

## EBV IgM Seroconversion Panel

**REF** Catalog No: SCP-EBV-001

The Biomex GmbH EBV IgM Seroconversion Panel consists of 27 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 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 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, HBsAg and Syphilis with CE marked tests.

#### Donor profile

- Sex: Male
- Age: 25
- 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®. Additional testing for EBV-CA IgA, IgG, IgM, EBNA-1 IgG and EBV-CA IgG relative avidity index as well as EBV-EA IgA, IgG and IgM are carried out with EUROIMMUN ELISA®. 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	EBV VCA IgM U/ml (1:10 dil.)	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 >40 U/mL	cut off >19 U/mL
1	0	02.10.2012	0.03	0.08	0.01	<10.0	<10.0	<10.0	<3.0
2	6	08.10.2012	0.03	0.08	0.01	<10.0	<10.0	<10.0	<3.0
3	10	12.10.2012	0.02	0.07	0.01	<10.0	<10.0	<10.0	<3.0
4	28	30.10.2012	0.50	2.26	0.01	16.2	>160	103	<3.0
5	35	06.11.2012	0.98	9.82	0.01	75.9	>160	503	<3.0
6	38	09.11.2012	1.32	9.66	0.01	74.9	>160	583	<3.0
7	42	13.11.2012	1.90	7.86	0.02	70.6	>160	361	<3.0
8	45	16.11.2012	2.43	6.17	0.02	68.7	>160	348	<3.0
9	48	19.11.2012	3.13	5.31	0.02	65.1	>160	177	<3.0
10	52	23.11.2012	4.41	4.03	0.02	61.3	>160	152	<3.0
11	56	27.11.2012	5.79	2.88	0.02	57.2	>160	128	<3.0
12	59	30.11.2012	6.88	2.45	0.02	52.8	>160	not detectable	<3.0
13	63	04.12.2012	8.79	1.98	0.02	52.3	116	nd	<3.0
14	66	07.12.2012	9.57	1.62	0.02	51.6	81.0	nd	<3.0
15	70	11.12.2012	10.51	1.40	0.02	52.0	82.9	nd	<3.0
16	73	14.12.2012	11.60	1.25	0.02	47.1	57.2	nd	<3.0
17	77	18.12.2012	12.90	1.08	0.02	49.6	55.0	nd	<3.0
21	94	04.01.2013	18.52	0.95	0.02	69.3	44.5	nd	<3.0
22	99	09.01.2013	21.25	0.82	0.03	87.6	45.6	nd	<3.0
23	105	15.01.2013	24.20	0.71	0.03	74.7	34.1	nd	<3.0
24	108	18.01.2013	24.26	0.63	0.05	107	38.5	nd	<3.0
25	112	22.01.2013	28.26	0.63	0.18	143	43.7	nd	<3.0
26	115	25.01.2013	29.92	0.61	0.25	127	33.1	nd	<3.0
27	122	01.02.2013	34.39	0.64	0.43	153	35.1	nd	<3.0
28	142	21.02.2013	42.49	0.74	1.05	192	32.6	nd	<3.0
29	146	25.02.2013	40.28	0.67	0.99	175	27.9	nd	<3.0
30	149	28.02.2013	41.34	0.60	1.05	152	26.1	nd	<3.0

**Assay Information:** **Abbott Architect:** EBV VCA IgG assay; Lot: 26446LI00; Exp. Date:12.10.2013; Test Date: 14.05.2013  
 EBV VCA IgM assay; Lot: 26561LI00; Exp. Date:12.09.2013; Test Date: 14.05.2013  
 EBV EBNA IgG assay; Lot: 26563LI00; Exp. Date:12.10.2013; Test Date: 14.05.2013  
**Diasorin Liaison:** no data available

