AccuSet™ Lyme Performance Panel

0845-0169 / Batch #10408567

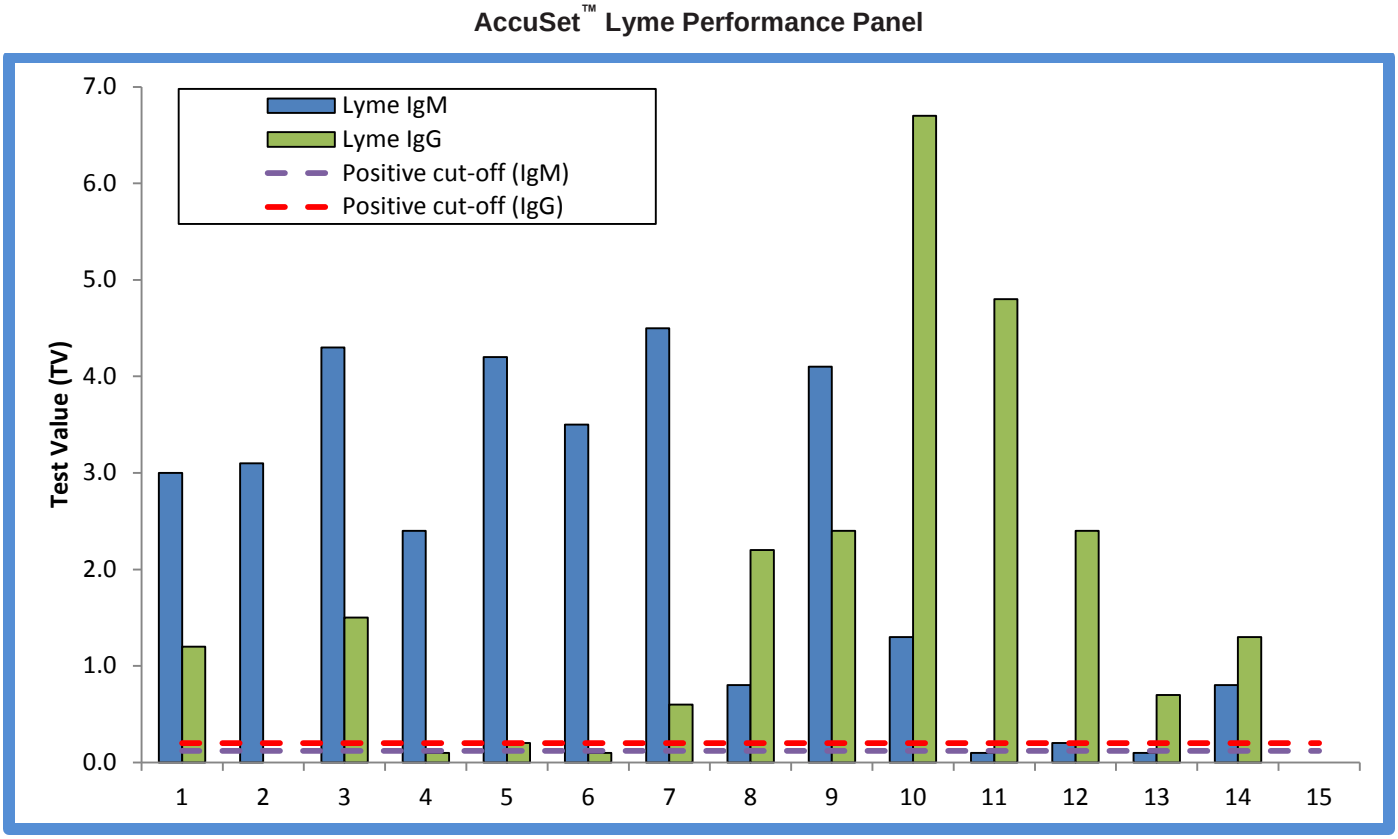
OVERVIEW

AccuSet™ Lyme Performance Panel 0845-0169 / Batch #10408567 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 Lyme disease. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available Lyme assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of antibody reactivities for several Lyme IgM and Lyme IgG test methods. Additionally, each panel member was tested on a laboratory developed qualitative PCR method for detection of Borrelia species and all members tested negative or target not detected. One sample is included as a non-reactive sample and is negative for all Lyme 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 Lyme IgM and Lyme IgG reactivity on the BioMerieux VIDAS® test system.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date	Country of Origin
01	10388035	BD392890	25-Jul-2018	United States
02	10387883	BD392872	12-Aug-2018	United States
03	10387881	BD381424	17-Jul-2018	United States
04	10387857	BD392868	23-Aug-2018	United States
05	10387846	BD392863	17-Jul-2017	United States
06	10387767	BD392866	15-Jun-2018	NA
07	10336874	BD365257	18-Aug-2017	NA
08	10388034	BD392889	21-May-2018	United States
09	10336869	BD365256	27-Jul-2017	NA
10	10387854	BD101215	15-Sep-2018	United States
11	10387847	BD392864	23-May-2018	United States
12	9256452	BD111319	15-Dec-2010	Germany
13	9235560	BD107145	26-Nov-2008	NA
14	9235025	BD107047	28-Oct-2008	NA
15	9254654	BD110929	26-Jan-2009	United States

