



More People Testing Positive for Chikungunya Virus in the U.S., Finds Study at ICAAC 2014

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Clinical testing volume and positivity rate both grew after the first case of the infectious disease spread to Western Hemisphere this year

MADISON, N.J., Sept. 8, 2014 /PRNewswire/ -- A growing number of patients in the United States are being tested – and testing positive – for the mosquito-borne chikungunya virus, according to a study presented at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in Washington, D.C. The study, by scientists from Quest Diagnostics (NYSE: DGX), the world's leading provider of diagnostic information services, is believed to be the first to characterize clinical test-ordering patterns and the positivity rate for the chikungunya virus in patients in the United States tested through a commercial clinical laboratory since an outbreak in the Caribbean in late 2013 heightened concerns of the possible spread of the virus to North America.



Quest Diagnostics, through the reference laboratory of its Focus Diagnostics business, was the first, and continues to be the only, commercial clinical laboratory in the United States to provide antibody and molecular testing for the chikungunya virus in the United States.

"Chikungunya is currently not a major health threat in the United States, and the real risk of contracting the virus at this time is exceedingly small unless traveling to an area of an active outbreak without proper mosquito protection," said lead author Hollis Batterman, M.D., medical director, for Quest's Focus Diagnostics clinical laboratory. "Our research is important because it provides insights into the strengths and limitations of clinical diagnostics to diagnose the infection. With these insights, public health authorities and the medical community will be better positioned to reliably identify infected patients, provide appropriate supportive care and differentiate from other infections, such as dengue fever, that can have a similar clinical presentation."

Chikungunya is an infectious disease that can cause fever, rash and/or painful joints. Long endemic in parts of Asia and Africa, laboratory-confirmed cases of the disease in the United States have, until recently, been limited to individuals who had contracted the virus in Africa or Asia. In late 2013, chikungunya virus was found for the first time in the Western Hemisphere. Locally acquired cases were identified for the first time in Puerto Rico and the U.S. Virgin Islands in April 2014 and in Florida in July 2014.

As of September 2, 2014, a total of 758 chikungunya virus disease cases have been reported from U.S. states to ArboNET, the national surveillance system for arthropod-borne diseases. This compares to an average of 28 people annually to test positive for recent Chikungunya virus infection between 2006-2013 in the United States, according to the U.S. Centers for Disease Control and Prevention (CDC).

Early symptoms of chikungunya can mimic other infectious diseases, including dengue fever. While chikungunya is rarely fatal, dengue can be, and reliable diagnosis is necessary for appropriate treatment. There is currently no standard treatment for chikungunya other than supportive care.

Study finds volume of testing and positivity rate increased in recent months

Clinical laboratory testing for chikungunya virus may involve molecular reverse transcription polymerase chain reaction (RT-PCR), which identifies the RNA of the virus, and immunoassays, which assess blood-serum levels of the antibodies Immunoglobulin M and G (IgM and IgG). Focus Diagnostics, which has a record of being the first commercial entity to offer clinical tests for emerging infectious diseases, such as the 2009 H1N1 virus, introduced its PCR and IgG and IgM tests for chikungunya in 2008. The lab-developed tests were validated and are provided through the Focus Diagnostics reference laboratory in Cypress, Calif. Physicians and hospitals can order the test services through Quest Diagnostics and Focus Diagnostics.

For the study, a team of medical experts at Quest Diagnostics and its Focus Diagnostics business analyzed de-identified results of RT-PCR and IgG/IgM tests for chikungunya ordered by clinicians between January 1 and August 2, 2014.

Key findings:

- Volume of tests increased over the summer. The investigators determined that 2,947 patient samples were tested for antibodies to the virus by Focus Diagnostics clinical laboratory between January 1 and August 2, 2014. Of this total, 82% (2,402) were tested in June and July, suggesting a surge in test volume over the summer. Another 589 RT-PCR tests were also performed on patients. Eighty eight specimens tested by both methods were also ordered and performed.
- One in five patients tested for antibodies were positive for the virus. Six hundred and forty two specimens, or about 22% of the total tested for antibodies, were IgG and/or IgM positive, suggesting a diagnosis of chikungunya.

- **Most patients underwent antibody testing well after initial infection.** Sixteen percent of specimens exhibited an IgG positive/IgM positive antibody pattern, compared to 5% of specimens that were IgG negative/IgM positive. In addition, the rate of IgG/IgM positive specimens increased since June. These findings suggest that most patients were tested well after initial infection with the virus.

The investigators also determined that of 589 specimens tested by RT-PCR, 168 – or nearly one in three (28%) – were positive for the chikungunya virus. All positive PCR tests were performed during or after April 2014, possibly because of increased awareness of chikungunya infection and PCR's role in diagnosing early infection. RT-PCR is helpful for detecting the virus within the first week of infection, but less reliably afterward. According to the CDC, individuals suspected of having chikungunya should be protected from additional mosquito exposure during the first week of illness to reduce the risk of further transmission.

The study's researchers did not have access to medical records to corroborate test results with clinical diagnosis by a physician. While a small percentage of specimens tested were from Puerto Rico and the U.S. Virgin Islands, where chikungunya is active, the vast majority were from specimens originating in the continental U.S. The investigators were not able to confirm if patients who tested positive were infected locally within the continental United States or as a result of travel to locations where chikungunya or mosquitoes that carry the virus are active.

"Our findings suggest that PCR and antibody testing should be considered in anyone with a compatible clinical syndrome who has traveled to or lives in areas with the species of mosquitos that carry the virus. The majority of seropositive samples were IgG/IgM positive, suggesting that most patients were tested later in the onset of infection. In the absence of PCR testing, antibody IgG/IgM patterns may be useful to infer onset of illness and potential risk of transmission if bitten by mosquitoes," Dr. Batterman said.

About Quest Diagnostics

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