

AccuSet[™] Zika Performance Panel

0845-0142 / Batch# 10245884

OVERVIEW

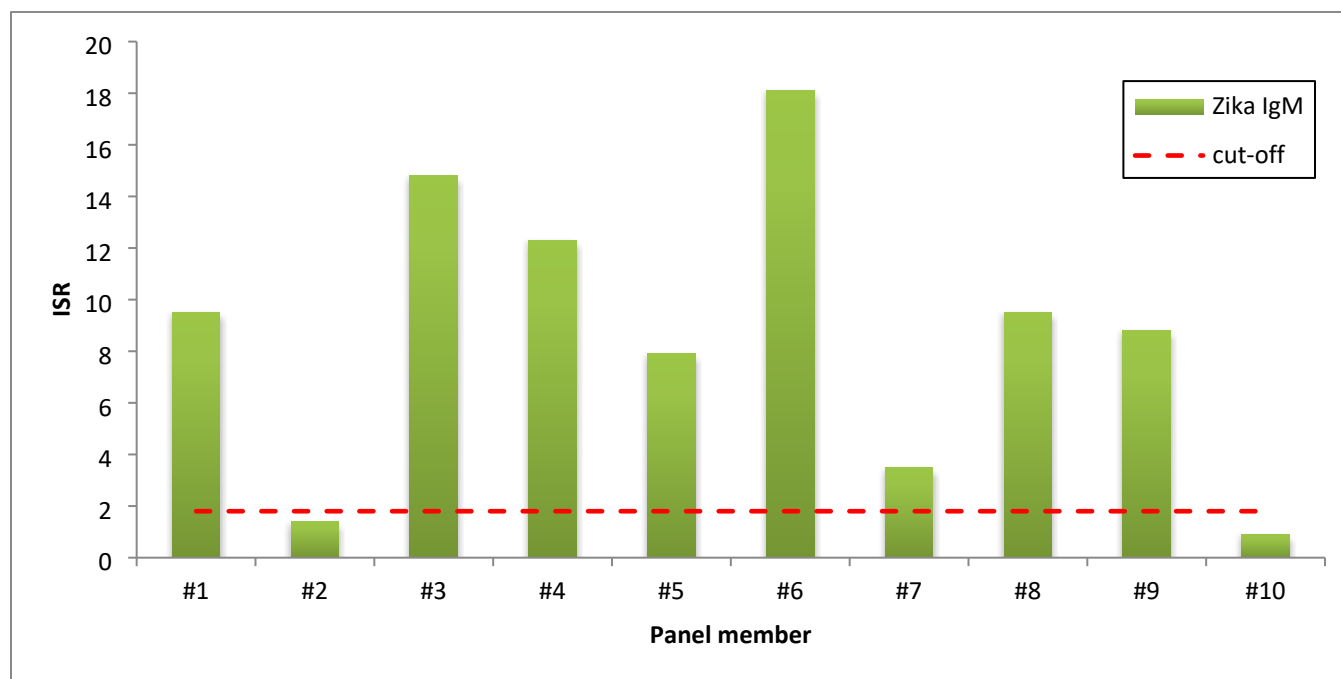
AccuSet[™] Zika Performance Panel (0845-0142) Batch# 10245884 is a 10-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to Zika infection. Each sample represents a single collection event. No preservatives were added.

Test results from available Zika assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of antibody reactivity to several Zika, Dengue, and Chikungunya assays.

For Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes. LGC SeraCare Life Sciences does not claim that others can duplicate test results exactly.

CAUTION: Potentially infectious materials. Follow Universal Precautions. The units that make up this panel were tested and found negative for anti-HIV-1/2, HBsAg and anti-HCV. This does not ensure the absence of these or other human pathogens.

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This graph demonstrates Zika IgM antibody reactivity amongst panel members utilizing test results from the InBios ZIKV Detect[™] IgM Capture ELISA.

