Fact Sheet for Health Care Providers: Interpreting LightMix® Ebola Zaire rRT-PCR Test Results

December 23, 2014

Dear Health Care Provider:

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to authorize the use of the LightMix® Ebola Zaire rRT-PCR Test with specified instruments to test for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) in EDTA whole blood or TriPure-inactivated whole blood 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 Roche Diagnostics 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 LightMix® Ebola Zaire rRT-PCR Test. 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. Roche Diagnostics, together with TIB MOLBIOL GmbH, has developed the LightMix® Ebola Zaire rRT-PCR Test 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 LightMix® Ebola Zaire rRT-PCR Test should be ordered only to presumptively diagnose Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection. This test is authorized for use with EDTA whole blood or TriPure-inactivated blood specimens. 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 or to similarly qualified non-U.S. laboratories.

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 LightMix® Ebola Zaire rRT-PCR Test indicates that the patient is presumptively infected with 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 Zaire virus species. Laboratory test results should always be considered in the context of clinical observations and epidemiologic data in making a final diagnosis.

The LightMix® Ebola Zaire rRT-PCR Test 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 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, public health, 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 LightMix® Ebola Zaire rRT-PCR Test 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 reported to the following:

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250-0457
USA
Telephone: Roche Response Center 1-800-526-1247

Give patients the **Fact Sheet for Patients: Understanding Results from the LightMix® Ebola Zaire rRT-PCR Test.**

Contact Information for Instrument Manufacturers:
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250-0457
USA
Telephone Roche Response Center: 1-800-526-1247

Contact Information for Technical Assistance for the
LightMix® Ebola Zaire rRT-PCR Test.

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250-0457
USA
Telephone Roche Response Center: 1-800-526-1247

Health care providers will be contacted by Roche Diagnostics in the event of any significant new findings observed during the course of the emergency use of the LightMix® Ebola Zaire rRT-PCR Test.