AccuSet™ Dengue Performance Panel

0845-0153 / Batch #10375776

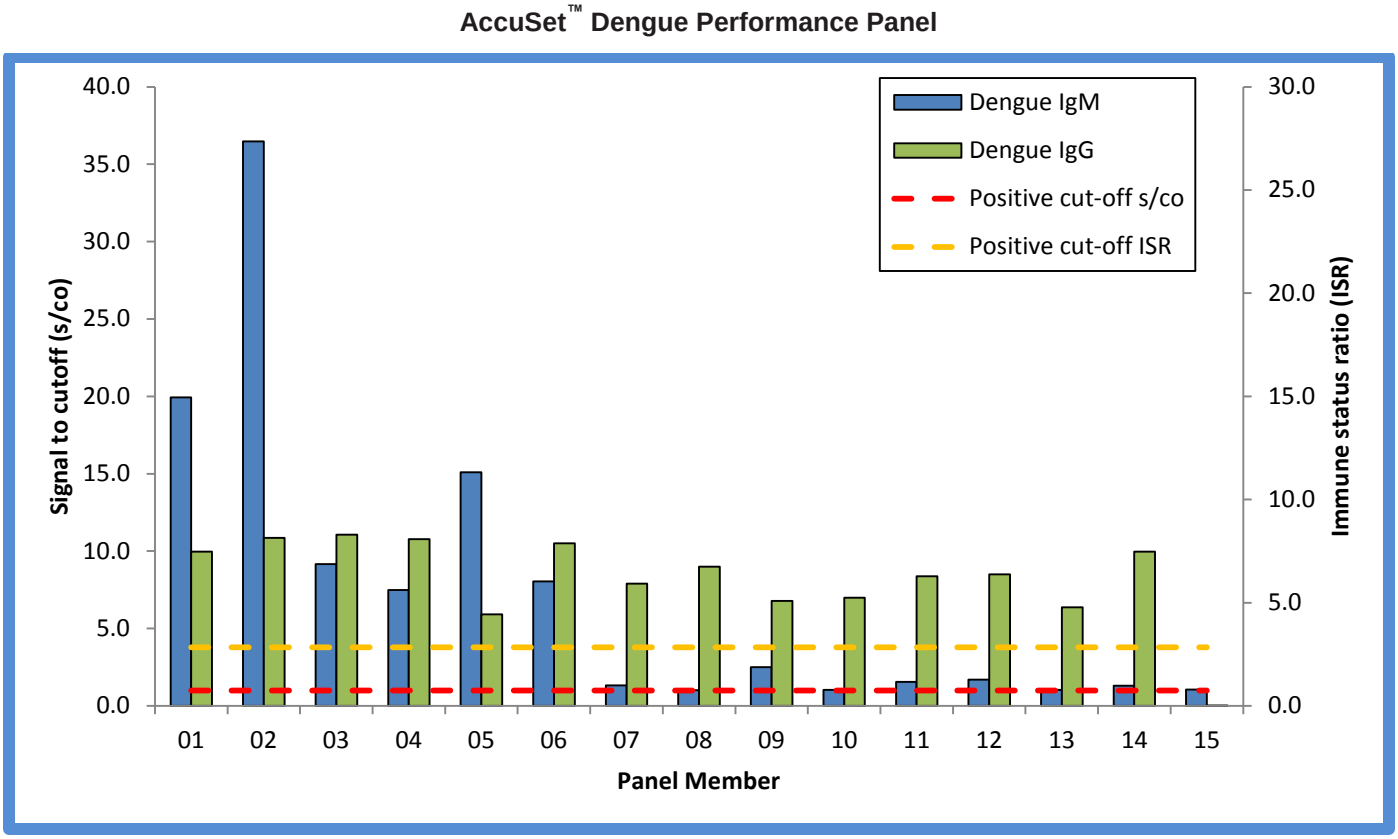
OVERVIEW

AccuSet™ Dengue Performance Panel 0845-0153 / Batch #10375776 is a 15-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent bleeds from multiple individuals positive for antibodies to the dengue virus. Each sample represents a single collection event. 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 demonstrates a range of antibody reactivities for several dengue test methods. One sample is included as a non-reactive sample and is negative for all dengue test methods performed.

