AccuSet™ Syphilis Performance Panel

0820-0422 / Batch #10521371

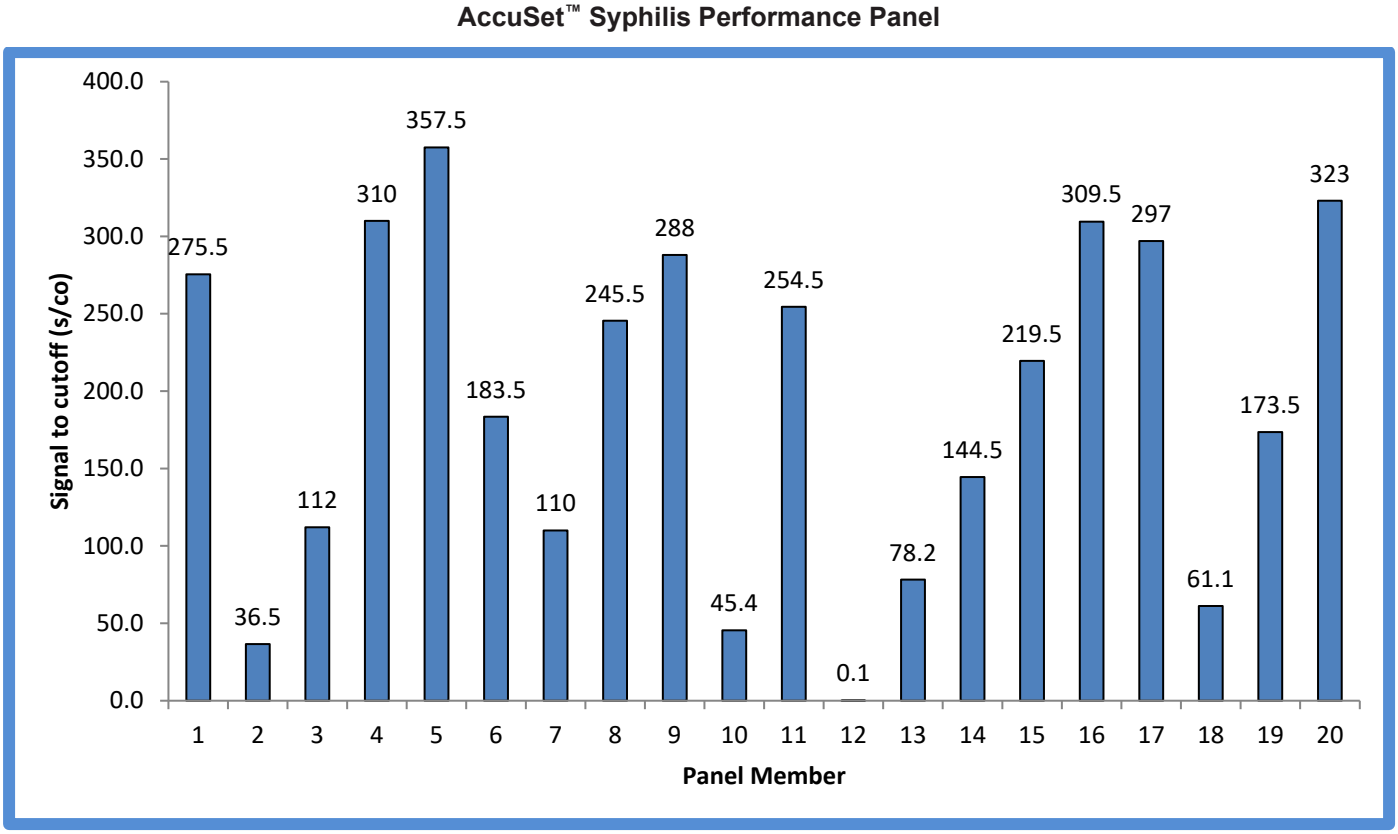
OVERVIEW

AccuSet™ Syphilis Performance Panel (0820-0422) is a 20-member validation panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.0 mL per vial). Panel members represent collections 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 cobas® Elecsys® *syphilis test method.*

AccuSet™ Syphilis Performance Panel

0820-0422 / Batch #10521371

Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Collection Date
01	9222472	NA	N/A
02	10267121	BD328555	06-Aug-2016
03	10267111	BD328551	06-Jan-2017
04	10267060	BD328525	29-Oct-2016
05	10267086	BD328535	28-May-2016
06	10267159	BD328578	06-Sep-2016
07	10267155	BD328577	29-Aug-2016
08	10513221	BD444932	08-Apr-2020
09	10513226	BD444935	26-Apr-2020
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	10513234	BD444938	29-Apr-2020
18	9203127	BD111324	30-Aug-2006
19	10112119	BD240189	10-Jan-2015
20	10112122	BD240192	12-Sep-2014

NA = Not Available

AccuSet™ Syphilis Performance Panel

0820-0422 / Batch #10521371

Rapid Plasma Reagin (RPR)[1]

