



October 8, 2019

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CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
1600 CLIFTON RD. NE,
ATLANTA, GA 30333, US

Re: EUA140008/A006
Trade/Device Name: CDC Ebola Virus NP Real-time RT-PCR Assay
Dated: August 13, 2019
Received: August 16, 2019

Dear Dr. Spiropoulou:

This is to notify you that your request to modify the Healthcare Provider and Patient Fact Sheets for the Centers for Disease Control and Prevention (CDC) Ebola Virus NP Real-time RT-PCR Assay that reflect changes to the CDC testing algorithm and updated epidemiological information concerning Ebola virus disease (EBV) has been granted. By submitting this amendment 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 CDC Ebola Virus NP Real-time RT-PCR Assay issued on March 2, 2015.

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