DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Mr. Jintao Chen
Director, Regulatory Affairs
Roche Molecular Systems, Inc.
4300 Hacienda Drive,
Pleasanton, CA 94588

November 23, 2016

Re: EUA160017/A001
Trade/Device Name: *LightMix® Zika rRT-PCR Test*
Dated: November 22nd, 2016
Received: November 23rd, 2016

Dear Mr. Chen:

This letter is to notify you that your request for the modification of the interpretation of results for the *LightMix® Zika rRT-PCR Test* has been granted. The modification requires that any result with a reported Cp value be further analyzed by determination of the Fluorescence Intensity Ratio (FIR), which is calculated by dividing the maximum fluorescence intensity of the specimen by the maximum fluorescence intensity of the Positive Control from the same run. A specimen result with a reported Cp value and a FIR value ≥ 10% is reported as positive for Zika virus. A specimen result with a reported Cp value and a FIR value < 10% is reported as indeterminate and should be retested. Upon review, the re-analyzed analytical and clinical data submitted in EUA160017/A001 support the use of the FIR value in the interpretation of results.

We also concur with updates made to the Instructions for Use for the *LightMix® Zika rRT-PCR Test* that reflect the use of the FIR value in the interpretation of results and the consequential changes in the data tables. We also concur with updates made to the Healthcare Provider and Patient Fact Sheets for the *LightMix® Zika rRT-PCR Test* that reflect changes made by the Centers for Disease Control and Prevention and the FDA in September 2016.

By submitting this amendment for review by FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the *LightMix® Zika rRT-PCR Test* issued August 26, 2016.

Sincerely yours,

Uwe Scherf, M.Sc., PhD.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosures