

OVERVIEW

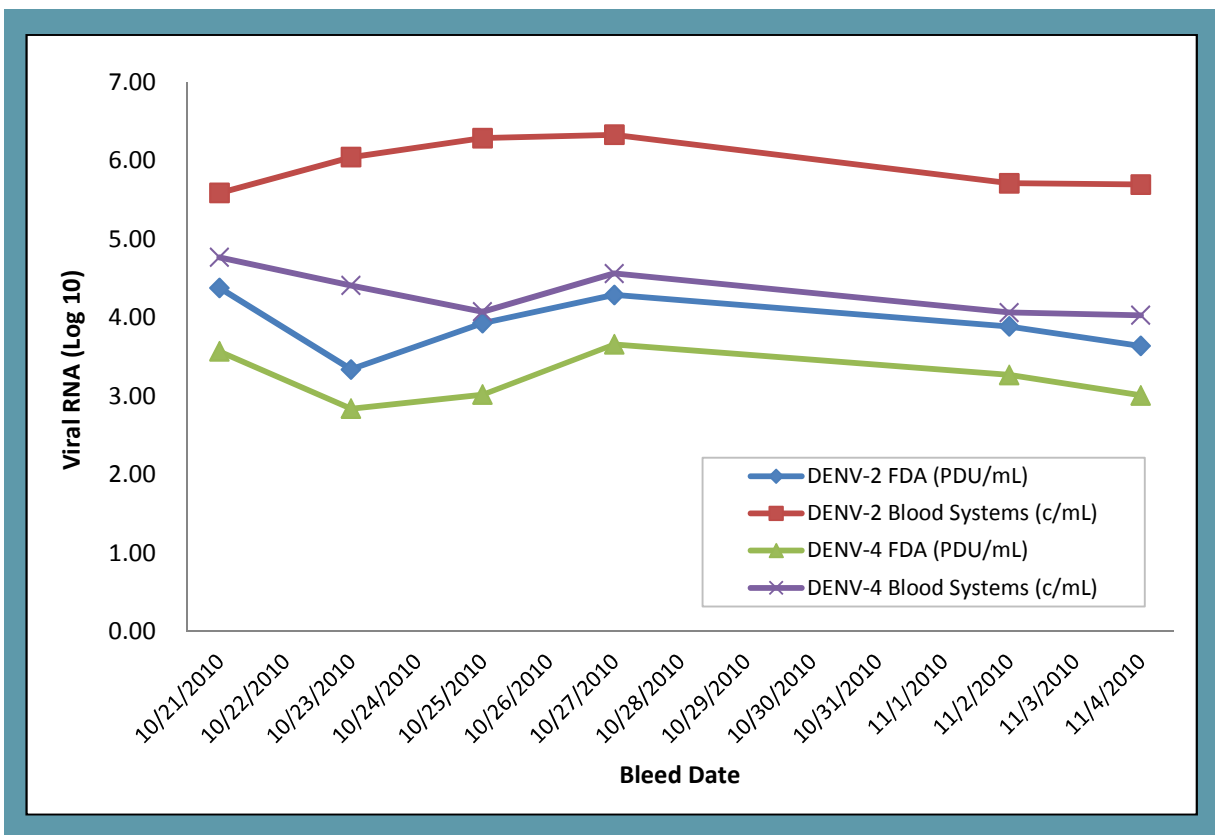
Dengue Early Infection Performance Panel (0845-0050) is a 6-member panel of undiluted, naturally occurring plasma samples. Panel members represent serial bleeds collected over the course of 14 days from a single individual during the development of a dengue infection and subsequent response. No preservatives were added.

Test results from commercially-available dengue assays are included for characterization of the panel members. This panel of human plasma samples is positive for dengue RNA, NS1 antigen, IgM and IgG antibodies.

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

CAUTION: Potentially infectious materials. Follow Universal Precautions. All panel members were found to be negative for HBsAg, anti-HIV, and anti-HCV.

Expression of Dengue Viral RNA during Progression of Infection



This graph demonstrates the development and progression of a dengue infection in a single individual. Dengue viral RNA for dengue virus serotypes 2 and 4 are measured with quantitative real-time PCR analysis.

DATA SHEET

Dengue Virus RNA

Dengue Virus RNA TaqMan RT-PCR (Qualitative)¹

Panel Member	Bleed Date	DENV-1	DENV-2	DENV-3	DENV-4
01	21-Oct-10	NEG	POS	NEG	POS
02	23-Oct-10	NEG	POS	NEG	POS
03	25-Oct-10	NEG	POS	NEG	POS
04	27-Oct-10	NEG	POS	NEG	POS
05	02-Nov-10	NEG	POS	NEG	POS
06	04-Nov-10	NEG	POS	NEG	POS
Test Date		22-Aug-12			
Test Site		RL			
Kit Part Code		NA			
Kit Lot No.		NA			
Kit Exp Date		NA			
Kit Regulatory Status		RUO			

¹Qualitative real-time PCR test performed at the Center for Biologics Evaluation and Research (CBER), US Food and Drug Administration (FDA).
 NEG = Negative; POS = Positive
 RL = Reference Lab; NA = Not Available; RUO = Research Use Only

