

EBV IgM Seroconversion Panel

REF Catalog No: SCP-EBV-002

The Biomex GmbH EBV IgM Seroconversion Panel consists of 25 members with each member containing 0.5 mL of human plasma. This panel illustrates the onset and decline of IgM and IgG Epstein Barr virus antibodies from one individual over a period of 210 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 IgM/IgG 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

Potentially infectious materials. Handle the product as if 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
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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: 24
- Ethnicity: Caucasian
- Residence: Germany

5. Detection Methods

Each panel member is assayed for VCA IgM, VCA IgG and EBNA IgG antibodies with Abbott ARCHITECT® and Diasorin LIAISON®. Testing is performed with CE marked test.

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.

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Panel Member	Day	Bleed Date	Abbott Architect			Diasorin Liaison		
			EBV VCA IgG S/CO	EBV VCA IgM S/CO	EBNA IgG S/CO	EBV VCA IgG U/ml	EBV VCA IgM U/ml	EBNA IgG U/ml
			cut off 1.0 S/CO	cut off 1.0 S/CO	cut off 1.0 S/CO	cut off 20 U/mL	cut off 40 U/mL	cut off 19 U/mL
1	0	22.04.2013	0.03	0.09	0.01	< 10.0	< 10.0	< 3.00
2	4	26.04.2013	0.02	0.09	0.01	< 10.0	< 10.0	< 3.00
3	22	14.05.2013	0.02	0.09	0.01	< 10.0	< 10.0	< 3.00
4	29	21.05.2013	0.02	0.08	0.01	< 10.0	< 10.0	< 3.00
5	32	24.05.2013	0.02	0.08	0.01	< 10.0	< 10.0	< 3.00
6	60	21.06.2013	0.91	6.64	0.04	70.5	>160	< 3.00
7	63	24.06.2013	0.82	6.45	0.03	65.6	>160	< 3.00
8	91	22.07.2013	5.86	2.05	0.17	81.3	157	< 3.00
9	109	09.08.2013	14.07	1.09	0.52	138	83.6	< 3.00
10	119	19.08.2013	18.25	0.76	0.82	150	62.0	7.24
11	123	23.08.2013	14.34	0.35	0.69	102	47.9	8.69
12	126	26.08.2013	17.26	0.30	1.14	113	41.3	16.10
13	130	30.08.2013	16.93	0.26	1.38	161	41.5	19.10
14	147	16.09.2013	27.92	0.27	4.98	215	32.6	52.20
15	151	20.09.2013	23.95	0.20	4.10	233	28.1	65.30
16	154	23.09.2013	24.22	0.13	3.98	217	27.1	67.00
17	158	27.09.2013	25.68	0.16	4.95	231	22.7	73.30
18	161	30.09.2013	29.22	0.16	5.35	211	18.6	80.20
19	176	15.10.2013	31.59	0.24	9.41	236	22.8	120.00
20	179	18.10.2013	32.27	0.19	9.11	262	21.5	138.00
21	182	21.10.2013	28.38	0.17	8.35	252	18.2	127.00
22	186	25.10.2013	29.50	0.14	8.54	228	18.2	115.00
23	203	11.11.2013	30.94	0.19	11.39	249	18.3	142.00
24	207	15.11.2013	28.18	0.12	9.35	226	17.2	142.00
25	210	18.11.2013	25.88	0.11	9.50	142	10.0	93.60

Assay Information:

Abbott Architect: no data available

Diasorin Liaison: Liaison VCA IgG assay; Lot: 030067X - Liaison EBV IgM assay; Lot: 049088X
Liaison EBNA IgG assay; Lot: 033065X

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