FDA has cleared under 510(k) are manufactured under the same quality system with the same lot release criteria. Roche Molecular Systems, Inc. should instruct customers who have remaining cobas SARS-CoV-2 & Influenza A/B Nucleic acid test for use on the cobas Liat System EUA labeled product inventory that they may use their EUA product in combination with the package insert/manufacturer instructions for use labeling associated with the 510(k) clearance issued on July 27, 2023. Roche Molecular Systems, Inc. should also instruct customers who have remaining cobas SARS-CoV-2 & Influenza A/B Quality Control Kit EUA product inventory that they may use their EUA product in combination with the package insert/manufacturer instructions for use labeling associated with the 510(k) clearance on July 27, 2023 and that the cobas SARS-CoV-2 & Influenza A/B Quality Control Kit EUA labeled product inventory may also be used in combination with the cobas SARS-CoV-2 & Influenza A/B nucleic acid test for use on the cobas Liat System product, which FDA has cleared under 510(k). FDA encourages Roche Molecular Systems, Inc. to use all appropriate means (e.g., mail, email, or website link) to notify affected customers of this EUA revocation and provide access to the package insert/manufacturer instructions for use labeling associated with the 510(k) clearance on July 27, 2023.

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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Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration