

OVERVIEW

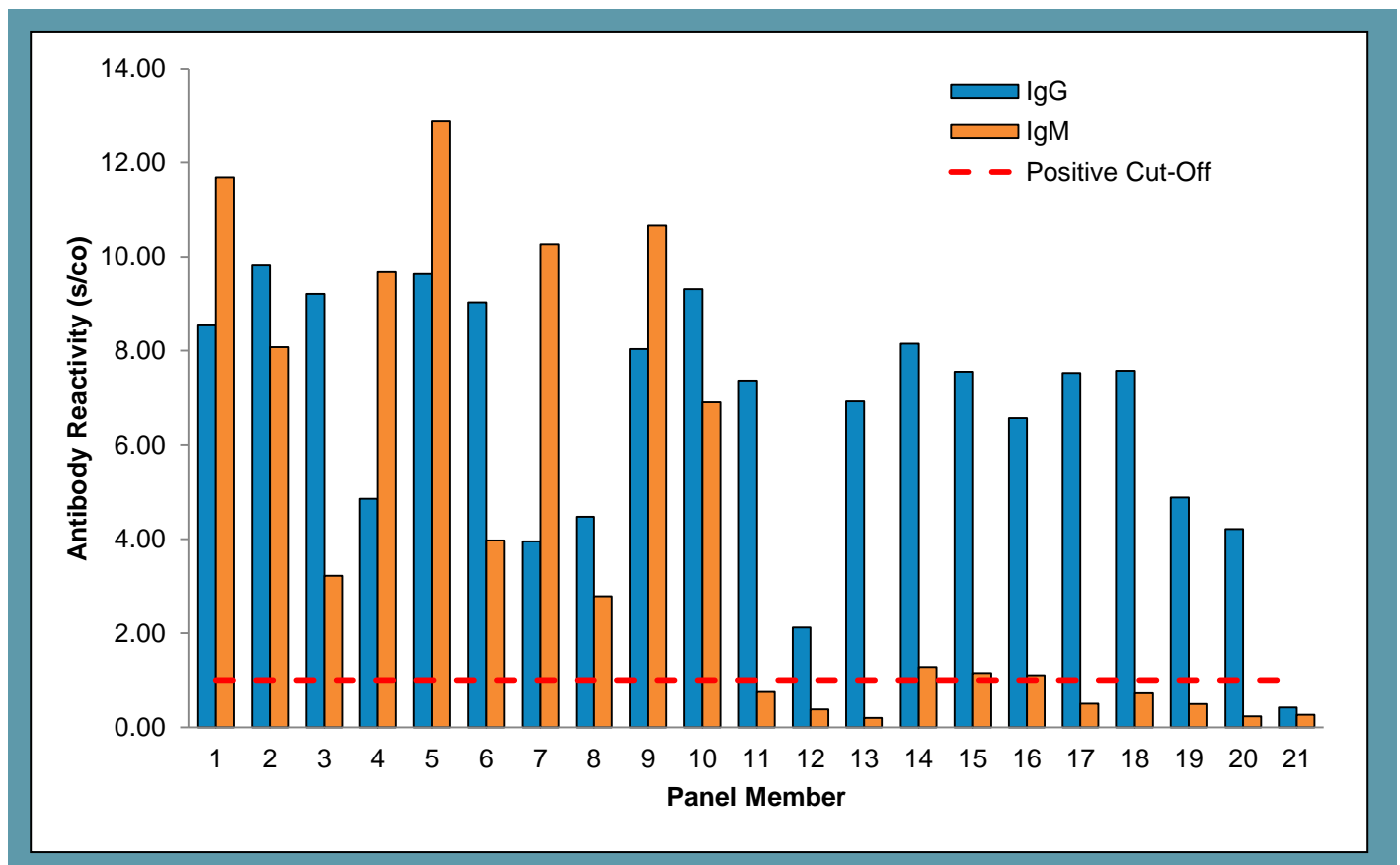
Dengue Mixed Titer AccuSet™ Performance Panel (0845-0074) is a 21-member validation panel of undiluted, naturally occurring plasma samples. Panel members represent bleeds from multiple individuals positive for antibodies to dengue virus. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available dengue antibody assays are included for characterization of the panel members. This panel of human plasma samples demonstrates reactivity ranging from negative to high positive for dengue IgG and IgM antibodies. One sample is included as a non-reactive sample and is negative in all dengue 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 for anti-HIV-1/2, HBsAg, and anti-HCV and were found negative. This does not ensure the absence of these or other human pathogens.

Dengue Mixed Titer AccuSet™ Performance Panel



This graph demonstrates dengue IgG and IgM antibody reactivity amongst panel members utilizing test results from Focus Diagnostics Dengue Virus IgG DxSelect™ and IgM Capture DxSelect™ test kits.

Dengue Mixed Titer AccuSet™ Performance Panel

0845-0074

DATA SHEET

Dengue IgG Antibody

Panel Member	EUROIMMUN Anti-Dengue Virus ELISA IgG (s/co) ^{1,2}	Calbiotech Dengue Virus IgG ELISA (s/co) ^{1,2}	Focus Diagnostics Dengue Virus IgG DxSelect™ (s/co) ^{1,2}	Panbio® Dengue IgG Capture ELISA (s/co) ^{1,2}	Standard Diagnostics Dengue IgG (s/co) ^{1,2}
01	4.51	1.64	8.54	5.07	7.87*
02	4.97	1.11	9.83	6.12*	7.87*
03	4.71	2.09	9.22	6.12*	7.87*
04	3.04	1.44	4.86	3.08	5.56
05	4.77	1.83	9.65	6.12*	7.87*
06	5.29	2.08	9.03	6.12*	7.87*
07	2.76	1.24	3.95	2.89	5.42
08	3.10	1.74	4.48	0.75	0.89
09	4.16	1.74	8.03	4.74	7.87*
10	4.73	1.75	9.32	6.12*	3.23
11	3.81	1.62	7.35	3.46	3.55
12	1.17	1.32	2.12	0.37	0.62
13	3.77	2.07	6.93	1.04 ³	1.54
14	4.52	1.97	8.15	1.59	3.98
15	4.05	1.95	7.55	0.88	2.71
16	3.68	1.67	6.57	0.87	2.18
17	3.50	1.94	7.52	1.85	2.67
18	3.83	1.85	7.57	1.48	2.37
19	2.97	1.84	4.89	0.28	0.91 ³
20	1.16	1.09	4.22	0.39	0.41
21	0.26	0.25	0.43	0.05	0.23
Test Date	18-Dec-14	03-Nov-14	04-Dec-14	22-Dec-14	18-Dec-14
Test Site	SC	SC	SC	SC	SC
Kit Part Code	EL266B	DE050G	EL1500G	01PE10	11EK10
Kit Lot No.	E140905AM	DEG4516	X23223	254008	232018
Kit Exp. Date	04-Sep-15	30-Nov-15	31-May-15	16-Jan-15	20-Feb-16
Kit Regulatory Status	CE	CE	CE	CE	CE

¹Results are reported as a signal to cut-off value (s/co); positive/reactive results are noted in bold red.

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

³Result is grey/equivocal.

*Result is above the limit of reactivity (ALR).

SC = SeraCare Life Sciences; CE = Conformité Européenne or CE Marking



Dengue Mixed Titer AccuSet™ Performance Panel

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DATA SHEET

Dengue IgM Antibody

Panel Member	EUROIMMUN Anti-Dengue Virus ELISA IgM (s/co) ^{1,2}	Calbiotech Dengue Virus IgM ELISA (s/co) ^{1,2}	Focus Diagnostics Dengue Virus IgM Capture DxSelect™ (s/co) ^{1,2}	Panbio® Dengue IgM Capture ELISA (s/co) ^{1,2}	Standard Diagnostics Dengue IgM (s/co) ^{1,2}
01	4.11	1.11	11.68	8.36*	8.80*
02	2.90	0.98 ³	8.07	8.36*	4.90
03	0.48	0.16	3.21	8.10	3.42
04	2.64	0.99 ³	9.68	8.36*	8.80*
05	6.11	1.26	12.88	8.36*	8.80*
06	0.52	0.24	3.97	8.36*	3.91
07	2.25	0.84	10.27	8.36*	8.80*
08	0.39	0.16	2.77	0.66	1.44
09	3.66	1.27	10.67	8.36*	8.80*
10	2.59	1.05 ³	6.91	8.36*	6.38
11	0.51	0.21	0.76	0.36	0.87
12	0.40	0.28	0.39	0.63	0.63
13	0.12	0.37	0.21	0.14	0.19
14	0.24	0.16	1.27	0.35	0.54
15	0.31	0.15	1.14	0.18	0.54
16	0.19	0.18	1.10 ³	0.23	0.38
17	0.29	0.23	0.51	0.45	0.30
18	0.25	0.49	0.73	0.23	0.29
19	0.29	0.19	0.50	0.52	0.28
20	0.22	0.19	0.24	0.25	0.28
21	0.19	0.11	0.27	0.19	0.16
Test Date	26-Dec-14	04-Dec-14	04-Dec-14	04-Dec-14	18-Dec-14
Test Site	SC	SC	SC	SC	SC
Kit Part Code	266B9601M	DE051M	EL1500M	E-DEN01M	233027
Kit Lot No.	E141117BE	DEM4165	X23248	13231	11EK20
Kit Exp. Date	16-Nov-15	31-Dec-14	30-Apr-15	28-Feb-15	01-Mar-16
Kit Regulatory Status	CE	CE	CE	CE	CE

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Dengue Rapid/Confirmatory

Panel Member	SD BIOLINE Dengue Duo (Dengue NS1 Ag + IgG/IgM) ¹			Panbio® Dengue Duo Cassette	
	IgG	IgM	Antigen	IgG	IgM
01	Positive	Positive	Negative	Negative	Positive
02	Positive	Positive	Negative	Positive	Negative
03	Positive	Negative	Negative	Positive	Negative
04	Negative	Positive	Negative	Negative	Positive
05	Positive	Positive	Negative	Positive	Negative
06	Positive	Negative	Negative	Positive	Negative
07	Negative	Negative	Negative	Negative	Negative
08	Negative	Negative	Negative	Negative	Negative
09	Negative	Positive	Negative	Negative	Positive
10	Positive	Negative	Negative	Positive	Negative
11	Negative	Negative	Negative	Negative	Negative
12	Negative	Negative	Negative	Negative	Negative
13	Negative	Negative	Negative	Negative	Negative
14	Negative	Negative	Negative	Negative	Negative
15	Negative	Negative	Negative	Negative	Negative
16	Negative	Negative	Negative	Negative	Negative
17	Negative	Negative	Negative	Negative	Negative
18	Negative	Negative	Negative	Negative	Negative
19	Negative	Negative	Negative	Negative	Negative
20	Negative	Negative	Negative	Negative	Negative
21	Negative	Negative	Negative	Negative	Negative
Test Date	26-Dec-14			23-Dec-14	
Test Site	SC			SC	
Kit Part Code	11FK45			01PF10	
Kit Lot No.	11DD1401			248016	
Kit Exp. Date	02-Jun-16			21-May-16	
Kit Regulatory Status	CE			CE	

¹Tests were run in duplicate; positive/reactive results are noted in bold red.
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The Package Insert for this panel in PDF form 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

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