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FDA Expands Use Authorization for Hologic's Aptima® Zika Virus Assay to Use with Urine Sample

Hologic, Inc. (Nasdaq: HOLX) has announced that the U.S. Food and Drug Administration (FDA) has expanded the emergency use authorization (EUA) for the company's Aptima® Zika virus diagnostic assay to be used with urine samples (collected alongside patient-matched serum or plasma specimens).

Hologic's Zika virus assay was authorized for emergency use with serum and plasma (blood) samples in June 2016. Its new use with urine samples lengthens the time period during which patients can be tested for Zika from seven days to 14 days following symptoms, as recommended by the U.S. Centers for Disease Control and Prevention (CDC).

"This action by FDA is significant because it gives many more people the opportunity to be tested with our highly sensitive assay," said Tom West, Division President of Diagnostic Solutions at Hologic. "In particular, this expanded indication allows us to better serve public health labs, increasing access to more people to detect and diagnose more disease."

The Aptima Zika Virus assay runs on Hologic's Panther® system, a market-leading, integrated platform that fully automates all aspects of nucleic acid amplification testing. By reducing hands-on time, the Panther system helps to minimize labor needs and the potential for manual errors. The Aptima Zika Virus assay is available for use in all 50 states, Puerto Rico and U.S. territories.

"We are driven to provide solutions to some of society's most urgent unmet health needs," said Steve MacMillan, Chairman, President and Chief Executive Officer of Hologic. "The suspension of the Medical Device Excise Tax enabled us to make additional investments in research and development and accelerate availability of this critically important test."

The Aptima Zika Virus assay is a molecular diagnostic tool for the qualitative detection of RNA from Zika virus in human specimens. The Aptima Zika Virus assay has not been FDA cleared or approved, and is only authorized for use for the duration of the FDA's authorization of the emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection.

The Aptima Zika Virus assay is designed to be used in individuals meeting CDC's 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), by laboratories in the United States that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories.

Source & Image Credit: Hologic

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