August 5, 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 EUA210388

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 nucleic acid test for use on the cobas Liat System, which includes the cobas SARS-CoV-2 Quality Control Kit, issued on June 17, 2021, and revised on September 23, 2021, January 4, 2022, August 11, 2022, October 26, 2022, February 16, 2023, May 18, 2023, June 16, 2023 and August 2, 2023.

Roche Molecular Systems, Inc. indicated that they have ceased the manufacture and distribution of the cobas SARS-CoV-2 nucleic acid test for use on the cobas Liat System reagents for the EUA labeled product, which includes the cobas SARS-CoV-2 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 Nucleic acid test for use on the cobas Liat System product that was cleared under K223783.

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 nucleic acid test for use on the cobas Liat System reagents, which also includes the cobas SARS-CoV-2 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 nucleic acid test for use on the cobas Liat System, which includes the cobas SARS-CoV-2 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 EUA210388 for the cobas SARS-CoV-2 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 nucleic acid test for use on the cobas Liat System, which includes the cobas SARS-CoV-2 Quality Control Kit, is no longer authorized for emergency use by FDA.

As discussed, FDA does not intend to object to the use of any remaining viable inventory of the cobas SARS-CoV-2 nucleic acid test for use on the cobas Liat System, which includes the cobas SARS-CoV-2 Quality Control Kit and that is the EUA labeled product that was distributed prior to revocation of the EUA per Roche Molecular Systems, Inc.'s plan to recommend that such product is used in conjunction with the cleared package insert/manufacturer instructions for use cleared as part of the December 4, 2023 510(k) cleared cobas SARS-CoV-2 Nucleic acid test for use on the cobas Liat System. Importantly, the cobas SARS-CoV-2 Nucleic acid test for use on the cobas Liat System product for which FDA had issued an EUA and the product that FDA has cleared under 510(k) are manufactured under the same quality system with the same lot release criteria. We request that Roche Molecular Systems, Inc. instruct customers who have remaining cobas SARS-CoV-2 Nucleic acid test for use on the cobas Liat System EUA-labeled product inventory to use their EUA product in combination with the package insert/manufacturer instructions for use labeling associated with the 510(k) clearance issued on December 4, 2023. We also request that Roche Molecular Systems, Inc. instruct customers who have remaining cobas SARS-CoV-2 Quality Control Kit EUA product inventory to use their EUA product in combination with the package insert/manufacturer instructions for use labeling associated with the 510(k) clearance on December 4, 2023 and that the cobas SARS-CoV-2 Quality Control Kit EUA-labeled product inventory may also be used in combination with the cobas SARS-CoV-2 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 December 4, 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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Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration