

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.

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.

Declaration of used symbols

| | | | | |
|----------------|------------|------------------------------|-----------------|------------------------|
| REF | LOT | | | |
| Catalog Number | Lot Number | Consult Instructions for Use | Manufactured by | Temperature Limitation |

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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

