



October 8, 2019

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TEAM LEAD, MOLECULAR PATHOGENESIS AND THERAPEUTICS  
VIRAL SPECIAL PATHOGENS BRANCH  
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)  
1600 CLIFTON RD. NE,  
ATLANTA, GA 30333, US

Re: EUA140007/A006  
Trade/Device Name: CDC Ebola Virus VP40 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 VP40 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 VP40 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