Dengue Virus RNA

Dengue Virus RNA TaqMan RT-PCR (Quantitative)¹

Panel Member	Bleed Date	DENV-2 (PDU/mL (log ₁₀))	DENV-2 (Ct) ²	DENV-4 (PDU/mL (log ₁₀))	DENV-4 (Ct) ²
01	21-Oct-10	24155 (4.38)	31.6	3704 (3.57)	36.0
02	23-Oct-10	2182 (3.34)	35.7	696 (2.84)	39.0
03	25-Oct-10	8495 (3.93)	33.4	1054 (3.02)	38.0
04	27-Oct-10	19410 (4.29)	32.0	4604 (3.66)	35.6
05	02-Nov-10	7736 (3.89)	33.5	1865 (3.27)	37.2
06	04-Nov-10	4341 (3.64)	34.6	1028 (3.01)	38.3
Test Date		22-Aug-12			
Test Site		RL			
Kit Part Code		NA			
Kit Lot No.		NA			
Kit Exp Date		NA			
Kit Regulatory Status		RUO			

¹Quantitative real-time PCR test performed at the Center for Biologics Evaluation and Research (CBER), US Food and Drug Administration (FDA).
²Results are reported as the average of six replicates.
 RL = Reference Lab; NA = Not Available; RUO = Research Use Only

Dengue Virus RNA

Dengue Virus RNA TaqMan RT-PCR (Quantitative)¹

Panel Member	Bleed Date	DENV-1 (Ct) ²	DENV-2 (Ct) ²	DENV-3 (Ct) ²	DENV-4 (Ct) ²
01	21-Oct-10	30.7	29.0	NEG	29.3
02	23-Oct-10	NEG	27.5	NEG	30.4
03	25-Oct-10	NEG	26.6	NEG	31.5
04	27-Oct-10	30.6	26.5	NEG	29.9
05	02-Nov-10	37.0	28.6	NEG	31.5
06	04-Nov-10	34.5	28.6	NEG	31.6

Test Date	20-Jun-12
Test Site	RL
Kit Part Code	NA
Kit Lot No.	NA
Kit Exp Date	NA
Kit Regulatory Status	RUO

¹Quantitative real-time PCR test performed at the Blood Systems Research Institute.

²Associated Ct values are reported as the average value from 2 runs.

NEG = Negative

RL = Reference Lab; NA = Not Available; RUO = Research Use Only

Dengue Virus RNA

Dengue Virus RNA TaqMan RT-PCR (Quantitative)¹

Panel Member	Bleed Date	DENV-1 (copies/mL) ²	DENV-2 (copies/mL) ²	DENV-3 (copies/mL) ²	DENV-4 (copies/mL) ²
01	21-Oct-10	212669	389910	NEG	58857
02	23-Oct-10	NEG	1116916	NEG	25735
03	25-Oct-10	NEG	1949351	NEG	11920
04	27-Oct-10	227445	2148557	NEG	36585
05	02-Nov-10	2231	519077	NEG	11651
06	04-Nov-10	13057	500149	NEG	10744

Test Date	20-Jun-12
Test Site	RL
Kit Part Code	NA
Kit Lot No.	NA
Kit Exp Date	NA
Kit Regulatory Status	RUO

¹Quantitative real-time PCR test performed at the Blood Systems Research Institute.

²Results are reported as copies/mL of plasma.

NEG = Negative

RL = Reference Lab; NA = Not Available; RUO = Research Use Only

Dengue Early Infection AccuSet™ Performance Panel

0845-0050

DATA SHEET

Dengue Virus NS1 Antigen

Panel Member	Bleed Date	Panbio Dengue Early ELISA NS1 Antigen ¹
01	21-Oct-10	28.2
02	23-Oct-10	7.0
03	25-Oct-10	28.2
04	27-Oct-10	28.2
05	02-Nov-10	6.9
06	04-Nov-10	28.2
Test Date	26-Feb-14	
Test Site	SC	
Kit Part Code	01PE40	
Kit Lot No.	253003	
Kit Exp Date	20-Aug-14	
Kit Regulatory Status	CE	

¹Results are reported as an index value. Values greater than 1.1 are considered positive/reactive and are noted in bold red.

SC = SeraCare; CE = Conformité Européenne or CE Marking

Dengue Virus Antibodies

Panel Member	Bleed Date	Panbio Dengue IgG Indirect ELISA ¹	Focus Diagnostics		Focus Diagnostics	
			Dengue Virus DxSelect™ IgG ^{2,3}	Calbiotech Dengue Virus IgM ELISA ^{1,3}	Dengue Virus DxSelect™ IgM ^{2,3}	Dengue Virus DxSelect™ IgM ^{2,3}
01	21-Oct-10	1.3	3.7	0.1	1.6	
02	23-Oct-10	1.6	4.4	0.2	2.2	
03	25-Oct-10	1.3	2.6	0.1	1.4	
04	27-Oct-10	1.1	3.7	0.1	1.6	
05	02-Nov-10	1.3	4.3	0.1	0.8	
06	04-Nov-10	1.2	3.0	0.2	1.5	
Test Date	21-Nov-11 and 18-Oct-12		28-Jan-14	07-Feb-14	28-Jan-14	
Test Site	SC		SC	SC	SC	
Kit Part Code	E-DEN01G		EL1500G	DE051M	EL1500M	
Kit Lot No.	11080		X23223	DEM4165	23248	
Kit Exp Date	28-Feb-13		31-May-15	31-Dec-14	30-Apr-15	
Kit Regulatory Status	CE		CE	IVD/CE	CE	

¹Results are reported as an index value. Values greater than 1.1 are considered positive/reactive and are noted in bold red. Values in the range of 0.9 – 1.1 are equivocal.

²Results are reported as an index value. Values greater than 1.0 are considered positive/reactive and are noted in bold red.

³Results are reported as the mean result of duplicate testing.

SC = SeraCare; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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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