Fact Sheet for Health Care Providers: Interpreting CDC Ebola Virus NP Real-Time RT-PCR (EBOV NP rRT-PCR) Assay Results

October 13, 2014

Dear Health Care Provider:

You are receiving this Fact Sheet because the U.S Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to authorize the use of the Centers for Disease Control and Prevention (CDC) EBOV NP rRT-PCR Assay with a specified instrument for the presumptive presence of Ebola virus (species *Zaire ebolavirus*) detected in whole blood, serum, plasma, and urine specimens. This assay should be performed on specimens from individuals with signs and symptoms of Ebola in conjunction with epidemiological risk factors.

FDA issued this EUA based on data submitted by CDC to FDA, and on the U.S. Secretary of Health and Human Services' (HHS) declaration that circumstances exist to justify the emergency use of *in vitro* diagnostic tests for the detection of Ebola virus. This EUA will terminate when the HHS Secretary's declaration terminates, unless FDA revokes it sooner.

Per CDC guidance, this test should be performed only on individuals with signs and symptoms of Ebola.

This Fact Sheet contains the minimum information necessary to inform you of the significant known and potential risks and benefits of the emergency use of the CDC EBOV NP rRT-PCR. For more information on this EUA, please see FDA's website (http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm).

Why is this test needed at this time?

At this time, there are no FDA-approved/cleared tests available that can detect Ebola virus in clinical specimens. Therefore, CDC has developed this test to detect Ebola virus infection in humans.

Current information about Ebola for health care workers, including case definitions and infection control guidelines, is available at http://www.cdc.gov/vhf/abroad/healthcare-workers.html. All information and guidelines, including those on Ebola virus laboratory testing, may change as we learn more about this virus. Please check CDC's Ebola website regularly for the most current information (http://www.cdc.gov/vhf/ebola/index.html).

If Ebola is suspected based on current clinical and/or epidemiological screening criteria recommended by public health authorities, the CDC EBOV NP rRT-PCR test should be ordered only to presumptively diagnose Ebola. This test is authorized for use with whole blood (EDTA), serum, plasma, and urine. As of October 6, 2014, whole blood is a priority for collection and testing. Specimens should be collected with appropriate infection control precautions for Ebola viruses following CDC guidance for case investigation and specimen collection and according to the manufacturer's instructions for the specimen collection device,

and sent to a qualified laboratory designated by CDC for analysis (http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html and http://www.cdc.gov/vhf/ebola/hcp/infection-prevention-and-control-recommendations.html).

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having Ebola. These specimens should be shipped according to the specified shipping protocol (http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html) only to a qualified laboratory designated by CDC for analysis.

What are the symptoms of Ebola?

Most patients with Ebola develop fever, severe headache, joint and muscle aches, weakness, diarrhea, vomiting, abdominal pain, and lack of appetite. Some cases also have a rash, conjunctival hemorrhage, hiccups, cough, sore throat, chest pain, difficulty breathing, difficulty swallowing, or other unexplained hemorrhage. Signs and symptoms may appear any time from 2 to 21 days after exposure to Ebola virus, although an incubation period of 8-10 days is typical.

Public health officials have determined that Ebola virus has the potential to spread to the United States and pose risks for the public health. The first imported Ebola case in the U.S. was identified on September 30, 2014. All Ebola cases confirmed as of September 2014 have been directly or indirectly linked through residence in or travel to African countries that are involved in the current Ebola virus epidemic.

What are the known and potential risks and benefits of the EBOV NP rRT-PCR?

Besides minimal potential discomfort during specimen collection, there is a very small risk that the test result reported is incorrect (see next paragraphs for more information). The benefit of having this test is that the results of this test, along with other information, can help with patient management and help prevent the spread of the virus.

What does it mean if the specimen tests positive for Ebola virus?

A positive test result from the EBOV NP rRT-PCR Assay indicates that RNA from Ebola virus was detected, and the patient is presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiologic data in making a final diagnosis and patient management decisions. For information on Ebola and guidelines on patient management, please refer to http://www.cdc.gov/vhf/ebola/index.html.

The CDC EBOV NP rRT-PCR Assay has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include any or all of the following: a recommendation for quarantine of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends, the ability to work, the impaired ability to detect and receive appropriate medical care for the true infection causing the symptoms, unnecessary prescription of a

treatment or therapy, or other unintended adverse effects. Any positive test result for Ebola should be immediately reported to and discussed with your appropriate public health authorities.

What does it mean if the specimen tests negative for Ebola virus?

A negative test presumes that Ebola virus RNA was not present in the specimen at the detection level of the assay. However, negative results do not rule out Ebola, and should not be used as the sole basis for treatment or other patient management decisions. The clinical features of the illness and the type and risk of exposure are the keys to making patient management and isolation decisions. A negative EBOV NP rRT-PCR Assay test result should not be interpreted as demonstrating that the patient does not have Ebola, particularly if it has only been a few days since the onset of symptoms. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate Ebola is likely, and diagnostic tests for other causes of hemorrhagic illness are negative. Risks to a patient of a false negative result include: delayed treatment, potential lack of treatment, or stopping treatment too soon. If Ebola is suspected by exposure history together with clinical findings, re-testing should be considered in consultation with public health authorities.

Reporting Adverse Events

You should report any adverse events, including problems with test performance or results, to MedWatch at www.fda.gov/medwatch, by submitting a MedWatch Form 3500 (available at http://www.fda.gov/medwatch/safety/FDA-3500_fillable.pdf) or by calling 1-800-FDA-1088.

Give patients the Fact Sheet for Patients: Understanding Results from the CDC EBOV NP rRT-PCR assay.

Contact Information for the Manufacturer:
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Any significant new findings observed during the course of the emergency use of the EBOV NP rRT-PCR Assay will be made available at http://www.cdc.gov/vhf/ebola/outbreaks/guinea/whats-new.html.