August 9, 2024

Aradhana Karthikeyan
Senior Manager Regulatory Affairs
Roche Molecular Systems, Inc
4300 Hacienda Drive
Pleasanton, CA 94588

Re: EUA230038/S002
Trade/Device Name: cobas liat SARS-CoV-2, Influenza A/B & RSV nucleic acid test
Dated: July 9, 2024
Received: July 10, 2024

Dear Aradhana Karthikeyan:

This is to notify you that your request to update the cobas liat SARS-CoV-2, Influenza A/B & RSV nucleic acid test to; (1) update the cobas liat SARS-CoV-2, Influenza A/B & RSV nucleic acid test Liat Assay Specific Package (LASP) script to CFRA v1.0.10, (2) update the cobas Liat Analyzer software to v3.5.1, and (3) update graphics for product labels, is granted. Upon review, we concur that the data and information submitted in EUA230038/S002 supports the requested updates for use with the cobas liat SARS-CoV-2, Influenza A/B & RSV nucleic acid test. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in more recent authorizations. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the cobas liat SARS-CoV-2, Influenza A/B & RSV nucleic acid test issued on June 7, 2024.

Sincerely yours,

For

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health