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FDA grants marketing authorization for new Zika diagnostic test

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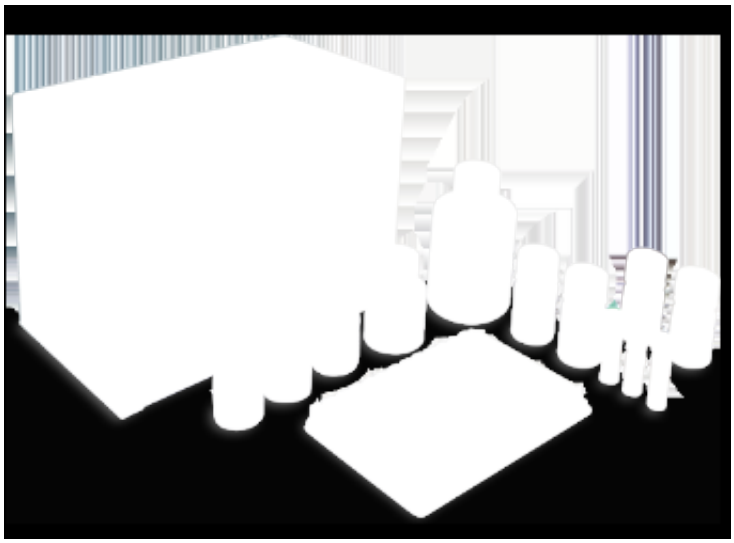
The FDA granted marketing authorization of the ZIKV Detect 2.0 IgM Capture ELISA to InBios International, Inc.



The U.S. Food and Drug Administration has authorized marketing of a diagnostic test to detect Zika virus immunoglobulin (IgM) antibodies in human blood.

The ZIKV Detect 2.0 IgM Capture ELISA 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 ZIKV Detect 2.0 IgM Capture ELISA—had been authorized only for emergency use under the FDA's Emergency Use Authorization (EUA) authority.

The ZIKV Detect 2.0 IgM Capture ELISA is designed to identify proteins (antibodies) produced by the body's immune system when it tests for Zika virus infection in the blood. IgM antibodies indicate an early immune response. 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.

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