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Panel Member	Day	Bleed Date	EUROIMMUN ELISA							
			EBV-CA IgA Ratio	EBV-CA IgG RU/ml	EBV-CA IgM Ratio	EBV-CA IgG relative avidity index (RAI) %	EBNA-1 IgG RU/ml	EBV-EA IgA Ratio	EBV-EA IgG RU/ml	EBV-EA IgM Ratio
			cut off > 1.1 Ratio	cut off > 22 RU/ml	cut off > 1.1 Ratio	low: < 40 %	cut off > 22 RU/ml	cut off > 1.1 Ratio	cut off > 22 RU/ml	cut off > 1.1 Ratio
1	0	02.10.2012	0.156	< 2.000	0.096	nd	< 2.000	0.124	< 2.000	0.051
2	6	08.10.2012	0.173	< 2.000	0.118	nd	< 2.000	0.230	< 2.000	0.057
3	10	12.10.2012	0.148	< 2.000	0.107	nd	< 2.000	0.150	< 2.000	0.051
4	28	30.10.2012	0.354	2.922	1.028	nd	< 2.000	0.635	18.610	0.973
5	35	06.11.2012	0.683	25.021	3.101	13.971	< 2.000	3.818	> 200.000	4.149
6	38	09.11.2012	0.617	29.606	3.462	12.539	< 2.000	2.839	190.777	3.223
7	42	13.11.2012	0.527	36.483	3.448	16.332	< 2.000	1.748	173.648	2.197
8	45	16.11.2012	0.506	48.272	2.932	19.175	< 2.000	1.308	158.276	1.680
9	48	19.11.2012	0.416	46.416	2.560	22.863	< 2.000	0.915	145.539	1.030
10	52	23.11.2012	0.403	38.229	2.037	18.644	< 2.000	0.635	128.996	0.723
11	56	27.11.2012	0.358	48.927	1.738	22.378	< 2.000	0.475	112.599	0.447
12	59	30.11.2012	0.350	36.592	1.462	23.896	< 2.000	0.344	94.884	0.330
13	63	04.12.2012	0.333	39.757	1.175	29.695	< 2.000	0.284	85.514	0.276
14	66	07.12.2012	0.300	39.102	1.090	19.437	< 2.000	0.226	75.120	0.184
15	70	11.12.2012	0.300	45.324	1.031	28.052	< 2.000	0.246	57.991	0.139
16	73	14.12.2012	0.329	38.448	0.873	23.664	< 2.000	0.207	56.966	0.124
17	77	18.12.2012	0.288	35.391	0.873	22.798	< 2.000	0.172	36.470	0.120
21	94	04.01.2013	0.276	50.237	0.855	24.638	< 2.000	0.182	20.659	0.139
22	99	09.01.2013	0.239	55.258	0.773	25.189	< 2.000	0.262	18.475	0.127
23	105	15.01.2013	0.235	54.494	0.586	26.374	< 2.000	0.144	12.983	0.108
24	108	18.01.2013	0.226	63.990	0.700	26.917	< 2.000	0.140	12.644	0.124
25	112	22.01.2013	0.251	74.906	0.759	29.076	< 2.000	0.137	11.492	0.143
26	115	25.01.2013	0.202	74.142	0.652	29.897	< 2.000	0.134	9.932	0.133
27	122	01.02.2013	0.214	84.730	0.703	32.683	< 2.000	0.150	7.763	0.136
28	142	21.02.2013	0.218	117.914	0.755	33.497	< 2.000	0.172	7.966	0.162
29	146	25.02.2013	0.202	108.417	0.582	34.619	< 2.000	0.144	6.542	0.136
30	149	28.02.2013	0.148	110.164	0.593	33.637	< 2.000	0.147	6.136	0.136

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### Assay Information: EUROIMMUN:

EBV-CA IgA ELISA; Lot:C150928DA; Exp. Date:27.09.2016; Test Date: 01.12.2015  
 EBV-CA IgG ELISA; Lot:C151106DA; Exp. Date:05.11.2016; Test Date: 02.12.2015  
 EBV-CA IgM ELISA; Lot:C150813DA; Exp. Date:12.08.2016; Test Date: 01.12.2015  
 EBV-CA IgG RAI; Lot:C151106DA; Exp. Date:05.11.2016; Test Date: 07.12.2015  
 EBNA-1 IgG ELISA; Lot:C150529DA; Exp. Date:28.05.2016; Test Date: 02.12.2015  
 EBV-EA IgA ELISA; Lot:C150825DA; Exp.Date:24.08.2016; TestDate: 01.12.2015  
 EBV-EA IgG ELISA; Lot:C151012DA; Exp.Date:11.10.2016; TestDate: 02.12.2015  
 EBV-EA IgM ELISA; Lot:C150722DC; Exp.Date:21.07.2016; TestDate: 01.12.2015

