



NEWS RELEASE

FDA Grants Emergency Use Authorization for Hologic's Aptima® Zika Virus Assay

6/17/2016

New Diagnostic Test for the Detection of the Zika Virus Now Available for Use on Fully Automated Panther System
MARLBOROUGH, Mass., June 17, 2016 /PRNewswire/ -- Hologic, Inc. (Nasdaq: HOLX) announced today that the U.S. Food and Drug Administration (FDA) granted emergency use authorization for the company's new, diagnostic assay for Zika virus infection. The Aptima® Zika Virus assay is a molecular diagnostic tool for the qualitative detection of RNA from Zika virus in human serum and plasma specimens. The Aptima Zika Virus 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 and/or diagnosis of Zika virus infection.

The Aptima Zika Virus assay runs on the Hologic Panther® system, a market-leading, integrated platform that fully automates all aspects of nucleic acid amplification testing. The Panther system substantially reduces hands-on time for laboratories, minimizing the labor required and the potential for manual errors. The Aptima Zika Virus assay will be available for use in all 50 states, Puerto Rico and U.S. territories, expanding the number of public and private labs that can test for the virus.

"We want to ensure that during this critical summer season and beyond, those at risk for the Zika virus have an opportunity to be tested with a highly sensitive assay," said Edward Evantash, M.D., medical director and vice president, Medical Affairs at Hologic. "Our new test will help to ensure accurate diagnoses and reduce subsequent spread of the infection."

The Aptima Zika Virus assay is designed to be used in individuals 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), 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.

"Our new Aptima Zika Virus assay is another reflection of our commitment to developing cutting-edge diagnostics that provide solutions for urgent unmet needs," said Tom West, division president, Diagnostic Solutions at Hologic. "Running the Aptima Zika Virus assay on the Panther system will offer quick results to epidemiologists and laboratories, which is likely to help both healthcare providers and their patients."

To learn more about the Aptima Zika Virus assay, please visit www.hologic.com/zika.

About Zika Virus

According to the **World Health Organization**, Zika virus is an emerging mosquito-borne virus that was first identified in rhesus monkeys in Uganda in 1947 and in humans in 1952. Outbreaks of Zika virus disease have been recorded in Africa, the Americas, Asia and the Pacific. Zika virus is transmitted to people primarily through the bite of an infected mosquito from the Aedes genus, mainly Aedes aegypti in tropical regions. This is the same mosquito that transmits dengue, chikungunya and yellow fever. Zika virus can also be transmitted through sexual contact and transmission by blood transfusion and perinatal transmission are currently being investigated. The U.S. Centers for Disease Control and Prevention is also investigating the link between Zika virus and Guillain-Barré syndrome, a serious and sometimes fatal muscle-wasting disease, and has stated that Guillain-Barré syndrome is "very likely triggered" by Zika in a small proportion of infections.^{1,2}

According to the **U.S. Centers for Disease Control and Prevention**, local mosquito-borne transmission of Zika virus in U.S. territories has been reported in the Commonwealth of Puerto Rico, the U.S. Virgin Islands, and American Samoa. No local mosquito-borne Zika virus disease cases have been reported in U.S. states, but there have been travel-associated cases.

About Hologic

Hologic, Inc. is a leading developer, manufacturer and supplier of premium diagnostic products, medical imaging systems and surgical products. The company's core business units focus on diagnostics, breast health, GYN surgical, and skeletal health. With a unified suite of technologies and a robust research and development program, Hologic is dedicated to The Science of Sure. For more information on Hologic, visit www.hologic.com.

Hologic Forward-Looking Statements

This press release may contain forward-looking information that involves risks and uncertainties, including statements about the use of Hologic's diagnostic products. There can be no assurance these products will achieve

the benefits described herein or that such benefits will be replicated in any particular manner with respect to an individual patient. The actual effect of the use of the products can only be determined on a case-by-case basis depending on the particular circumstances and patient in question. In addition, there can be no assurance that these products will be commercially successful or achieve any expected level of sales. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any such statements presented herein to reflect any change in expectations or any change in events, conditions or circumstances on which any such statements are based.

Hologic, The Science of Sure, Aptima and Panther are trademarks (or registered trademarks) of Hologic, Inc. in the United States and/or other countries.

1 Cao-Lormeau VM, et al. Guillain-Barré syndrome outbreak associated with Zika virus infection in French Polynesia: a case-control study. Lancet [http://dx.doi.org/10.1016/S0140-6736\(16\)00562-6](http://dx.doi.org/10.1016/S0140-6736(16)00562-6).

2W. Rasmussen SA, et al. Zika Virus and Birth Defects – Reviewing the Evidence for Causality. CDC. Zika and Guillain-Barré Syndrome. <http://www.cdc.gov/zika/about/gbs-qa.html>. Updated April 14, 2016. Accessed June 1, 2016.

Hologic Investor Contact

Michael Watts

Vice President, Investor Relations and Corporate Communications

(858) 410-8588

michael.watts@hologic.com

Hologic Media Contact

Jane Mazur

Senior Director, Divisional Communications

+1 (585) 355-5978

jane.mazur@hologic.com

SOURCE Hologic, Inc.