NEWS RELEASE

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

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MARLBOROUGH, Mass., Sept. 8, 2016 /**PRNewswire**/ -- Hologic, Inc. (Nasdaq: HOLX) announced today 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.

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 perinatally and through sexual contact, and transmission by blood transfusion is a strong possibility according to the U.S. Centers for Disease Control and Prevention.1 The CDC 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.2,3

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. Local mosquito-borne Zika virus disease cases have been confirmed in Florida Miami-Dade and Broward counties4, and there have been travel-associated cases in Florida and a number of other U.S. states.

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.

1 **http://www.cdc.gov/zika/transmission/index.html**

2Cao-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**.

3W. 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.

4**http://www.floridahealth.gov/diseases-and-conditions/zika-virus**

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
(585) 355-5978
jane.mazur@hologic.com

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