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

Dr. SVEN CRAMER
DIRECTOR, REGULATORY AFFAIRS,
ALTONA DIAGNOSTICS GMBH
MÖRKENSTRAβE 12,
22767 HAMBURG, GERMANY

March 6, 2017

Re: EUA160009/A002
Trade/Device Name: REALSTAR® ZIKA VIRUS RT-PCR KIT U.S.
Dated: March 2nd, 2017
Received: March 6th, 2017

Dear Dr. Cramer:

This is to notify you that your request for the addition of the EDTA plasma as an authorized clinical specimen for use with the RealStar® Zika Virus RT-PCR Kit U.S. has been granted. Upon review, the analytical data submitted in EUA160009/A002 supports the addition of EDTA plasma as an authorized specimen type for testing using the RealStar® Zika Virus RT-PCR Kit U.S. We have also reviewed and concur with the results of the FDA Reference Material testing.

We are also concurring with updates made to the Instructions for Use and Fact Sheets for the RealStar® Zika Virus RT-PCR Kit U.S. that reflect the addition of EDTA plasma as an authorized specimen type and include the analytical sensitivity evaluation using the FDA Reference Materials.

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 RealStar® Zika Virus RT-PCR Kit U.S. issued May 13, 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