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

MICHAEL SEYMOUR, MANAGER,
REGULATORY AFFAIRS & QUALITY ASSURANCE
VIRACOR EUROFINS
1001 NW TECNOLOGY DRIVE,
LEE'S SUMMIT, MO 64086 US

February 28, 2017

Re: EUA160012/A001
Trade/Device Name: Zika Virus Real-time RT-PCR Test
Dated: February 15, 2017
Received: February 17, 2017

Dear Mr. Seymour:

This is to notify you that your request to (1) modify the Instructions for Use labeling and the Fact Sheets authorized with the Zika Virus Real-time RT-PCR Test with the new company name, Viracor Eurofins and (2) modify the Fact Sheets authorized with the Zika Virus Real-time RT-PCR Test 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 Virus Real-time RT-PCR Test issued July 19, 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