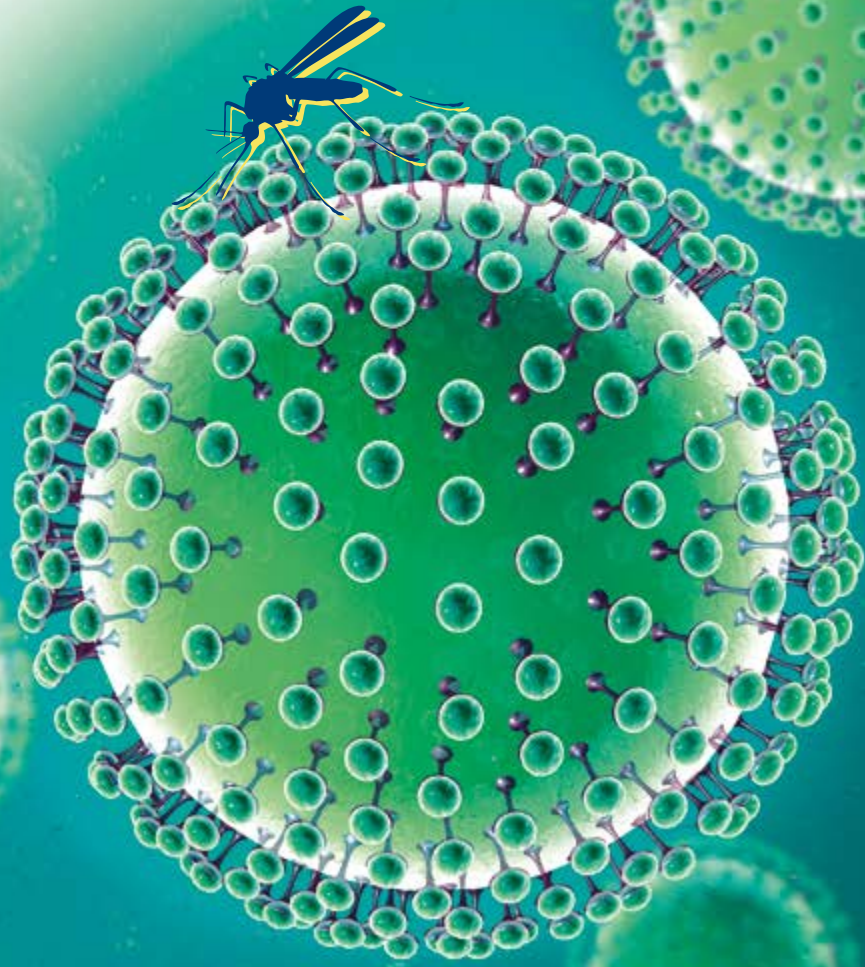


LIAISON[®] X Zika Capture IgM II

The fully automated solution for specific and accurate diagnosis of Zika acute or recent virus infection



Infectious Disease

LIAISON® XL Zika Capture IgM II

A new standard for Zika acute or recent infection diagnosis on a fully automated platform

Zika virus is a mosquito-borne flavivirus and is closely related to dengue, yellow fever, Japanese encephalitis, and West Nile viruses. Zika virus was first identified in 1947 in a sentinel monkey in the Zika forest of Uganda but did not begin spreading widely throughout the Americas until 2015. Zika virus is a disease which is spread to people primarily through the bite of an infected mosquito (*Aedes aegypti* and *Aedes albopictus*). **Most people infected with Zika virus do not have symptoms, but when present they are usually mild. Zika virus infection during pregnancy has been linked to adverse pregnancy and birth outcomes, most notably microcephaly and other serious brain anomalies. This association has resulted in an ongoing public-health emergency.**

Virus-specific IgM and neutralizing antibodies are typically present within the first week of illness and may be detectable for up to 12 weeks. Combined with patient demography and clinical findings, detection of IgM antibodies to Zika virus provides an essential tool for diagnosing and following up an acute or recent infection.

A fully automated solution with high sensitivity and specificity, evaluated in pregnant women from endemic areas

76 subjects from the Dominican Republic, including 23 pregnant women, confirmed positive for Zika virus by nucleic acid testing were positive for Zika antibodies in at least one of the serial bleeds by the LIAISON® XL Zika Capture IgM II and the comparator. Negative agreement testing included 250 subjects from an area non-endemic for Zika virus (continental United States) and 250 subjects from an area endemic for Zika virus (Dominican Republic). Of the 250 subjects from the Dominican Republic, 37 were pregnant women.

Population	LIAISON® XL Zika Capture IgM II Assay				
	Positive	Negative	Total	Negative Agreement	95% Confidence Intervals
Non-endemic (U.S)	1*	249	250	99.6%	97.8 – 99.9%
Endemic (Dominican Republic)^	5**	245	250	98.0%	95.4 – 99.1%

*Sample was negative for Zika IgM by the comparator assay.

**Samples were negative for Zika IgM by the comparator assay.

^37 pregnant subjects were included in the normal subject population and were negative.

Main features of LIAISON® XL Zika Capture IgM II

Sample Type: Serum

Assay format: CLIA qualitative capture assay

Conjugate: Recombinant Zika virus NS1 antigen

Sample Volume: 25 µL

Integral on board stability: 3 weeks

Number of tests: 100

Ordering information

LIAISON® XL Zika Capture IgM II code 317150

LIAISON® XL Zika Capture IgM II Control Set code 317151

AVAILABLE ON **LIAISON® X ONLY**

Product availability subject to required regulatory approval



The Diagnostic Specialist

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