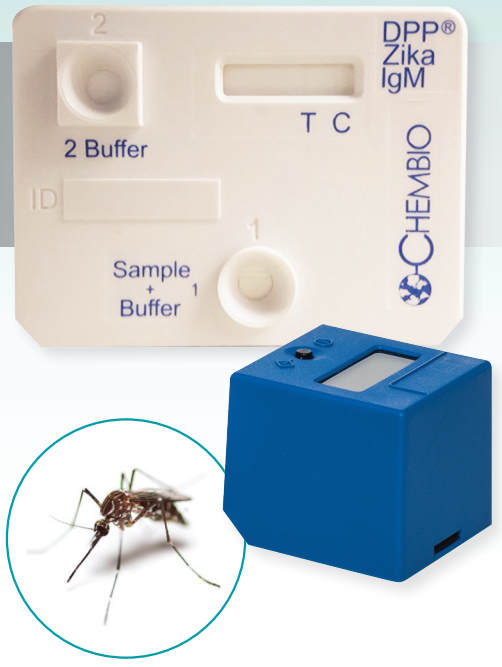
DPP® Zika IgM Assay System

The 15-minute rapid test for detecting Zika virus infection



For the detection of Zika virus IgM antibodies in fingerstick whole blood, EDTA venous whole blood, EDTA plasma and serum.

Key features

- Fast: Provides results in as little as 15 minutes
- Flexible: Detects Zika virus IgM antibodies from 8 days up to 12 weeks
- Easy to use: Provides objective results using simple, handheld digital reader (DPP® Micro Reader)

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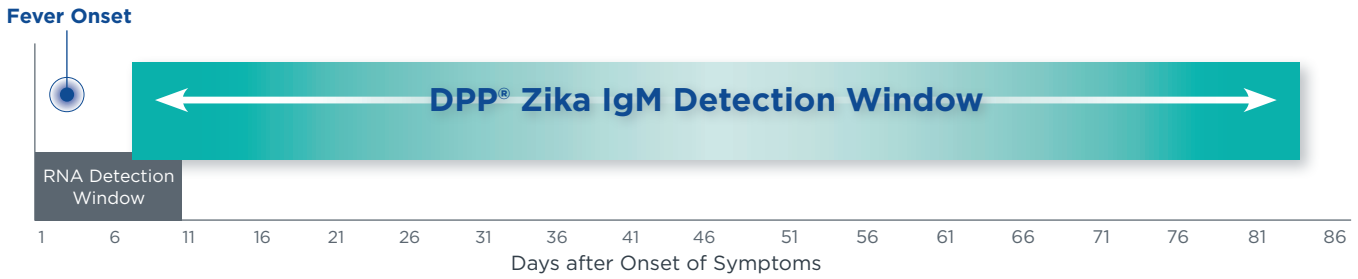
DPP® Zika IgM Assay System

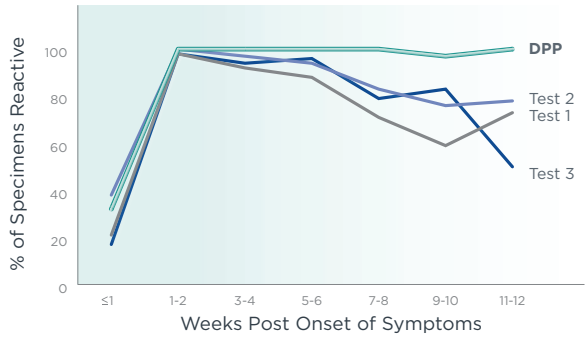
Product Performance:

Wide testing window

DPP® Zika IgM Assay System detected Zika antibodies **as early as day 8 and reliably detected for approximately 12 weeks**[1]



DPP® Zika IgM Assay System vs. laboratory-based serological assays[2]



Days Post Onset of Symptoms (weeks)	% Detected (# Reactive/Total)			
	DPP Zika IgM Assay System	Test 1	Test 2	Test 3
0-7 (≤ 1 wk)	32.1% (17/53)	20.7% (11/53)	38% (20/52)	17% (7/41)
8-83 (>1-12 wks)	99.7% (343/344)	82.8% (285/344)	90.2% (314/348)	93.3% (139/149)

Serial samples from 50 confirmed Zika-positive cases were tested using DPP and other lab-based assays.[1]

Showed equivalent specificity across all blood matrices

Matrix	% concordance with presumed negative samples
Fingerstick whole blood	100% (102/102)
EDTA venous whole blood	98% (239/244)
EDTA plasma	100% (89/89)
Serum	98% (583/594)

DPP® Zika IgM Assay System showed equivalent specificity across all blood matrices.[1]

[1]Data from package insert
[2]Authorized under EUA by FDA

ORDERING INFORMATION		
	Description	Catalog Number
	DPP® Zika IgM Assay	65-9555-0
	DPP® Zika IgM Micro Reader (required for data interpretation)	61-1070-0
	DPP® Zika IgM Control Pack	62-1001-0

- The test has not been FDA cleared or approved;
- The test has been authorized by FDA under an EUA for use by authorized laboratories;
- The text has been authorized only for the diagnosis of Zika virus infection and not for any other viruses or pathogens; and
- The test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of the Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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