AccuSet™ Zika Performance Panel

0845-0142 / Batch # 10245884

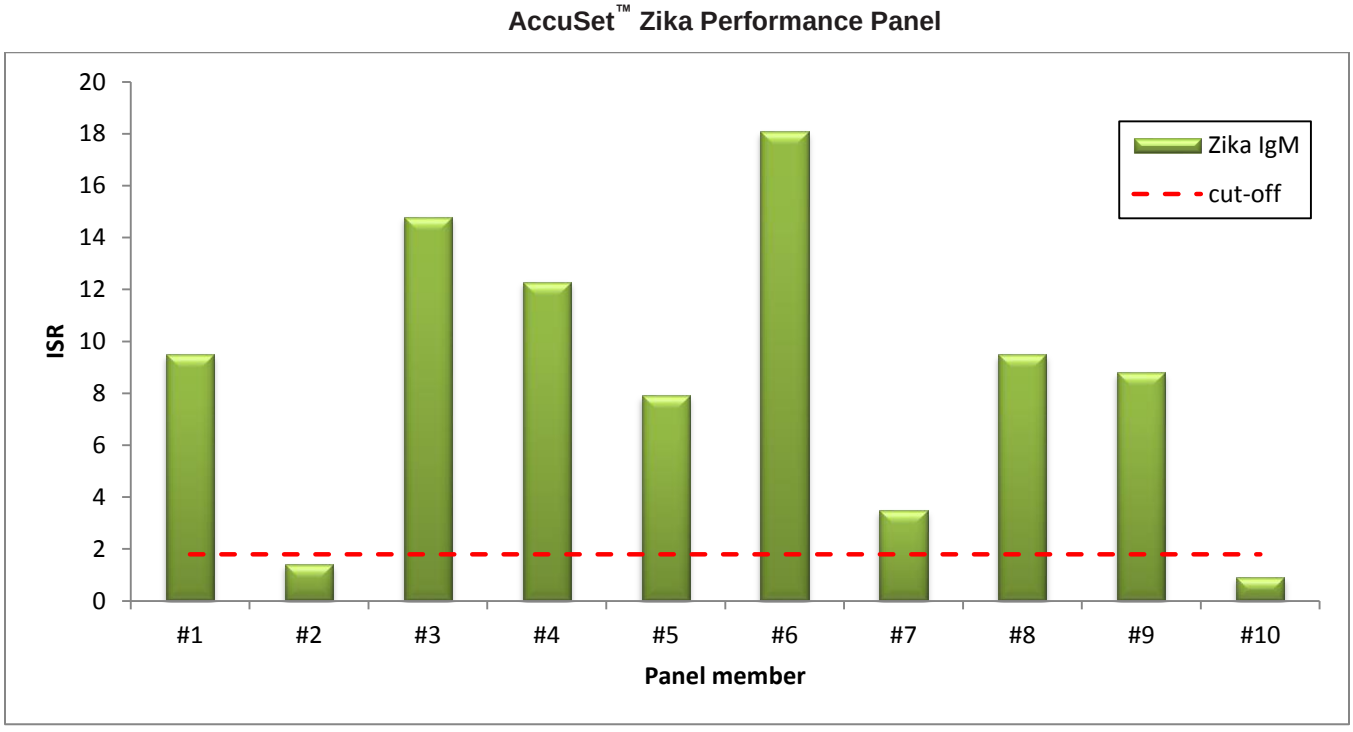
OVERVIEW

AccuSet™ Zika Performance Panel (0845-0142) 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. One sample is included as a non-reactive sample and is negative for all Zika IgM test methods performed.

For Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes. 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.



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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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)

	Trioplex rt-PCR (C_t)[1]			CDC Zika IgM (p/n)[2]	CDC Zika PRNT (endpoint titration)[3]
Panel Member	Zika	Dengue	Chikungunya		
01	NEG	NEG	NEG	**19.0**	**≥1:320**
02	NEG	NEG	NEG	1.5	NT
03	**33.63**	NEG	NEG	**32.6**	**≥1:1280**
04	**35.26**	NEG	NEG	**24.1**	**≥1:320**
05	NEG	NEG	NEG	**15.8**	**≥1:40**
06	NEG	NEG	NEG	**29.8**	**≥1:320**
07	NEG	NEG	NEG	**6.3**	**1:80**
08	NEG	NEG	NEG	**13.3**	**≥1:320**
09	NEG	NEG	NEG	**12.2**	**≥1:320**
10	NEG	NEG	NEG	**3.6**	**≥1:320**
Test Date		24-Feb-2017		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
Kit Regulatory Status		EUA		EUA	LDT

[1]Results are reported as a threshold cycle (C_t); positive/reactive results are noted in bold red.

