

OVERVIEW

Syphilis Seroconversion Panel PSS901 is a 9-member panel of undiluted, naturally occurring plasma samples, collected in the United States over 60 days in 2012 from a 41-year old female. No preservatives were added.

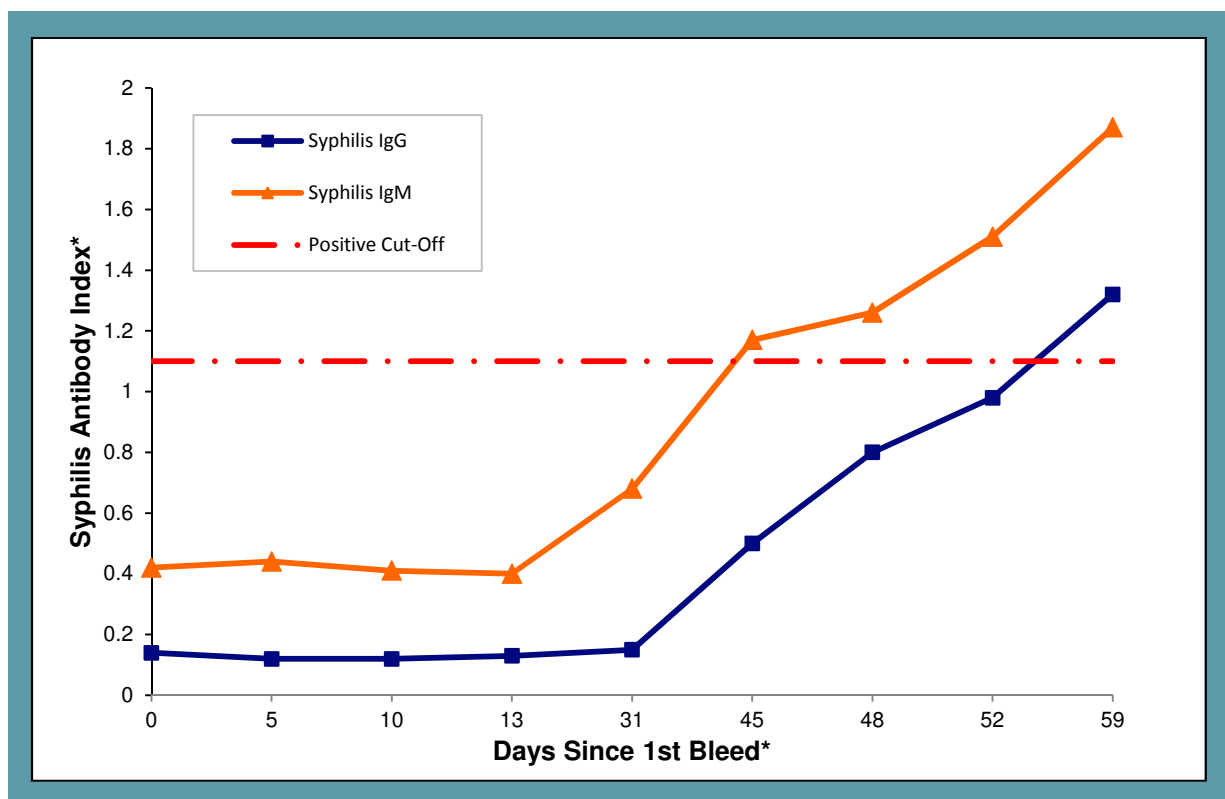
Test results from commercially available syphilis assays are included. This panel converts from negative to positive for both non-treponemal and treponemal-specific tests, demonstrating an early syphilis infection.

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

CAUTION: Potentially infectious materials. Follow Universal Precautions. Some panel members were found positive for syphilis; all were found negative for HBsAg, anti-HCV, and anti-HIV.

For assistance, contact SeraCare Technical Support at 508.244.6400.

EVOLUTION OF SYPHILIS MARKERS IN EARLY INFECTION



*This graph demonstrates the evolution of an early syphilis infection, illustrated with Trinity Biotech CAPTIA™ Syphilis IgG and IgM test results. *Graph not to scale.*

Syphilis Seroconversion Panel PSS901 (0615-0017)

DATA SHEET

Non-Treponemal - Rapid Plasma Reagin (RPR)

Panel Member	Bleed Date	Days Since 1st Bleed	Remel RPR Card Test	Becton Dickinson Macro-Vue™ RPR Card Test
PSS901-01	22 Feb 12	0	NEG	NEG
PSS901-02	27 Feb 12	5	NEG	NEG
PSS901-03	03 Mar 12	10	NEG	NEG
PSS901-04	06 Mar 12	13	NEG	NEG
PSS901-05	24 Mar 12	31	POS	POS
PSS901-06	07 Apr 12	45	POS	POS
PSS901-07	10 Apr 12	48	POS	POS
PSS901-08	14 Apr 12	52	POS	POS
PSS901-09	21 Apr 12	59	POS	POS
Test Date			03 May 13	03 May 13
Test Site			SC	SC
Kit Part Code			R16302	275005
Kit Lot No.			284578	2089104
Kit Expiration Date			31 Aug 13	30 Apr 14
Kit Regulatory Status			IVD	IVD/CE

Treponemal – Quantitative Antibody Assays (Total, IgG and IgM)

