U.S. FOOD & DRUG ADMINISTRATION

February 26, 2021

Jorge Muñoz-Jordán PhD, Team Lead,
Diagnostics and Research, Dengue Branch
Centers for Disease Control and Prevention (CDC)
1324 Canada Street, San Juan, PR 00920

Re: EUA160006/S002
Trade/Device Name: Trioplex Real-time RT-PCR Assay
Dated: October 27, 2020
Received: October 27, 2020

Dear Dr. Muñoz-Jordán:

This is to notify you that your request to update the Instructions for Use (IFU), Package Insert, and product labels of the Trioplex Real-time RT-PCR Assay to; (1) update the shelf-life stability for the CDC Trioplex rRT-PCR Primer and Probe Set and the CDC Trioplex Real-time RT-PCR Positive Control Set reagents and (2) update the contact information, is granted. Upon review, we concur that the data and information submitted in EUA160006/S002 supports the requested updates to the Trioplex Real-time RT-PCR Assay. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Trioplex Real-time RT-PCR Assay issued on March 17, 2016.

Sincerely yours,

_____

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov