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. Roy Johnson
Manager, Regulatory Affairs
Luminex Corporation
12212 Technology Blvd.
Austin, TX 78727

January 7, 2017

Re: EUA160015/A001
Trade/Device Name: xMAP® MultiFlex™ Zika RNA Assay

Dated: November 28, 2016
Received: November 29, 2016

Dear Mr. Johnson:

This is to notify you that your request to modify the Fact Sheets authorized with the xMAP® MultiFlex™ Zika RNA Assay to combine the Fact Sheet for Patients and the Fact Sheet for Pregnant Women into one Fact Sheet for Patients and to include updated language to align with the latest CDC Zika Laboratory Guidance, implemented in November 2016, has been granted. 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 xMAP® MultiFlex™ Zika RNA Assay issued August 4, 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

Enclosure