LAURA ROSE, REGULATORY AFFAIRS TEAM LEAD,  
DIVISION OF PREPAREDNESS AND EMERGING INFECTIONS  
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)  
1600 CLIFTON RD. NE,  
MS-C18 DIVISION OF PREPAREDNESS AND EMERGING INFECTIONS,  
ATLANTA, GA 30333 US  

December 6, 2016  

Re: EUA160004/A004  
   Trade/Device Name: Zika MAC-ELISA  
   Dated: November 21, 2016  
   Received: November 22, 2016  

Dear Ms. Rose:  

This is to notify you that your request to modify the Fact Sheets authorized with the Zika MAC-ELISA 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 Zika MAC-ELISA issued June 29, 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