



Zika Test from Quest Diagnostics Authorized by the FDA for Emergency Use

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First Test from a Commercial Lab to Receive Emergency Use Authorization for Testing Patients in the United States, including Puerto Rico, for Zika Infection

MADISON, N.J., April 28, 2016 /PRNewswire/ -- Quest Diagnostics (NYSE: DGX), the world's leading provider of diagnostic information services, today announced that it has received a U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for the Zika Virus RNA Qualitative Real-Time RT-PCR test (Zika RT-PCR test). The test was developed by the reference laboratory business of Quest's Focus Diagnostics, Inc., subsidiary. The proprietary molecular test is intended for the qualitative detection of RNA from the Zika virus in human serum specimens from certain individuals.



The test is the first from a commercial laboratory provider to be granted an EUA for testing patients for Zika virus RNA. Until now, the only Zika tests authorized by the FDA under EUA were available from the CDC and were only used in qualified laboratories designated by the CDC. Quest Diagnostics plans to make the new test broadly available to physicians for patient testing, including in Puerto Rico, early in the week of May 2.

"The availability of our new molecular Zika test provides physicians broad access to a diagnostic tool for managing the Zika outbreak," said Rick L. Pesano, M.D., Ph.D., vice president, research and development, Quest Diagnostics. "Quest's expertise in molecular, infectious disease, and women's health diagnostics, and relationships with half of the country's physicians and hospitals, allow us to quickly make useful tests widely available for clinical use. This capability uniquely positions Quest to complement the response of public health laboratories for Zika outbreaks where access to FDA authorized diagnostic tests can potentially influence the quality of patient management."

The EUA authorizes qualified laboratories designated by Focus Diagnostics, Inc., and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high complexity tests, to perform the Zika RT-PCR test. This test can potentially be performed at any CLIA high-complexity laboratory in the Quest Diagnostics network, which includes several dozen CLIA high-complexity labs in the United States, including in Toa Baja, Puerto Rico. For now, only the company's Focus Diagnostics reference laboratory in San Juan Capistrano, Calif., which developed and validated the new test, will perform this test.

International and U.S. health officials have confirmed Zika infection during pregnancy can cause fetal microcephaly and other birth defects, and warned that local outbreaks in the United States are possible. Symptoms of Zika include fever, rash, joint pain, and red eyes (conjunctivitis). The CDC recommends RT-PCR testing during approximately the first seven days of symptoms onset for certain patients. A negative result does not preclude infection, and additional serological testing to evaluate the body's immune response to infection may be considered within 2-12 weeks after symptom onset.

The CDC recommends testing for individuals with symptoms suggestive of Zika infection who have traveled within the last two weeks to an area with ongoing transmission; asymptomatic pregnant women with a history of residence in or travel to areas of active Zika infection; asymptomatic pregnant women whose male sexual partners have traveled to or lived in an area of active Zika infection; and infants born to mothers who live or traveled to areas with Zika virus transmission during their pregnancy, including both molecular and serologic testing of infants who are being evaluated for evidence of a congenital Zika virus infection.

In addition, Quest Diagnostics plans to offer serological test services assuming FDA authorization of serological test kits for emergency use.

The FDA EUA for the Zika RT-PCR test is the second EUA Focus Diagnostics has received for an emerging infectious disease diagnostic test. In 2009, the company was granted the first EUA for a commercial lab test for the 2009 H1N1 influenza pandemic virus.

Focus Diagnostics, Inc., includes reference laboratory and product manufacturing businesses. Quest expects to complete the sale of the product manufacturing business to Diasorin in the second quarter of 2016, but will continue to wholly own the Focus reference laboratory business that developed the Zika RT-PCR test as well as intellectual property related to the test.

About the Zika Virus RNA Qualitative Real-Time RT-PCR Test (Zika RT-PCR test)

Zika Virus RNA Qualitative Real-Time RT-PCR test is a real-time RT-PCR test intended only for the qualitative detection of RNA from the Zika virus in human serum specimens from patients meeting Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated). Testing is limited

to qualified laboratories designated by Focus Diagnostics, Inc.

This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA and is only authorized for the duration of the declaration. Within the United States, positive results of this test must be reported to CDC. The diagnosis of Zika virus infection must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification of Zika virus. Negative results do not preclude Zika virus infection and should not be used as the sole basis for patient management decisions.

This test is intended for use by trained clinical laboratory personnel qualified by state and federal regulations who have received specific training on the use of the test in qualified laboratories designated by Focus Diagnostics, Inc., and, in the United States, certified under CLIA to perform high complexity tests.

For more information about the Zika RT-PCR test, please visit www.QuestDiagnostics.com/Zika.

About Quest Diagnostics

Quest Diagnostics empowers people to take action to improve health outcomes. Derived from the world's largest database of clinical lab results, our diagnostic insights reveal new avenues to identify and treat disease, inspire healthy behaviors and improve health care management. Quest annually serves one in three adult Americans and half the physicians and hospitals in the United States, and our 44,000 employees understand that, in the right hands and with the right context, our diagnostic insights can inspire actions that transform lives. www.QuestDiagnostics.com.

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Contacts:

Wendy Bost, Quest Diagnostics (Media): 973-520-2800

Dan Haemmerle, Quest Diagnostics (Investors): 973-520-2900

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