AccuSet™ Syphilis Performance Panel

0820-0300 / Batch #10330704

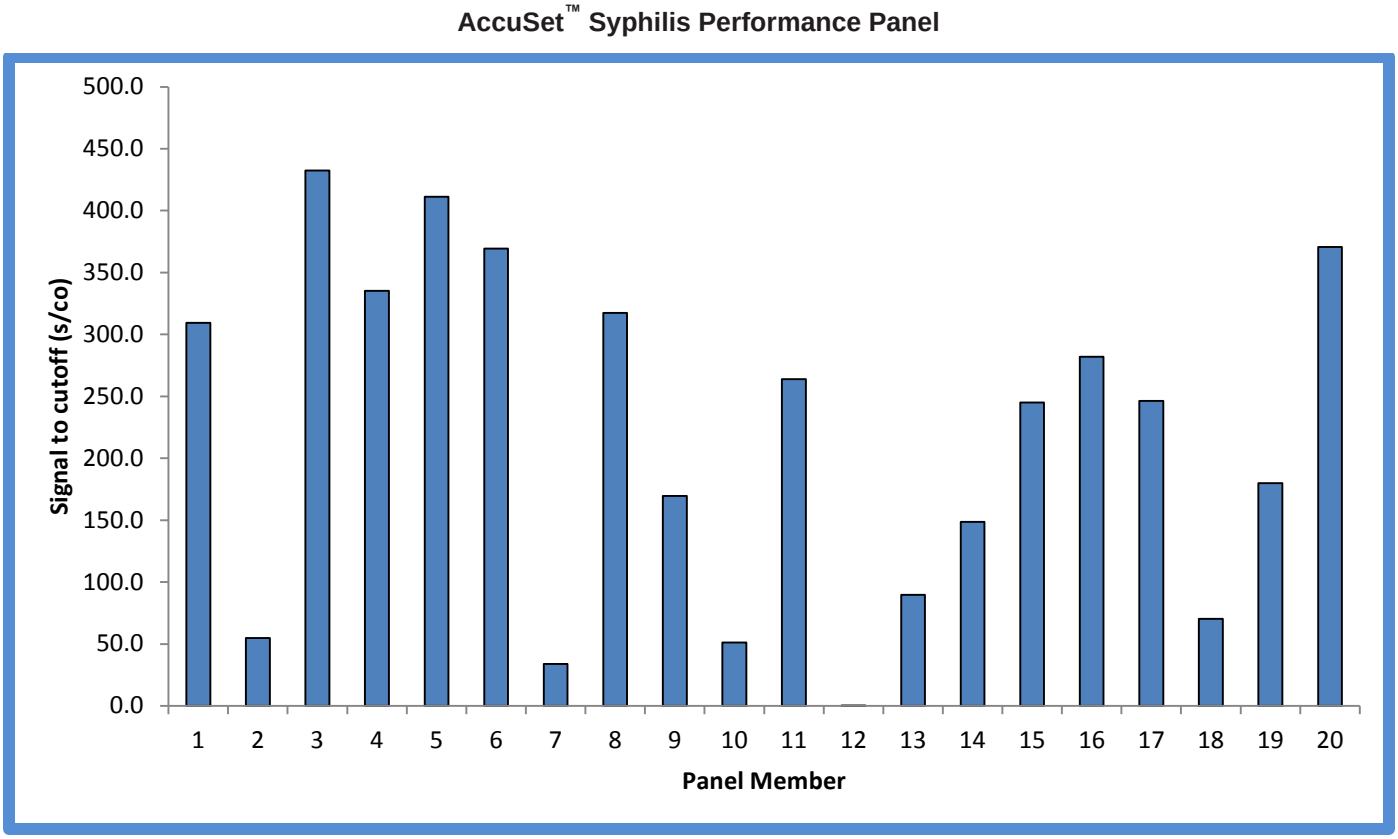
OVERVIEW

AccuSet™ Syphilis Performance Panel (0820-0300) is a 20-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 treponema pallidum. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available rapid plasma reagin (RPR) and treponema pallidum antibody assays are included for characterization of the panel members. This panel of human plasma samples demonstrates a range of antibody reactivity for several RPR and treponema pallidum test methods. One sample is included as a non-reactive sample and is negative for all RPR and treponema pallidum 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 Roche Elecsys syphilis test method.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Bleed Date
01	9222472	NA	NA
02	9244334	BD110092	11-Nov-2009
03	10267046	BD328515	19-Feb-2016
04	10267060	BD328525	29-Oct-2016
05	10267086	BD328535	28-May-2016
06	10267088	BD328536	03-Jul-2016
07	10267098	BD328542	18-Jul-2016
08	10267106	BD328549	17-Oct-2016
09	BM142373	NA	17-Jan-2000
10	BM147827	RR11127	15-Oct-2004
11	BM206255	BD102686	04-May-2006
12	9252292	NA	NA
13	9231151	BD106747	19-May-2008
14	9231403	BD106790	23-May-2008
15	BM201380	BD100687	26-Jan-2005
16	BM216451	BD102985	29-May-2006
