



November 6, 2017

MARI MEYER, VICE PRESIDENT,
REGULATORY AND CLINICAL AFFAIRS, NORTH AMERICA
DIASORIN INCORPORATED
1951 NORTHWESTERN AVENUE,
STILLWATER, MN 55082, US

Re: EUA170003/A001
Trade/Device Name: LIAISON XL Zika Capture IgM Assay
Dated: October 26, 2017
Received: October 27, 2017

Dear Ms. Meyer:

This is to notify you that your request to update the Instructions for Use for the LIAISON XL Zika Capture IgM Assay to: (1) improve the overall clarity of the procedural steps involved in the proper handling of the conjugates provided with the kit, (2) add a section on conditions of authorization for the laboratory to align with latest EUA requirements, and (3) include the 95% confidence interval for the negative percent agreement, 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 LIAISON XL Zika Capture IgM Assay issued April 5, 2017.

Sincerely yours,

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