



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  
MÖRKENSTRASSE 12,  
22767 HAMBURG, GERMANY

October 31, 2016

Re: EUA160009/A001  
Trade/Device Name: REALSTAR® ZIKA VIRUS RT-PCR KIT U.S.  
Dated: September 15<sup>th</sup>, 2016  
Received: September 19<sup>th</sup>, 2016

Dear Dr. Cramer:

This is to notify you that your request for the addition of the MagNA Pure 96 Instrument (Roche) and the NucliSENS® easyMAG® Instrument (bioMérieux) and their respective extraction chemistry/reagents as authorized extraction methods for use with the RealStar® Zika Virus RT-PCR Kit U.S. has been granted. Upon review, the analytical and clinical data submitted in EUA160009/A001 supports the addition of the MagNA Pure 96 Instrument (Roche) and the NucliSENS® easyMAG® Instrument (bioMérieux) and their respective extraction chemistry/reagents as authorized extraction methods for use with the RealStar® Zika Virus RT-PCR Kit U.S.

We are also concurring with updates made to the Instructions for Use for the RealStar® Zika Virus RT-PCR Kit U.S. that (1) reflect the addition of the MagNA Pure 96 Instrument (Roche) and the NucliSENS® easyMAG® Instrument (bioMérieux) and their respective extraction chemistry/reagents as authorized extraction methods, and (2) involve an update to the Intended Use Statement to better reflect the current CDC guidance for U.S. Laboratories Testing for Zika Virus Infection. We are also concurring with updates made to the Healthcare Provider and Patient Fact Sheets for the RealStar® Zika Virus RT-PCR Kit U.S. 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 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