For Research Use Only. Not for use in diagnostic procedures. Data are offered 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 reactivity amongst panel members from the InBios DENV Detect™ IgM Capture ELISA (Dengue IgM) and Focus Diagnostics Dengue Virus IgG DxSelect™ (Dengue IgG) assays.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date	Country of Origin
01	9266163	NA	NA	India
02	9266164	NA	NA	India
03	10296533	BD343221	NA	El Salvador
04	10296534	BD343221	NA	El Salvador
05	10336933	BD370309	28-Aug-2012	El Salvador
06	10336935	BD370310	15-Aug-2015	El Salvador
07	10127375	BD250536	12-Jun-2015	Honduras
08	10127377	BD250538	12-Jun-2015	Honduras
09	10127416	BD250574	12-Jun-2015	Honduras
10	10127360	BD250521	11-Jun-2015	Honduras
11	10127408	BD250512	09-Jun-2015	Honduras
12	10127357	BD250518	11-Jun-2015	Honduras
13	10127474	BD250632	11-Jun-2015	Honduras
14	10127385	BD250545	15-Jun-2015	Honduras
15	9256934	NA	NA	NA

NA = Not Available

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Dengue RNA and NS1

Panel Member	Reference Lab Dengue Virus (1-4) Subtype by PCR DENV-1	DENV-2	DENV-3	DENV-4	Bio-Rad Platelia™ Dengue NS1 Ag (s/co)[1,2]
01	TND	TND	TND	TND	**8.3**
02	TND	**R**	TND	TND	0.1
03	TND	TND	TND	TND	0.0
04	TND	TND	TND	TND	0.1
05	TND	TND	TND	TND	0.0
06	TND	TND	TND	TND	0.0
07	TND	TND	TND	TND	0.1
08	TND	TND	TND	TND	0.1
09	TND	TND	TND	TND	0.1
10	TND	TND	TND	TND	0.1
11	TND	TND	TND	TND	0.0
12	TND	TND	TND	TND	0.1
13	TND	TND	TND	TND	0.0
14	TND	TND	TND	TND	0.1
15	TND	TND	TND	TND	0.0
Test Date		19-Oct-2018			07-Nov-2018
Test Site		RL			SC
Kit Part Code		NA			72830
Kit Lot No.		NA			8A0047
Kit Exp. Date		NA			05-Jun-2019
Kit Regulatory Status		LDT			IVD/CE

[1]Results are reported as a 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.
TND = Target Not Detected; R = Reactive
NA = Not Available; RL = Reference Lab; SC = SeraCare
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking; LDT = Lab Developed Test

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Dengue IgM and IgG

Panel Member	InBios DENV Detect™ IgM Capture ELISA (ISR)[1,4]	PanBio Dengue IgM Capture ELISA (TV)[3,4]	PanBio Dengue IgG Indirect ELISA (TV)[3,4]	Focus Diagnostics Dengue Virus IgG DxSelect™ (s/co)[2,4]
01	**19.9**	**>4.0**[5]	**>4.0**[5]	**10.0**
02	**36.5**	**>4.0**[5]	**>4.0**[5]	**10.9**
03	**9.2**	**>4.0**[5]	**>4.0**[5]	**11.1**
04	**7.5**	**>4.0**[5]	**>4.0**[5]	**10.8**
05	**15.1**	**2.2**	**>4.0**[5]	**5.9**
06	**8.0**	**>4.0**[5]	**>4.0**[5]	**10.5**
07	1.3	0.1	**2.7**	**7.9**
08	1.0	0.2	**>4.0**[5]	**9.0**
09	2.5	0.7	**2.7**	**6.8**
10	1.0	0.1	**2.7**	**7.0**
11	1.5	0.1	**3.0, >4.0**[5]	**8.4**
12	1.7	0.2	**2.9, >4.0**[5]	**8.5**
13	1.0	0.2	**2.3**	**6.4**
14	1.3	0.2	**>4.0**[5]	**10.0**
15	1.1	0.2	0.0	0.0
Test Date	07-Nov-2018	03-Dec-2018	03-Dec-2018	24-Oct-2018
Test Site	SC	RL	RL	SC
Kit Part Code	DDMS-1	NA	NA	EL1500G
Kit Lot No.	XK5073	01P20DCC8	01P30DCC1	X2600N
Kit Exp. Date	01-Oct-2019	01-Oct-2019	21-Sep-2020	30-Nov-2018
Kit Regulatory Status	IVD/CE	CE	CE	CE

[1]Results are reported as an immune status ratio (ISR); positive/reactive results are noted in bold red.
[2]Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.
[3]Results are reported as a test value (TV); positive/reactive results are noted in bold red.
[4]Results are reported as the mean result of duplicate testing, if applicable.
[5]Off-scale
NA = Not Available; SC = SeraCare; RL = Reference Lab
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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.