FDA NEWS RELEASE

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For Immediate Release: April 8, 2011

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FDA permits marketing of first test to help diagnose dengue fever

The U.S. Food and Drug Administration today allowed marketing of the first test to help diagnose people with signs and symptoms of dengue fever or dengue hemorrhagic fever, a leading cause of illness and death in the tropics and subtropics.

The dengue virus is transmitted to humans by the bite of an infected *Aedes* mosquito. As many as 100 million people worldwide are infected by the virus each year, according to the U.S. Centers for Disease Control and Prevention (CDC).

Symptoms of dengue fever include high fever, severe headache, severe pain behind the eyes, joint pain, muscle and bone pain, rash and mild bleeding involving the nose or gums, and easy bruising.

Most reported dengue cases in the continental United States occur in people returning from travels to tourist destinations in Latin America, the Caribbean and Southeast Asia. Dengue is also endemic in the U.S. in Puerto Rico, the Virgin Islands and some U.S.-affiliated Pacific Islands. Recently, dengue outbreaks have occurred in Hawaii, Texas, and Florida.

The DENV Detect IgM Capture ELISA test detects antibodies to dengue virus in blood samples from patients who have signs and symptoms of dengue. The test will be available for use in clinical laboratories and will assist in the diagnosis of dengue, which can improve patient care and management.

The DENV Detect IgM Capture ELISA test is based on technology patented by the CDC and manufactured by Seattle-based Inbios Inc.

"Cases of dengue fever or dengue hemorrhagic fever can be potentially fatal for people who do not recognize the symptoms," said Alberto Gutierrez, Ph.D., director of the Office of In Vitro Diagnostics Device Evaluation and Safety in FDA's Center for Devices and Radiological Health. "This test will now aid health care professionals in their effort to more effectively diagnose dengue."

The FDA reviewed data for the test via the "de novo" pathway, an alternative path to market for devices that are low to moderate risk and may not require premarket approval

(PMA), but are of a new type, and therefore may not be able to be cleared in a "510(k)" premarket notification.

People who believe they have dengue should immediately contact a health care professional. There are no FDA-licensed vaccines to prevent dengue and no medicines specifically approved to treat the infection.

The test should not be used in people who do not show signs or symptoms of dengue. Diagnostic testing for dengue is complicated by the fact that an IgM antibody response to the dengue virus infection is not detectable until 3-5 days after the onset of fever, which can produce a negative test result even though a person has dengue. During this "IgM negative window" the dengue virus is present in the bloodstream.

There are currently no FDA-cleared or approved tests for direct detection of dengue virus.

This new test shows cross-reaction with other closely related viruses such as those that cause West Nile disease. However, in most patient testing situations found in the United States, a positive test result in a patient with signs or symptoms consistent with dengue should be considered presumptive evidence of dengue.

For more information:

FDA: Medical Devices
http://www.fda.gov/MedicalDevices/default.htm

FDA: Evaluation of Automatic Class III Designation (De Novo) Decision Summaries
http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHTransparency/ucm232269.htm

CDC: Dengue
http://www.cdc.gov/dengue/

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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