Panel Member	Bleed Date	Days Since 1st Bleed	Abbott Architect Syphilis Total (s/co) ¹	Trinity Biotech CAPTIA™ Syphilis IgG (Ab Index) ²	Trinity Biotech CAPTIA™ Syphilis IgM Capture (Ab Index) ³	Trinity Biotech Trep-Sure™ Syphilis (Index) ⁴
PSS901-01	22 Feb 12	0	0.0450	0.145	0.417	1.07 ⁴
PSS901-02	27 Feb 12	5	0.0400	0.123	0.445	0.475
PSS901-03	03 Mar 12	10	0.0300	0.123	0.408	0.419
PSS901-04	06 Mar 12	13	0.0300	0.125	0.396	0.576
PSS901-05	24 Mar 12	31	0.125	0.155	0.683	3.68
PSS901-06	07 Apr 12	45	5.04	0.503	1.17	4.07
PSS901-07	10 Apr 12	48	9.11	0.798	1.26	4.98
PSS901-08	14 Apr 12	52	14.1	0.976 ²	1.51	4.20
PSS901-09	21 Apr 12	59	27.4	1.32	1.87	11.2
Test Date			03 Jun 13	28 May 13, 29 May 13	29 May 13	02 Aug 13
Test Site			RL	SC	SC	SC
Kit Part Code			NA	800-970	800-935	TS-96
Kit Lot No.			22131LP19	800-970-083	800-935-021	TS-96-083
Kit Expiration Date			21 Aug 13	30 Apr 14	31 Oct 13	31 Jan 14
Kit Regulatory Status			IVD/CE	IVD/CE	IVD/CE	IVD/CE

¹Results are reported as the mean result of duplicate testing expressed as a signal to cut-off value (s/co); results in red are considered positive/reactive. ²Results are reported as the mean result of four replicates expressed as an antibody index value; a value between 0.9 and 1.1 is equivocal; results in red are considered positive/reactive.

³Results are reported as the mean result of duplicate testing expressed as an antibody index value; results in red are considered positive/reactive. ⁴Results are reported as the mean result of duplicate testing expressed as an index value; a value between 0.8 and 1.2 is equivocal; results in red are considered positive/reactive.

NEG = Negative; POS = Positive; SC = SeraCare; RL = Reference Lab; IVD = In Vitro Diagnostic; CE = Conformité or CE Marking



Syphilis Seroconversion Panel

PSS901 (0615-0017)

DATA SHEET

Treponemal – Qualitative Antibody Assays (Total, IgG and IgM)

Panel Member	Bleed Date	Days Since 1st Bleed	DiaSorin Liaison Treponema Syphilis	Olympus PK™ TP Syphilis	Fujirebio Serodia® TPPA Syphilis	Trinity Biotech MarBlot Syphilis IgG	Trinity Biotech MarBlot Syphilis IgM
PSS901-01	22 Feb 12	0	NEG	NEG	NEG	NEG	NEG
PSS901-02	27 Feb 12	5	NEG	NEG	NEG	NEG	NEG
PSS901-03	03 Mar 12	10	NEG	NEG	NEG	NEG	NEG
PSS901-04	06 Mar 12	13	NEG	NEG	NEG	NEG	NEG
PSS901-05	24 Mar 12	31	NEG	NEG	NEG	NEG	NEG
PSS901-06	07 Apr 12	45	POS	NEG	POS	IND	POS
PSS901-07	10 Apr 12	48	POS	POS	POS	IND	POS
PSS901-08	14 Apr 12	52	POS	POS	POS	IND	POS
PSS901-09	21 Apr 12	59	POS	POS	POS	POS	POS
Test Date			29 May 13	29 May 13	30 May 13	05 Jun 13	06 Jun 13
Test Site			RL	RL	SC	SC	SC
Kit Part Code			NA	NA	6384	40-5020G	40-5020M
Kit Lot No.			NA	NA	308448	8285K	8295K
Kit Expiration Date			NA	NA	27 Jan 14	31 Aug 13	31 Aug 13
Kit Regulatory Status			NA	IVD	IVD	IVD/CE	IVD/CE

NEG = Negative; POS = Positive; IND = Indeterminate; NA = Not Available
 SC = SeraCare; RL = Reference Lab; IVD = In Vitro Diagnostic; CE = Conformité or CE Marking

Syphilis Seroconversion Panel PSS901 (0615-0017)

DATA SHEET

Treponemal – Qualitative Antibody Assays (Total, IgG and IgM)

Panel Member	Bleed Date	Days Since 1st Bleed	BioRad BioPlex™ 2200 Syphilis IgG	BioRad EIA Syphilis IgM
PSS901-01	22 Feb 12	0	PENDING	NEG
PSS901-02	27 Feb 12	5	PENDING	NEG
PSS901-03	03 Mar 12	10	PENDING	NEG
PSS901-04	06 Mar 12	13	PENDING	NEG
PSS901-05	24 Mar 12	31	PENDING	NEG
PSS901-06	07 Apr 12	45	PENDING	POS
PSS901-07	10 Apr 12	48	PENDING	POS
PSS901-08	14 Apr 12	52	PENDING	POS
PSS901-09	21 Apr 12	59	PENDING	POS
Test Date			NA	27 Aug 13
Test Site			RL	RL
Kit Part Code			NA	NA
Kit Lot No.			NA	NA
Kit Expiration Date			NA	NA
Kit Regulatory Status			IVD	IVD

NEG = Negative; POS = Positive
 PENDING = Pending Results
 NA = Not Available
 RL = Reference Lab

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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