**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

LAURA ROSE, REGULATORY AFFAIRS TEAM LEAD, January 12, 2017
DIVISION OF PREPAREDNESS AND EMERGING INFECTIONS
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/A003
Trade/Device Name: Trioplex rRT-PCR
Dated: December 02, 2016
Received: December 06, 2016

Dear Ms. Rose:

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) clarify the volume of lysis buffer preferred for use with the authorized easyMAG extraction instrument, (2) the addition of a singleplex reaction option for the Trioplex rRT-PCR, and to (3) clarify the expected positive control values/ranges in the Trioplex Positive Control package insert, has been granted. Upon review, we concur that the data submitted in EUA160006/A003 supports the addition of a singleplex reaction option for the Trioplex rRT-PCR. We also concur with the related updates of the Instructions for Use for the Trioplex rRT-PCR and the clarifications made to the Trioplex Positive Control package insert. 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., PhD.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure