FDA OKs marketing of first Zika virus antibodies Dx

August 2019—The U.S. Food and Drug Administration authorized marketing of a diagnostic test to detect Zika virus immunoglobulin antibodies in human blood. The ZIKV Detect 2.0 IgM Capture ELISA (InBios, Seattle) is the first Zika diagnostic test the FDA has allowed to be marketed in the U.S.; previously, tests for detecting Zika virus IgM antibodies, including the InBios test, had been authorized only for emergency use.

The ZIKV Detect 2.0 IgM Capture ELISA is for use only in patients with clinical signs and symptoms consistent with Zika virus infection and/or who meet the CDC's Zika virus epidemiological criteria, such as history of residence in or travel to a geographic region with active Zika transmission at the time of travel.

Results of this test are intended to be used in conjunction with clinical observations, patient history, epidemiological information, and other laboratory evidence to make patient management decisions. Positive results must be confirmed by following the latest CDC guidelines for the diagnosis of Zika virus infection. Negative results may be seen in specimens collected before day four after the onset of symptoms or after the window of detectable IgM closes, and therefore do not preclude the possibility of Zika virus infection, past or present. Test results are available in about four hours.

The FDA reviewed data from a clinical study of 807 test samples and a variety of analytical studies, which demonstrated that the ZIKV Detect 2.0 IgM Capture ELISA was safe and effective at identifying IgM antibodies against Zika virus in blood. In samples from patients collected seven days or later after onset of symptoms, the InBios Zika kit correctly identified greater than 90 percent of patients confirmed positive for Zika IgM and greater than 96 percent of patients confirmed negative.

This test is not authorized by the FDA for testing blood or plasma donors.

InBios, 206-344-5821