# U.S. FDA Grants Abbott The First Commercial Authorization For A Molecular Test To Detect Zika Virus Using Whole Blood

- FDA expands emergency use authorization for Abbott Real*Time* ZIKA molecular test beyond previous authorization to identify Zika using serum, plasma, and urine only

ABBOTT PARK, Ill., Feb. 2, 2017 /PRNewswire/ -- Abbott (NYSE: ABT) announced today that the U.S. Food and Drug Administration (FDA) has authorized its molecular test, the Abbott RealTi*m*e ZIKA test, to detect Zika virus in whole blood (when collected alongside a patient-matched serum or plasma sample) for emergency use. This is the first molecular test made by a commercial manufacturer authorized to detect Zika in whole blood samples, which is significant since recent research suggests Zika virus can be detected in whole blood for a longer period of time (up to two months) and at higher levels versus testing with serum and urine sample types.[1,2,3]

"Diagnosing a Zika infection can be challenging, especially since people might not have any symptoms or only have mild symptoms that last a few days," said John Hackett, Ph.D., divisional vice president, applied research and technology, Diagnostics Products, Abbott. "Abbott's molecular test may provide the ability to identify the active virus over a longer time period with whole blood and could provide a more accurate diagnosis. Our test can also distinguish Zika from other viruses such as dengue or chikungunya, which helps doctors make informed diagnoses to help people get back to better health."

The Abbott RealTi*m*e ZIKA test is designed for use on the *m*2000 RealTi*m*e System – the company's molecular diagnostics instrument used in hospital and reference labs in the U.S. and around the world. Providing results within five to seven hours, the test is highly sensitive to detect if someone is infected with Zika. It is also automated, allowing people who work in the lab to be more efficient and spend less time preparing and handling samples, reducing the chances of error and increasing speed to diagnosis.

**ABBOTT R&D EFFORTS RELATED TO ZIKA**

Abbott has several additional R&D projects underway (currently in development and not yet FDA approved, cleared or authorized) to help address testing needs related to the current Zika outbreak.

- Today's existing tools to detect Zika and other tropical diseases are laboratory-based and require reliable power sources, but often, testing is needed in remote areas where there are no labs. To address this issue, the U.S. Defense Advanced Research Projects Agency (DARPA) awarded a contract to Abbott to develop a testing panel for Zika and multiple tropical fever pathogens for use on a mobile platform to meet the needs of testing in rural and remote areas.
- Another issue to address is the development of serology tests that do not cross-react with other tropical disease antibodies. Through a grant from the U.S. Agency for International Development (USAID), Abbott is exploring the development of a serology test to solve this challenge.

According to the World Health Organization, Zika remains a significant enduring public health challenge.[4] More than 4,800 people who live in the U.S. have been infected with Zika (primarily from travel outside the U.S.), and more than 35,000 people are infected and reside in U.S. territories, mainly in Puerto Rico.[5] Zika virus is primarily spread to people through bites from infected mosquitoes but can also be passed from pregnant women to their fetuses or through sexual transmission.[6] It is important to quickly and accurately determine whether someone has a Zika infection to track and potentially help prevent the spread of the virus. For more information, visit the CDC website at http://www.cdc.gov/zika/.

**ADDITIONAL DETAILS ABOUT ABBOTT'S EMERGENCY USE AUTHORIZATION**

The U.S. Food and Drug Administration (FDA) modified the EUA for Abbott's RealTi*m*e ZIKA molecular test that can detect Zika virus RNA in serum, plasma, whole blood (EDTA) and urine (whole blood and urine collected alongside a patient-matched serum or plasma specimen) from individuals meeting the Centers for Disease Control and Prevention (CDC) Zika virus clinical and/or CDC Zika virus epidemiological criteria. The Abbott Realti*m*e ZIKA assay has not been FDA-cleared or approved and is only authorized for use for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus or diagnosis of Zika virus infection or both, unless the authorization is terminated or revoked sooner. This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens.

**About Abbott**

At Abbott, we're committed to helping you live your best possible life through the power of health. For more than 125 years, we've brought new products and technologies to the world -- in nutrition, diagnostics, medical devices and branded generic pharmaceuticals -- that create more possibilities for more people at all stages of life. Today, 94,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve.

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[1] Lustig Y, Mendelson E, Paran N, Melamed S, Schwartz E. Detection of Zika virus RNA in whole blood of imported Zika virus disease cases up to 2 months after symptom onset, Israel, December 2015 to April 2016. Euro Surveill. 2016;21(26):pii=30269.

DOI: http://dx.doi.org/10.2807/1560-7917.ES.2016.21.26.30269

[2] Murray KO, Gorchakov R, Carlson AR, Berry R, Lai L, Natrajan M, et al. Prolonged Detection of Zika Virus in Vaginal Secretions and Whole Blood. Emerg Infect Dis. 2017;23(1):99-101. https://dx.doi.org/10.3201/eid2301.161394

[3] Most Zika molecular tests currently available use plasma, serum or urine samples only, except for the Centers for Disease Control and Prevention's Trioplex Real-time RT-PCR assay, which can also use whole blood. http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM491592.pdf

[4] World Health Organization Statement: Fifth meeting at the Emergency Committee under the International Health Regulations regarding microcephaly, other neurological disorders and Zika virus. Website: http://www.who.int/mediacentre/news/statements/2016/zika-fifth-ec/en/. Accessed: January 10, 2017.

[5] Case Counts in the U.S. Centers for Disease Control and Prevention. Website:www.cdc.gov/zika/geo/united-states.html. Accessed January 9, 2017.

[6] Transmission & Risks. U.S Centers for Disease Control and Prevention. Website: https://www.cdc.gov/zika/transmission/index.html. Accessed January 19, 2017.

SOURCE Abbott

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