

OVERVIEW

AccuVert[™] Syphilis Seroconversion Panel 0615-0044 / Batch #10632252 is a modified dispense of previous AccuVert Syphilis Seroconversion Panel 0615-0017 (with two members from that panel unavailable). This is a 7-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.2 mL per vial) collected over 59 days in 2012 from a 41-year old female during a period of Syphilis seroconversion. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available Syphilis assays are included for characterization of the panel members. 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 offered for informational purposes. LGC/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 anti-HIV-1/2, anti-HCV, and HBsAg. This does not ensure the absence of these or other human pathogens.

25 Syphilis Total Ab Positive cut-off (S/CO) 20 Signal to Cutoff (S/CO) 15 10 5 0 5 15 25 35 45 55 **Days Since First Bleed**

AccuVert™ Syphilis Seroconversion Panel

This graph demonstrates the evolution of early syphilis infection amongst panel members from the Abbott ARCHITECT Syphilis Total test method.

Page 1 of 4 October 2023



Panel Member Information

0615-0044	0615-0017				
Panel Member	Panel Member*	SeraCare Batch #	SeraCare Donor ID #	Bleed Date	Days Since 1st Bleed
	01	9260239	BD111360	22-Feb-2012	0
01	02	9260240	BD111360	27-Feb-2012	5
02	03	9260241	BD111360	03-Mar-2012	10
03	04	9260242	BD111360	06-Mar-2012	13
04	05	9260243	BD111360	24-Mar-2012	31
05	06	9260244	BD111360	07-Apr-2012	45
	07	9260245	BD111360	10-Apr-2012	48
06	08	9260238	BD111360	14-Apr-2012	52
07	09	9260246	BD111360	21-Apr-2012	59

^{*} Members in grey are no longer available. Data provided for informational purposes only.

Non-Treponemal - Rapid Plasma Reagin (RPR)

		BD Macro-Vue™ RPR	
Panel Member	ASI RPR Card Test Syphilis ¹	Card Test ¹	
01	NEG	NEG	
02	NEG	NEG	
03	NEG	NEG	
04	NEG	NEG	
05	POS	POS	
06	POS	POS	
07	POS	POS	
Test Date	05-Aug-2022	01-Aug-2022	
Test Site	SC	SC	
Kit Part Code	900100	274449	
Kit Lot No.	0M25R3	1277599	
Kit Exp. Date	31-Aug-2022	31-Oct-2023	

¹Positive/reactive results are noted in bold red.

SC = SeraCare

POS = Positive; NEG = Negative

508.244.6400 • 800.676.1881 Toll Free • 508.634.3334 Fax www.seracare.com



Treponemal – Antibody Assays (Total, IgG and IgM)

Panel Member	Abbott ARCHITECT Syphilis TP Total (S/CO) ¹	Roche Elecsys Syphilis Total (COI)¹	Trinity Biotech CAPTIA™ Syphilis (T. Pallidum)-G (S/CO)¹	DRG Treponema pallidum IgM ELISA (DRG Units)¹
01	0.14	0.14	0.10	2.08
02	0.12	0.12	0.10	1.43
03	0.10	0.11	0.09	1.42
04	0.31	0.38	0.11	3.95
05	7.21	2.09	1.25	6.36
06	15.19	24.44	2.05	9.29
07	18.23	51.95	2.68	32.25
Test Date	03-Aug-2022	04-Aug-2022	08-Aug-2022	01-Sep-2022
Test Site	SC	RL	SC	SC
Kit Part Code	8D06	NA	800-970	EIA-4267R
Kit Lot No.	38429BE00	592016	800-970-156	129M/K022
Kit Exp. Date	14-Mar-2023	31-Dec-2022	28-Dec-2023	31-May-2023

¹Results are reported as the mean result of duplicate testing; positive/reactive results are noted in bold red.

508.244.6400 • 800.676.1881 Toll Free • 508.634.3334 Fax

SC = SeraCare; RL = Reference Lab; NA = Not Available



Syphilis Confirmatory Assay

Panel Member	INNOGENETICS® INNO-LIA™ Syphilis Score¹ Band Results					
	01	NEG	-	-	<u>-</u>	-
02	NEG	-	-	-	-	
03	NEG	-	-	-	-	
04	IND	-	1+	-	-	
05	POS	1+	2+	1+	-	
06	POS	2+	2+	2+	+/-	
07	POS	2+	2+	2+	1+	
Test Date	19-Aug-2022					
Test Site	RL					
Kit Part Code	NA					
Kit Lot No.	409528					
Kit Exp. Date	31-May-2023					

¹Results reported are from singlicate testing; positive/reactive results are noted in bold red.

508.244.6400 • 800.676.1881 Toll Free • 508.634.3334 Fax

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 CDx-Info@LGCGroup.com or by phone at 508.244.6400.

www.seracare.com

Page **4** of **4** October 2023

RL = Reference Lab; NA = Not Available

NEG = Negative; POS = Positive; IND = Indeterminate