

Treponema Pallidum Seroconversion Panel

REF Catalogue No: SCP-TP-001

The BIOMEX GmbH Treponema Pallidum Seroconversion Panel consists of 30 members with each member containing 0.5 mL of human citrate plasma. This panel illustrates the onset and decline of Treponema pallidum antibodies from one individual over a period of 149 days.

1. Intended Use

This Seroconversion Panel (SCP) is intended for standard testing by diagnostic manufacturers and researchers during assay development, evaluation, troubleshooting and post-marked surveillance of antibody test systems and methods. Moreover, it serves as validation tool for diagnostic sensitivity, determination of analytical sensitivity, identification of cut-off values or to study the humoral immune response to this infection.

2. Storage and Stability

Store the SCP at -20°C to -80°C. Thaw samples at room temperature and mix gently by inversion before usage. Avoid foaming, contamination and repeated freeze and thaw cycles. After usage, return immediately to storage conditions.

3. Warnings and Precautions

Infectious material. This product is capable of transmitting infectious diseases.

Do not pipette by mouth.

Prevention:

P264: Wash hands thoroughly after handling.

P270: Do not eat, drink or smoke when using this product

P273: Avoid the release to the environment

Disposal:

P501: Dispose of waste in accordance to applicable local or national regulations. Waste must be disposed in a secured manner.

Declaration of used symbols

Catalog Number	Lot Number	Consult Instructions for Use	Manufactured by	Temperature Limitation

4. Donor Information

All panel members have been tested and found negative/non-reactive for anti-HIV 1/2, anti-HCV and HBsAg with CE marked tests.

Donor profile:

- Sex: Male
- Age: 19
- Ethnicity: Caucasian
- Residence: Germany
- Risk group for STD
- Infection through sexual contact in January 2024
- No history of intravenous drug use, blood transfusion or organ transplant
- Symptoms:
 - Small untypical lesion that healed spontaneously within a few days (January 2024)
 - Rashes (starting: 27.03.2024)
 - Itching of the extremities (starting 29./30.03.2024)
 - Hair loss (starting 29./30.03.2024)
 - Swelling of the lymph nodes in the neck (starting 29./30.03.2024)
 - Fever (starting 29./30.03.2024)
 - Shivering (starting 29./30.03.2024)
- The infection was treated with Amoxicillin 1000 mg 1-1-1 from 30.03.2024 till 09.04.2024
- Donor also was treated with Penicillin G i.m. 05.06.2024

5. Detection Methods

Each panel member is tested for Treponema Pallidum antibodies with Abbott ARCHITECT® , Diasorin LIAISON XL® and Roche COBAS® e411, for VDRL with NewBio RPR from IFFMEDIC and with INNO-LIA® Syphilis Score from Fudjirebio.

Testing was performed with CE marked tests.

6. Limitations and Restrictions

This panel is for Research Use Only and not intended for human or animal diagnostics, or for therapeutic purposes. Each laboratory has the responsibility to ascertain the suitability of the SCP for its particular application and to establish their own guidelines for interpretation of results. Data is provided for informational purposes only.

The BIOMEX GmbH does not claim that others can duplicate these test results exactly. Page 1 of 2

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Panel member	Date	Days	Abbott Architect Treponema Pallidum Ab	Roche Cobas e411 Treponema Pallidum Ab	DiaSorin Liaison XL Treponema Pallidum Ab	VDRL NewBio RPR IFFMEDIC	INNO-LIA Syphilis Fujirebio			
			cut off ≥ 1,0 S/CO	cut off ≥ 1,0 COI	cut off 1,1 Index		TpN47	TpN17	TpN15	TmpA
1	24.01.2024	0	0,05	0,13	<0,100	nd	nd	nd	nd	nd
2	31.01.2024	7	0,05	0,14	<0,100	nd	nd	nd	nd	nd
3	07.02.2024	14	0,06	0,13	<0,100	nd	nd	nd	nd	nd
4	27.02.2024	34	0,05	0,14	<0,100	negative (undiluted)	nd	nd	nd	nd
5	05.03.2024	41	0,45	0,25	1,42	negative (undiluted)	(+/-)	-	-	-
6	08.03.2024	44	0,77	0,57	7,31	negative (undiluted)	-	(+/-)	-	-
7	12.03.2024	48	1,23	1,57	11,20	negative (undiluted)	(+/-)	1+	-	-
8	15.03.2024	51	2,20	3,29	14,10	negative (undiluted)	(+/-)	1+	(+/-)	-
9	19.03.2024	55	3,97	4,82	18,00	weak positive (undiluted)	2+	2+	1+	-
10	03.04.2024	70	24,22	44,23	>70	1:16	2+	2+	1+	(+/-)
11	09.04.2024	76	24,51	43,65	>70	1:16	2+	2+	2+	(+/-)
12	12.04.2024	79	23,90	39,80	>70	1:8	2+	3+	2+	1+
13	16.04.2024	83	22,61	30,71	57,60	1:4	2+	2+	2+	1+
14	19.04.2024	86	23,15	31,22	63,10	1:2	2+	2+	2+	1+
15	23.04.2024	90	22,64	30,31	57,10	1:2	2+	2+	2+	1+
16	26.04.2024	93	22,46	39,03	65,80	1:2	2+	2+	2+	1+
17	29.04.2024	96	23,12	36,22	67,10	positive (undiluted)	3+	3+	2+	2+
18	03.05.2024	100	24,00	47,65	>70	positive (undiluted)	2+	3+	3+	2+
19	07.05.2024	104	23,97	39,28	>70	positive (undiluted)	3+	3+	3+	2+
20	10.05.2024	107	24,37	43,82	>70	positive (undiluted)	3+	3+	3+	2+
21	13.05.2024	110	23,28	36,80	49,20	positive (undiluted)	3+	3+	3+	2+
22	16.05.2024	113	24,32	39,43	48,30	weak positive (undiluted)	3+	3+	3+	2+
23	21.05.2024	118	24,28	40,91	50,10	positive (undiluted)	3+	3+	3+	2+
24	24.05.2024	121	23,55	39,43	45,00	positive (undiluted)	3+	3+	3+	2+
25	27.05.2024	124	24,14	39,90	44,40	negative (undiluted)	2+	3+	2+	1+
26	31.05.2024	128	23,35	39,04	42,10	negative (undiluted)	2+	2+	2+	1+
27	03.06.2024	131	23,36	32,00	32,90	nd	2+	2+	2+	2+
28	14.06.2024	142	23,12	32,77	29,10	nd	2+	2+	2+	2+
29	18.06.2024	146	22,84	34,82	31,60	nd	2+	2+	2+	2+
30	21.06.2024	149	22,11	33,47	27,00	nd	2+	2+	2+	2+