NA = Not Available

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Lyme PCR, Lyme Total

Panel Member	DiaSorin LIAISON® Borrelia burgdorferi Lyme IgM/IgG assay (Index)[1,3]	Trinity Biotech Captia™ Borrelia burgdorferi IgG/IgM ELISA (ISR)[2,3]
01	**3.6**	**2.0**
02	**2.1**	0.8
03	**4.6**	**2.2**
04	**2.4**	**2.3**
05	**6.1**	**1.4**
06	**3.3**	1.0[5]
07	**3.8**	**2.0**
08	**3.9**	**1.8**
09	**11.0**	**2.4**
10	**>12.9, >12.9**[4]	**2.4**
11	**>12.9, 12.4**[4]	**1.9**
12	**3.1**	1.0[5]
13	**4.5**	**1.1**
14	**9.7**	**2.2**
15	0.0	0.2
Test Date	07-Apr-2019	05-Apr-2019
Test Site	RL	SC
Kit Part Code	NA	2346580
Kit Lot No.	NA	2346580-561
Kit Exp. Date	NA	30-Apr-2020
Kit Regulatory Status	IVD	IVD/CE

[1]Results are reported as index value (Index); positive/reactive results are noted in bold red.
[2]Results are reported as an Immunoglobulin Status Ratio (ISR); positive/reactive results are noted in bold red.
[3]Results are reported as the mean result of duplicate testing.
[4]Each replicate result is reported individually.
[5]Result is reported within the assay's equivocal range.
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IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Markingt

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Lyme IgM, Lyme IgG

Panel Member	BioMerieux VIDAS® Lyme IgM II assay (TV)[1,3]	MarDx B. burgdorferi Disease EIA IgM Test System (LIV)[2,3]	BioMerieux VIDAS® Lyme IgG II assay (TV)[1,3]	MarDx B. burgdorferi Disease EIA IgG Test System (LIV)[2,3]
01	**3.0**	**4.2**	**1.2**	0.9[4]
02	**3.1**	1.1[4]	0.0	0.3
03	**4.3**	**5.3**	**1.5**	1.0[4]
04	**2.4**	**4.8**	0.1	0.2
05	**4.2**	**2.0**	**0.2**	0.4
06	**3.5**	**1.3**	0.1	0.2
07	**4.5**	**4.9**	**0.6**	0.5
08	**0.8**	**2.2**	**2.2**	**1.9**
09	**4.1**	**6.7**	**2.4**	0.4
10	**1.3**	0.6	**6.7**	**4.1**
11	0.1	0.1	**4.8**	**1.7**
12	0.2[4]	0.4	**2.4**	1.0[4]
13	0.1	0.4	**0.7**	0.6
14	**0.8**	**2.1**	**1.3**	**1.7**
15	0.0	0.2	0.0	0.4
Test Date	05-Apr-2019	04-Apr-2019	05-Apr-2019	04-Apr-2019
Test Site	RL	SC	RL	SC
Kit Part Code	NA	40-8696M	NA	40-8696G
Kit Lot No.	1006839710	015	1006775080	005
Kit Exp. Date	10-Dec-2019	30-Nov-2019	27-Nov-2019	31-Jul-2019
Kit Regulatory Status	IVD	IVD/CE	IVD	IVD/CE

[1]Results are reported as Test Value (TV); positive/reactive results are noted in bold red.
[2]Results are reported as a Lyme Index Value (LIV); positive/reactive results are noted in bold red.
[3]Results are reported as the mean result of duplicate testing.
[4]Result is reported within the assay's equivocal range.
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Lyme Western Blot[1]

Panel Member	MarDx B. burgdorferi (IgM) MarBlot Strip Test System Band Pattern	Result	MarDx B. burgdorferi (IgG) MarBlot Strip Test System Band Pattern	Result
01	**23, 41**	**P**	23, 41, 66	N
02	23	N	41, 66	N
03	**23, 41**	**P**	23, 41, 66	N
04	**23, 41**	**P**	23, 41, 45, 58	N
05	**23, 39, 41**	**P**	23, 41, 66	N
06	23	N	23, 41, 66	N
07	**23, 39, 41**	**P**	23, 41, 66	N
08	**23, 39, 41**	**P**	**18, 23, 28, 31, 39, 41, 58, 66**	**P**
09	**23, 39, 41**	**P**	23, 41, 66	N
10	**23, 39**	**P**	**18, 23, 30, 31, 39, 41, 45, 58, 66, 93**	**P**
11	No Bands	N	**18, 23, 30, 31, 39, 41, 45, 58, 66, 93**	**P**
12	23	N	**30, 31, 41, 58, 66, 93**	**P**
13	No Bands	N	**30, 31, 39, 41, 58, 66, 93**	**P**
14	**23, 41**	**P**	**18, 23, 39, 41, 58, 66**	**P**
15	No Bands	N	58	N
Test Date	05-Apr-2019		08-Apr-2019	
Test Site	SC		SC	
Kit Part Code	40-5065M		40-5065G	
Kit Lot No.	0300K		0296K	
Kit Exp. Date	30-Sep-2019		30-Nov-2019	
Kit Regulatory Status	IVD/CE		IVD/CE	

[1]Positive/reactive results are noted in bold red.
P = Positive; N = Negative
SC = SeraCare
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.