17	BM216818	BD103211	03-Nov-2006
18	9203127	BD111324	30-Aug-2006
19	10112119	BD240189	10-Jan-2015
20	10112122	BD240192	12-Sep-2014

NA = Not Available

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Rapid Plasma Reagin (RPR)[1]

Panel Member	BD Macro-Vue RPR Card Test	ASI RPR Card Test	Pulse Rapid Plasma Reagin Test
01	**1:64**	**1:40**	**1:40**
02	**1:4**	**1:5**	**1:1**
03	**1:32**	**1:20**	**1:20**
04	**1:2**	**1:1**	**1:1**
05	**1:32**	**1:20**	**1:40**
06	**1:64**	**1:40**	**1:40**
07	**1:32**	**1:20**	**1:20**
08	**1:32**	**1:20**	**1:20**
09	**1:2**	**1:1**	**1:1**
10	NEG	NEG	NEG
11	**1:8**	**1:5**	**1:5**
12	NEG	NEG	NEG
13	**1:2**	**1:1**	**1:1**
14	NEG	NEG	NEG
15	**1:2**	**1:1**	**1:1**
16	**1:2**	**1:1**	**1:1**
17	**1:2**	**1:1**	**1:1**
18	NEG	NEG	NEG
19	**1:8**	**1:5**	**1:5**
20	**1:32**	**1:40**	**1:40**
Test Date	06-Apr-2018	13-Apr-2018	11-Apr-2018
Test Site	SC	SC	SC
Kit Part Code	274449	900100	10605
Kit Lot No.	7033901	7D10R3	809008
Kit Exp. Date	28-Feb-2019	31-Jan-2019	01-Dec-2018
Kit Regulatory Status	IVD/CE	IVD/CE	IVD

[1]RPR results are endpoint dilutions. Positive/reactive results are noted in bold red.
NEG = Negative
SC = SeraCare
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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Treponema Pallidum Assays

