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

STACEY SPIES, REGULATORY AFFAIRS TEAM LEAD, March 1, 2017
LABORATORY PREPAREDNESS AND RESPONSE BRANCH
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
1600 CLIFTON RD. NE,
MS-C18 DIVISION OF PREPAREDNESS AND EMERGING INFECTIONS,
ATLANTA, GA 30333 US

Re: EUA160006/A004
Trade/Device Name: Trioplex rRT-PCR
Dated: February 21, 2017
Received: February 22, 2017

Dear Ms. Spies:

This is to notify you that your request to modify the Instructions for Use labeling for the CDC Trioplex Real-time RT-PCR Assay (Trioplex rRT-PCR) to include the results of the FDA Reference Material testing with the Trioplex rRT-PCR and to correct some typographical errors has been granted. The minor updates to the authorized Trioplex rRT-PCR Fact Sheets requested by FDA have also 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 Trioplex rRT-PCR issued March 17, 2016.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure