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

April 11, 2017

SUSAN SCHNEIDER, RAC,
EXECUTIVE DIRECTOR QUALITY & REGULATORY AFFAIRS
QUEST DIAGNOSTICS
2121 N. CALIFORNIA BLVD., SUITE #290
WALNUT CREEK, CA 94596

Re: EUA160007/A004
Trade/Device Name: Zika Virus RNA Qualitative Real-Time RT-PCR
Dated: April 3, 2017
Received: April 4, 2017

Dear Ms. Schneider:

This is to notify you that your request to modify the Instructions for Use labeling and the Fact Sheets authorized with the Zika Virus RNA Qualitative Real-Time RT-PCR test with the new company name, Quest Diagnostics Infectious Disease, Inc. 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 Virus RNA Qualitative Real-Time RT-PCR test issued October 7, 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