Panel Member	BD Macro-Vue™ RPR Card Test[1,3]	ASI RPR Card Test[1,3]	Beckman Coulter PK® TP System[2,3]
01	**1:64**	**1:32**	**R**
02	**1:16**	**1:8**	**R**
03	**1:16**	**1:16**	**R**
04	**1:2**	**1:2**	**R**
05	**1:32**	**1:32**	**R**
06	**1:4**	**1:4**	**R**
07	**1:32**	**1:32**	**R**
08	**1:64**	**1:64**	**R**
09	**1:32**	**1:16**	**R**
10	NEG	NEG	**R**
11	**1:8**	**1:8**	**R**
12	NEG	NEG	**R**
13	**1:2**	**1:1**	**R**
14	**1:1**	**1:1[4]**	**R**
15	**1:2**	**1:2**	NR
16	**1:4**	**1:2**	**R**
17	**1:32**	**1:32**	**R**
18	NEG	NEG	**R**
19	**1:8**	**1:8**	**R**
20	**1:64**	**1:32**	**R**
Test Date	19-Oct-2020	12-Oct-2020 and 20-Oct-2020	13-Oct-2020
Test Site	SC	SC	RL
Kit Part Code	274449	900100	NA
Kit Lot No.	9274714	9H08R3 and 0H15R3	VR00125
Kit Exp. Date	31-Oct-2021	31-Mar-2021 and 31-Mar-2022	31-May-2021

[1]RPR results are endpoint dilutions. Positive reactive results are noted in bold red.
[2]Test results reported as R = Reactive or NR = Non-reactive.
[3]Results are reported from duplicate testing.
[4]Weak positive.
SC = SeraCare, RL = Reference Lab, NA = Not Available, NEG = Negative

AccuSet™ Syphilis Performance Panel

0820-0422 / Batch #10521371

Treponemal Pallidum Assays (IgG/IgM)

Panel Member	DiaSorin Liaison® Treponema Assay (Index)[1,3]	Abbott ARCHITECT Syphilis TP Assay (s/co)[2,3]	Roche cobas® Elecsys® Syphilis Assay (s/co)[2,3]
01	**31.2**	**20.0**	**275.5**
02	**46.8**	**16.6**	**36.5**
03	**>70.0**	**20.6**	**112.0**
04	**67.1**	**18.6**	**310.0**
05	**58.0**	**23.5**	**357.5**
06	**>70.0**	**17.6**	**183.5**
07	**>70.0**	**18.8**	**110.0**
08	**35.9**	**21.5**	**245.5**
09	**56.6**	**21.5**	**288.0**
10	**44.7**	**14.3**	**45.4**
11	**55.9, >70.0**	**18.6**	**254.5**
12	<0.10	**0.1**	**0.1**
13	**67.4**	**14.3**	**78.2**
14	**>70.0**	**16.7**	**144.5**
15	**>70.0**	**19.3**	**219.5**
16	**62.5, >70.0**	**20.3**	**309.5**
17	**59.5**	**23.0**	**297.0**
18	**25.7**	**11.2**	**61.1**
19	**67.6**	**19.1**	**173.5**
20	**44.0**	**22.8**	**323.0**
Test Date	13-Oct-2020	16-Oct-2020	20-Oct-2020
Test Site	RL	SC	RL
Kit Part Code	NA	8D06	NA
Kit Lot No.	113058	15658BE00	NA
Kit Exp. Date	19-Sep-2021	18-Jun-2021	NA

[1]Results are reported as index values; 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 the mean result of duplicate testing, except where noted.

SC = SeraCare, RL = Reference Lab, NA = Not available.

AccuSet™ Syphilis Performance Panel

0820-0422 / Batch #10521371

Treponemal Pallidum Assays

Panel Member	DRG® Treponema Pallidum IgM ELISA (s/co)[1,2]	ZEUS IFA™ Fluorescent Treponemal Antibody-Absorption (FTA-ABS) Qual Test[2]	Trinity Biotech CAPTIA™ Syphilis T. Pallidum-G (s/co)[1,2]	INNO-LIA™ Syphilis Score (Band Pattern)[2]
01	**6.98**	**R**	**2.78**	**15, 17, 47, TmpA**
02	0.29	**R**	**1.34**	**15, 17, 47, TmpA**
03	0.95	**R**	**2.06**	**15, 17, 47, TmpA**
04	0.30	**R**	**1.96**	**15, 17, 47, TmpA**
05	**1.11**	**R**	**3.64**	**15, 17, 47, TmpA**
06	0.44	**R**	**1.84**	**15, 17, 47, TmpA**
07	**1.93**	**R**	**1.81**	**15, 17, 47, TmpA**
08	**4.62**	**R**	**2.89**	**15, 17, 47, TmpA**
09	0.58	**R**	**2.48**	**15, 17, 47, TmpA**
10	0.77	**R**	**1.96**	**15- 17, 47, TmpA**
11	0.88	**R**	**2.74**	**15, 17, 47, TmpA**
12	0.04	NR	0.10	NEG
13	0.38	**R**	**1.66**	**15, 17, 47, TmpA**
14	0.26	**R**	**2.18**	**15, 17, 47, TmpA**
15	0.26	**R**	**2.09**	**15, 17, 47, TmpA**
16	0.25	**R**	**2.88**	**15, 17, 47, TmpA**
17	**1.74**	**R**	**2.69**	**15, 17, 47, TmpA**
18	0.22	**R**	**1.37**	**15, 17, 47, TmpA**
19	**1.58**	**R**	**2.46**	**15, 17, 47, TmpA**
20	**1.73**	**R**	**3.74**	**15, 17, 47, TmpA**
Test Date	29-Oct-2020	15-Oct-2020	13-Oct-2020	28-Oct-2020
Test Site	SC	RL	SC	RL
Kit Part Code	EIA-4267R	NA	800-970	80542
Kit Lot No.	129M/K070	NA	800-970-141	407371
Kit Exp. Date	31-Jul-2021	NA	28-Apr-2021	31-Mar-2021

[1]Results are reported as a signal to cutoff ratio (s/co); positive/reactive results are noted in bold red.
[2]Results are reported from duplicate samples or as the mean result of duplicate testing.
NA = Not available; R = Reactive; NR = Non-reactive, NEG = Negative
RL = Reference Lab; SC = SeraCare

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.