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

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

NEG = Negative; NT = Not tested;

RL = Reference Lab; EUA = Emergency Use Authorization; LDT = CLIA approved Lab-developed test

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)[2,3]	EuroImmun Anti-Zika IgG ELISA (s/co)[2,3]	Dia.PRO Anti-Zika IgG ELISA (s/co)[2,3]	BioCan Tell Me Fast Zika IgM / IgG Rapid Test[3]	
					Zika IgM	Zika IgG
01	**9.5**	0.2	**4.5**	**>13.0**	NEG	NEG
02	1.4	0.1	**2.9**	**11.9**	NEG	NEG
03	**14.8**	**1.3**	**4.9**	**>13.0**	NEG	NEG
04	**12.3**	0.9	**5.4**	**>13.0**	NEG	NEG
05	**7.9**	0.4	**4.9**	**>13.0**	NEG	NEG
06	**18.1**	0.2	**3.8**	**>13.0**	NEG	**POS**
07	**3.5**	0.8	**3.7**	**11.9**	NEG	**POS**
08	**9.4**	0.6	**5.0**	**>13.0**	NEG	NEG
09	**8.8**	0.5	**5.0**	**>13.0**	NEG	NEG
10	0.9	0.6	**5.6**	**>13.0**	**POS**	NEG
Test Date	10-Mar-2017	13-Mar-2017	13-Mar-2017	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	E160512AI	E160526AC	0816/3	BJ815C021517	
Kit Exp. Date	05-Jul-2017	11-May-2017	25-May-2017	30-Nov-2017	31-Jan-2019	
Kit Regulatory Status	EUA	CE	CE	CE	CE, ANVISA	

[1]Results are reported as Immune Status Ratio (ISR); *presumptive* positive results have a value ≥1.80 and are noted in bold red.
[2]Results are reported as signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.
[3]Results are reported as the mean result of duplicate testing.
SC = SeraCare; NEG = Negative; POS = Positive
EUA = Emergency Use Authorization; CE = Conformité Européenne or CE Marking; ANVISA = Brazilian Health Regulatory Agency

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Zika IgM

	DiaSorin LIAISON® XL Zika Capture IgM[2]			
Panel Member	**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			

[1]Results are reported as an Index value; positive/reactive results are noted in bold red.
[2]Results 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 IgM / IgG

Panel Member	InBios DENV *Detect*™ IgM Capture ELISA (s/co)[1,2]	InBios DENV *Detect*™ IgG ELISA (s/co)[1,2]	Chikungunya IgM IFA w/ Reflex to titer	Chikungunya IgG IFA w/ Reflex to titer
01	0.4	**6.9**	NEG	**1:320**
02	0.4	**7.8**	NEG	**1:320**
03	0.6	**4.7**	NEG	NEG
04	0.9	**9.1**	NEG	NEG
05	0.6	**9.0**	NEG	NEG
06	**2.1**	**8.2**	NEG	NEG
07	0.5	**6.5**	NEG	**1:1280**
08	0.6	**7.8**	NEG	**1:640**
09	0.6	**7.3**	NEG	**1:1280**
10	0.4	**8.4**	NEG	**1:640**
Test Date	23-Mar-2017	23-Mar-2017	09-May-2017	09-May-2017
Test Site	SC	SC	RL	RL
Kit Part Code	DDMS-1	DDGS-R	NA	NA
Kit Lot No.	VA1198	UL1112	NA	NA
Kit Exp. Date	09-Jan-2018	27-Sep-2017	NA	NA
Kit Regulatory Status	IVD/CE	RUO	LDT	LDT

[1]Results are reported as signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.
[2]Results are reported as the mean result of duplicate testing.
SC = SeraCare ; RL = Reference Lab
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking;
RUO = Research Use Only; LDT = CLIA approved Lab-developed test

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