**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 6, 2017

STACEY SPIES, REGULATORY AFFAIRS TEAM LEAD,
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/A005
Trade/Device Name: Trioplex rRT-PCR
Dated: April 3, 2017
Received: April 4, 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 (1) add the QuantStudio Dx Real-Time PCR instrument for use with the Trioplex rRT-PCR, (2) correct some typographical errors, and (3) make some revisions to improve clarity, has been granted. Upon review, we concur that the analytical data submitted in EUA160006/A005 supports the addition of the QuantStudio Dx Real-Time PCR instrument for use with the Trioplex rRT-PCR.

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