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Performance Panel

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed date	Age	Gender	Country of Origin
01	10226463	BD309168	18-Feb-2016	44	Female	Dominican Republic
02	10231898	BD309236	29-Sep-2016	35	Female	El Salvador
03	10226469	BD309171	20-Jul-2016	65	Female	Dominican Republic
04	10226471	BD309172	28-Jul-2016	32	Male	Dominican Republic
05	10226487	BD309172	17-Aug-2016	32	Male	Dominican Republic
06	10231110	BD309166	03-Feb-2016	49	Female	El Salvador
07	10231114	BD309167	18-Jul-2016	33	Female	El Salvador
08	10231116	BD309167	05-Aug-2016	33	Female	El Salvador
09	10231118	BD309167	12-Aug-2016	33	Female	El Salvador
10	10181145	BD281919	09-Feb-2016	23	Female	Honduras

Zika/Dengue/Chikungunya RNA, Zika IgM and Plaque-Reduction Neutralization Test (PRNT)

Panel Member	Roche cobas 6800/8800 (S/CO) ¹	CDC Zika IgM (p/n) ²	CDC Zika PRNT (endpoint titration) ³
01	TND	19.0	≥1:320
02	TND	1.5	NT
03	TND	32.6	≥1:1280
04	TND	24.1	≥1:320
05	TND	15.8	≥1:40
06	TND	29.8	≥1:320
07	TND	6.3	1:80
08	TND	13.3	≥1:320
09	TND	12.2	≥1:320
10	TND	3.6	≥1:320
Test Date	27-Mar-2026	24-Feb-2017	24-Feb-2017
Test Site	RL	RL	RL
Kit Part Code	NA	NA	NA
Kit Lot No.	NA	NA	NA
Kit Exp. Date	NA	NA	NA

¹Results are reported the mean result of duplicate testing; positive/reactive results are noted in bold red.

²For results considered IgM reactive; the p/n value of the test specimen must be ≥3.0. Positive/reactive results are noted in bold red.

³Results considered positive have endpoint titrations ≥1:20. Positive/reactive results are noted in bold red.

NT = Not tested; RL = Reference Lab; NA = Not available

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Zika IgM, Zika IgG and Rapid Test

Panel Member	InBios ZIKV Detect™ IgM Capture ELISA (ISR) ^{1,3}	EuroImmun Anti-Zika IgM ELISA (s/co) ^{2,4}	EuroImmun Anti-Zika IgG ELISA (RU/mL) ^{3,4}	Dia.PRO Anti-Zika IgG ELISA (s/co) ^{2,4}	BioCan Tell Me Fast Zika IgM / IgG Rapid Test ⁴	
					Zika IgM	Zika IgG
01	9.5	0.25	>200.00	>13.0	NEG	NEG
02	1.4	0.03	128.53	11.9	NEG	NEG
03	14.8	1.68	>200.00	>13.0	NEG	NEG
04	12.3	1.02*	>200.00	>13.0	NEG	NEG
05	7.9	0.40	>200.00	>13.0	NEG	NEG
06	18.1	0.16	>200.00	>13.0	NEG	POS
07	3.5	1.00*	>200.00	11.9	NEG	POS
08	9.4	0.58	>200.00	>13.0	NEG	NEG
09	8.8	0.67	>200.00	>13.0	NEG	NEG
10	0.9	0.75	>200.00	>13.0	POS	NEG
Test Date	10-Mar-2017	16-Apr-2026	16-Apr-2026	24-Apr-2017	21-Mar-2017	
Test Site	SC	SC	SC	SC	SC	
Kit Part Code	900213-00	EI2668-9601M	EI2668-9601G	ZIKAAG.CE	B815C	
Kit Lot No.	UK1259	E250423BB	E250227AS	0816/3	BJ815C021517	
Kit Exp. Date	05-Jul-2017	22-Jul-2026	26-May-2026	30-Nov-2017	31-Jan-2019	

¹Results are reported as Immune Status Ratio (ISR); *presumptive* positive results have a value ≥ 1.80 and are noted in bold red.

