



This is an official
DHEC Health Advisory

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10377-DAD-05-05-2016-ZIKA

ZIKA Test Approved for Commercial Labs

Summary:

The U.S. Food and Drug Administration (FDA) has approved 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 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.

Healthcare providers in South Carolina are reminded of the statutory requirement to report all cases of suspected Zika virus disease to DHEC whether submitting tests to a commercial laboratory or to the state Bureau of Laboratories.

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 virus infection who have illness onset within two weeks of travel 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 have symptoms suggestive of Zika virus infection; and infants with microcephaly or central nervous system deficits born to mothers who lived 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. For assistance in determining if patients' clinical histories and epidemiological risk factors are consistent with Zika virus and warrant testing, health care providers should contact the DHEC Regional Epidemiology Office in their area.

The Quest Zika RT-PCR test has been authorized by FDA under an EUA and is only authorized for the duration of the declaration. When used for patients in South Carolina, positive results of this test must be reported to DHEC.

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.

Although this advisory refers to a specific commercial laboratory for information, this should not be considered an official endorsement.

Resources for Additional Information

- <http://www.cdc.gov/zika>
- <http://www.scdhec.gov/zika>

DHEC contact information for reportable diseases and reporting requirements

Reporting of Zika virus disease is consistent with South Carolina Law requiring the reporting of diseases and conditions to your state or local public health department. (State Law # 44-29-10 and Regulation # 61-20) as per the DHEC 2016 List of Reportable Conditions available at: <http://www.scdhec.gov/Library/CR-009025.pdf>

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512).

Regional Public Health Offices – 2016

Mail or call reports to the Epidemiology Office in each Public Health Region

MAIL TO:

<p style="text-align: center;"><u>Lowcountry</u> 4050 Bridge View Drive, Suite 600 N. Charleston, SC 29405 Fax: (843) 953-0051</p>	<p style="text-align: center;"><u>Midlands</u> 2000 Hampton Street Columbia, SC 29204 Fax: (803) 576-2993</p>	<p style="text-align: center;"><u>Pee Dee</u> 145 E. Cheves Street Florence, SC 29506 Fax: (843) 661-4859</p>	<p style="text-align: center;"><u>Upstate</u> 200 University Ridge Greenville, SC 29602 Fax: (864) 282-4373</p>
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CALL TO:

<p style="text-align: center;"><u>Lowcountry</u> Berkeley, Charleston, Dorchester Phone: (843) 953-0043 Nights/Weekends: (843) 441-1091</p> <p>Beaufort, Colleton, Hampton, Jasper Phone: (843) 322-2453 Nights/Weekends: (843) 441-1091</p> <p>Allendale, Bamberg, Calhoun, Orangeburg Phone: (803) 268-5833 Nights/Weekends: (843) 441-1091</p>	<p style="text-align: center;"><u>Midlands</u> Kershaw, Lexington, Newberry, Richland Phone: (803) 576-2749 Nights/Weekends: (888) 801-1046</p> <p>Chester, Fairfield, Lancaster, York Phone: (803) 286-9948 Nights/Weekends: (888) 801-1046</p> <p>Aiken, Barnwell, Edgefield, Saluda Phone: (803) 642-1618 Nights/Weekends: (888) 801-1046</p>	<p style="text-align: center;"><u>Pee Dee</u> Chesterfield, Darlington, Dillon, Florence, Marlboro, Marion Phone: (843) 661-4830 Nights/Weekends: (843) 915-8845</p> <p>Clarendon, Lee, Sumter Phone: (803) 773-5511 Nights/Weekends: (843) 915-8845</p> <p>Georgetown, Horry, Williamsburg Phone: (843) 915-8804 Nights/Weekends: (843) 915-8845</p>	<p style="text-align: center;"><u>Upstate</u> Anderson, Oconee Phone: (864) 260-5801 Nights/Weekends: (866) 298-4442</p> <p>Abbeville, Greenwood, Laurens, McCormick Phone: (864) 227-5947 Nights/Weekends: (866) 298-4442</p> <p>Cherokee, Greenville, Pickens, Spartanburg, Union Phone: (864) 372-3133 Nights/Weekends: (866) 298-4442</p>
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For information on reportable conditions, see <http://www.scdhec.gov/Health/FHPF/ReportDiseaseAdverseEvents/ReportableConditionsInSC/>

DHEC Bureau of Disease Control
Division of Acute Disease Epidemiology
2100 Bull St • Columbia, SC 29201
Phone: (803) 898-0861 • Fax: (803) 898-0897
Nights / Weekends: 1-888-847-0902

Categories of Health Alert messages:

Health Alert	Conveys the highest level of importance; warrants immediate action or attention.
Health Advisory	Provides important information for a specific incident or situation; may not require immediate action.
Health Update	Provides updated information regarding an incident or situation; unlikely to require immediate action.
Info Service	Provides general information that is not necessarily considered to be of an emergent nature.