

Fact Sheet for Health Care Providers: Interpreting RealStar[®] Ebolavirus RT-PCR Kit 1.0 Results

November 10, 2014

Dear Health Care Provider:

If you have received this Fact Sheet, it is because the U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to authorize the use of the altona Diagnostics GmbH RealStar[®] Ebolavirus RT-PCR Kit 1.0 with specified instruments to test for the presumptive detection of Ebola virus (including Ebola Zaire virus detected in the West Africa outbreak in 2014) in EDTA plasma specimens from individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors.

FDA issued this EUA based on data submitted by altona Diagnostics GmbH 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.

This test should be performed only on individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors.

The information in this Fact Sheet is the minimum necessary to inform you of the significant known and potential risks and benefits of the emergency use of the RealStar[®] Ebolavirus RT-PCR Kit 1.0. For more information on this EUA, please see FDA's website at <http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm>.

Why is this test needed at this time?

At this time, no FDA-approved/cleared tests that can detect Ebola Zaire virus (detected in the West Africa outbreak in 2014) in clinical specimens are available. altona Diagnostics GmbH has developed the RealStar[®] Ebolavirus RT-PCR Kit 1.0 to detect Ebola virus (including Ebola Zaire virus detected in the West Africa outbreak in 2014) infections in the specified population.

If infection with Ebola Zaire virus (detected in the West Africa outbreak in 2014) is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, the RealStar[®] Ebolavirus RT-PCR Kit 1.0 should be ordered only to presumptively diagnose Ebola virus (including Ebola Zaire virus detected in the West Africa outbreak in 2014) infection. This test is authorized for use with EDTA plasma. Specimens should be collected with appropriate infection control precautions for Ebola viruses, according to instructions for the specimen collection device.

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having Ebola virus infection. These specimens should be shipped for analysis according to the specified shipping protocol only to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high complexity tests.

Current information about Ebola virus disease for health care workers, including case definitions and infection control, is available in the guideline, *Infection Control for Viral Hemorrhagic Fevers in the African Health Care Setting*, developed by the U.S. Centers for Disease Control and Prevention (CDC) in conjunction with the World Health Organization (WHO) and found 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 continue to learn more about this virus. Please check the CDC Ebola website regularly for the most current information (<http://www.cdc.gov/vhf/ebola/index.html>).

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

A positive test result from the RealStar® Ebolavirus RT-PCR Kit 1.0 indicates that the patient is presumptively infected with Ebola virus (including Ebola Zaire virus detected in the West Africa outbreak in 2014). The test does not indicate the stage of infection, nor does it distinguish between different Ebola virus species. Laboratory test results should always be considered in the context of clinical observations and epidemiologic data in making a final diagnosis.

The RealStar® Ebolavirus RT-PCR Kit 1.0 has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, the patient may be placed in isolation or in contact with other potentially infected/infected patients. While isolation or quarantine measures may likely already be in place for symptomatic persons meeting the case definition, there is a chance that quarantine may also be used for asymptomatic persons who test positive. All laboratories using this test must follow the recommended or standard confirmatory testing and reporting guidelines.

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

A negative test presumes that Ebola virus (including Ebola Zaire virus detected in the West Africa outbreak in 2014) was not present at the detection level of the assay. However, negative results do not preclude Ebola virus infection, 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 RealStar® Ebolavirus RT-PCR Kit 1.0 result should not be interpreted as demonstrating that the patient does not have Ebola virus infection. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that Ebola virus infection is likely, and diagnostic tests for other causes of illness are negative.

Reporting Adverse Events

Any adverse events should be sent to the following email address:
support@altona-diagnostics.com

Give patients the *Fact Sheet for Patients: Understanding Results from the RealStar® Ebolavirus RT-PCR Kit 1.0*.

Contact Information for Instrument Manufacturers:

ABI Prism® 7500 SDS and 7500 Fast SDS
Applied Biosystems
850 Lincoln Centre Drive
Foster City, CA 94404
USA
Phone: 1-650-638-5800 | Toll Free: 1-800-327-3002

LightCycler® 480 Instrument II
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50414
Indianapolis, IN 46250-0414
USA
Phone: 1-800-262-4911

CFX96™ system/Dx real-time system
BIO-RAD
Life Science Research
2000 Alfred Nobel Drive
Hercules, CA 94547
USA
Phone: 1-510-741-1000 | Toll Free: 1-800-424-6723

Contact Information for Technical Assistance for the RealStar® Ebolavirus RT-PCR Kit 1.0:

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Health care providers will be contacted by altona Diagnostics GmbH in the event of any significant new findings observed during the course of the emergency use of the RealStar® Ebolavirus RT-PCR Kit 1.0.