Panel Member	Bio-Rad Bio-Plex 2200 Syphilis IgG Assay (AI)[1,4]	DiaSorin Liaison Treponema Assay (Index)[2,4]	Abbott ARCHITECT Syphilis TP Assay (s/co)[3,4]	Beckman Coulter PK TP System
01	**>8.0**	**35.8**	**20.3**	**POS**
02	**>8.0**	**39.6**	**16.5**	**POS**
03	**>8.0**	**>70.0**	**22.0**	**POS**
04	**>8.0**	**59.9**	**18.5**	**POS**
05	**>8.0**	**44.7**	**23.3**	**POS**
06	**>8.0**	**37.5**	**21.2**	**POS**
07	**>8.0**	**46.6**	**15.6**	**POS**
08	**>8.0**	**65.4**	**20.6**	**POS**
09	**>8.0**	**>70.0**	**16.7**	**POS**
10	**>8.0**	**48.1**	**9.5**	**POS**
11	**>8.0**	**61.7**	**16.3**	**POS**
12	NEG	NEG	0.0	NEG
13	**>8.0**	**>70.0**	**13.6**	**POS**
14	**>8.0**	**>70.0**	**13.6**	**POS**
15	**>8.0**	**>70.0**	**16.7**	**POS**
16	**>8.0**	**>70.0**	**17.9**	**POS**
17	**>8.0**	**>70.0**	**17.7**	**POS**
18	**>8.0**	**39.0**	**9.5**	**POS**
19	**>8.0**	**63.7**	**16.0**	**POS**
20	**>8.0**	**46.4**	**21.7**	**POS**
Test Date	04-Apr-2018	04-Apr-2018	09-Apr-2018	03-Apr-2018
Test Site	RL	RL	RL	RL
Kit Part Code	NA	NA	8D06-29	NA
Kit Lot No.	NA	113048	82301LI00	NA
Kit Exp. Date	NA	30-Dec-2018	09-Oct-2018	NA
Kit Regulatory Status	IVD/CE	IVD	IVD/CE	NA

[1]Results are reported as antibody index units (AI); positive/reactive results are noted in bold red.
[2]Results are reported as index values; positive/reactive results are noted in bold red.
[3]Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.
[4]Results are reported as the mean result of duplicate testing.
NA = Not available; POS = Positive; NEG = Negative
RL = Reference Lab
IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

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Treponema Pallidum Assays

Panel Member	Roche Elecsys Syphilis Assay (s/co)[1,2]	Zeus IFA Fluorescent Treponemal Antibody-Absorption Test System	Trinity Biotech CAPTIA Syphilis T.Pallidum-G (s/co)[1,2]	INNO-LIA Syphilis Score (Band Pattern)
01	**309.3**	**R**	**3.8**	**15, 17, 47, TmpA**
02	**54.9**	**R**	**2.2**	**15, 17, 47, TmpA**
03	**432.5**	**R**	**4.2**	**15, 17, 47, TmpA**
04	**335.3**	**R**	**3.2**	**15, 17, 47, TmpA**
05	**411.1**	**R**	**5.2**	**15, 17, 47, TmpA**
06	**369.3**	**R**	**4.9**	**15, 17, 47, TmpA**
07	**33.9**	**R**	**2.7**	**15, 17, 47, TmpA**
08	**317.5**	**R**	**3.1**	**15, 17, 47, TmpA**
09	**169.5**	**R**	**3.4**	**15, 17, 47, TmpA**
10	**51.2**	**R**	**2.7**	**15,- 17, 47, TmpA**
11	**264.0**	**R**	**3.7**	**15, 17, 47, TmpA**
12	0.1	NR	0.1	NEG
13	**89.8**	**R**	**2.9**	**15, 17, 47, TmpA**
14	**148.6**	R	**3.0**	**15, 17, 47, TmpA**
15	**245.0**	**R**	**3.4**	**15, 17, 47, TmpA**
16	**281.9**	**R**	**4.3**	**15, 17, 47, TmpA**
17	**246.2**	**R**	**3.8**	**15, 17, 47, TmpA**
18	**70.3**	**R**	**2.0**	**15, 17, 47, TmpA**
19	**179.9**	**R**	**3.3**	**15, 17, 47, TmpA**
20	**370.6**	**R**	**4.8**	**15, 17, 47, TmpA**
Test Date	09-Apr-2018	05-Apr-2018	09-Apr-2018	11-Apr-2018
Test Site	RL	RL	SC	RL
Kit Part Code	NA	NA	800-970	80542
Kit Lot No.	NA	NA	800-970-128	404061
Kit Exp. Date	NA	NA	31-Jul-2019	31-Dec-2018
Kit Regulatory Status	IVD	IVD/CE	IVD/CE	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.
NA = Not available; R = Reactive; NR = Non-reactive; NEG = Negative
RL = Reference Lab; SC = SeraCare
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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.