²Results are reported as signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.

³Results are reported as relative units per mL (RU/mL); positive/reactive results are noted in bold red.

⁴Results are reported as the mean result of duplicate testing.

*Results are in the grayzone

SC = SeraCare; NEG = Negative; POS = Positive

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Zika IgM

Panel Member	DiaSorin LIAISON® XL Zika Capture IgM ²			
	ZIKV-M (Index) ¹	ZIKV-C (Index) ¹	Interpretation (EUA)	Interpretation (CE)
01	2.1	11.4	PR - POS	POS
02	0.4	1.3	NEG	NEG
03	3.0	12.9	PIgM – POS	POS
04	5.5	18.9	PIgM – POS	POS
05	1.9	12.9	PR – POS	POS
06	1.3	7.2	PR - POS	POS
07	12.7	3.3	PIgM – POS	POS
08	13.1	16.1	PIgM – POS	POS
09	11.4	15.3	PIgM – POS	POS
10	3.9	14.3	PIgM - POS	POS
Test Date	05-Jun-2017			
Test Site	MFG			
Kit Part Code	317130D			
Kit Lot No.	133618B			
Kit Exp. Date	27-Feb-2018			
Kit Regulatory Status	EUA, CE			

¹Results are reported as an Index value; positive/reactive results are noted in bold red.

²Results are reported as the mean result of duplicate testing.

MFG = Assay Manufacturer;

NEG = Negative; POS = Positive; PR – POS = Presumptive Recent Zika Positive; PIgM – POS = Presumptive Zika IgM Positive

EUA = Emergency Use Authorization; CE = Conformité Européenne or CE Marking

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Dengue, Chikungunya & West Nile IgM / IgG

Panel Member	InBios DENV Detect™ IgM Capture ELISA (ISR) ^{2,3}	InBios DENV Detect™ IgG ELISA (ISR) ^{2,3}	Chikungunya IgM IFA w/ Reflex to titer ⁴	Chikungunya IgG IFA w/ Reflex to titer ⁴	Focus Dx West Nile IgM Capture DxSelect™ (s/co) ^{1,2}	Focus Dx West Nile IgG DxSelect™ (s/co) ^{1,2}
01	1.48	18.09	NEG	1:640	0.0	5.1
02	1.33	14.06	NEG	1:640	0.0	4.2
03	8.35	17.88	NEG	NEG	0.2	4.0
04	7.00	21.45	NEG	NEG	0.0	4.5
05	4.38	27.50	NEG	NEG	0.0	3.9
06	6.51	17.22	NEG	NEG	0.1	4.5
07	5.54	13.31	NEG	1:2560	0.2	4.6
08	7.10	18.07	NEG	1:2560	0.1	4.8
09	7.93	15.23	NEG	1:2560	0.1	4.5
10	1.13	22.89	NEG	1:1280	4.7	4.4
Test Date	30-Mar-2026	30-Mar-2026	09-May-2017	31-Mar-2026 03-Apr-2026	16-Aug-2017	16-Aug-2017
Test Site	SC	SC	RL	RL	SC	SC
Kit Part Code	DDMS-1	DDGS-R	NA	NA	EL0300M	EL0300G
Kit Lot No.	EM6234	FA6136	NA	NA	1765N	33179
Kit Exp. Date	15-Dec-2026	05-Jan-2027	NA	NA	30-Nov-2018	30-Sep-2018

¹Results are reported as signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.

²Results are reported as the mean result of duplicate testing.

³ Results are reported as Immune Status Ratio (ISR); presumptive positive results have a value ≥ 2.84 and are noted in bold red.

⁴Results are reported as singlicate testing; positive/reactive results are noted in bold red.

SC = SeraCare ; RL = Reference Lab

The package insert for this panel can be found at www.seracare.com.

A printed copy of the package insert or data sheet may be requested by email at info@seracare.com or by phone at 508.244.6400.