



**PACKAGE INSERT (Catalogue No: EBV001SCP)**

**Lot No: 20110862**

Epstein-Barr Virus (EBV) Seroconversion Panel

### **PRODUCT DESCRIPTION**

The EBV Seroconversion Panel consists of 14 members with each member containing 1 vial of 1.0 mL of human plasma. Panel members collected in this longitudinal series are from a single donor during the progression of an early EBV infection. This panel illustrates the onset and follow up of IgM and IgG Epstein-Barr virus antibodies over a period of 182 days. Panel members are undiluted, naturally occurring plasma samples collected in 4% sodium citrate. Units were aseptically filtered. No preservative has been added. All panel members are ready to use.

### **INTENDED USE**

This Seroconversion Panel (SCP) is intended for use by diagnostic manufacturers and researchers during assay development, evaluation, and troubleshooting EBV test methods.

### **STORAGE AND STABILITY**

Panel members should be stored at -20°C or colder. 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.

### **WARNINGS AND PRECAUTIONS**

All blood products should be treated as potentially infectious. All human source materials used in the manufacture of this SCP, were tested and found negative for all US FDA required relevant transfusion-transmitted infections as described in 21 CFR 610.40. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents; appropriate care should be taken in the use of this product. These materials should be disposed in accordance to applicable local or national regulations. Waste must be disposed in a secured manner.

It is of the utmost importance that proper biosafety guidelines are followed by clinical laboratories when handling samples from EBV patients. Follow Universal Precautions<sup>1</sup>.

### **DONOR INFORMATION**

All panel members used in the preparation of this product have been tested and found negative by tests for antibodies to HIV 1/2, HCV and non-reactive for HBsAg. Pooled samples were found non-reactive for HIV-1 RNA, HBV DNA and HCV RNA by Nucleic Acid Test. All testing is performed with kits approved by the FDA.

The donor has been tested and found negative for syphilis according to FDA guidelines. All samples are collected under informed consent and an IRB protocol. All member units were collected at an FDA licensed donor center within the US.

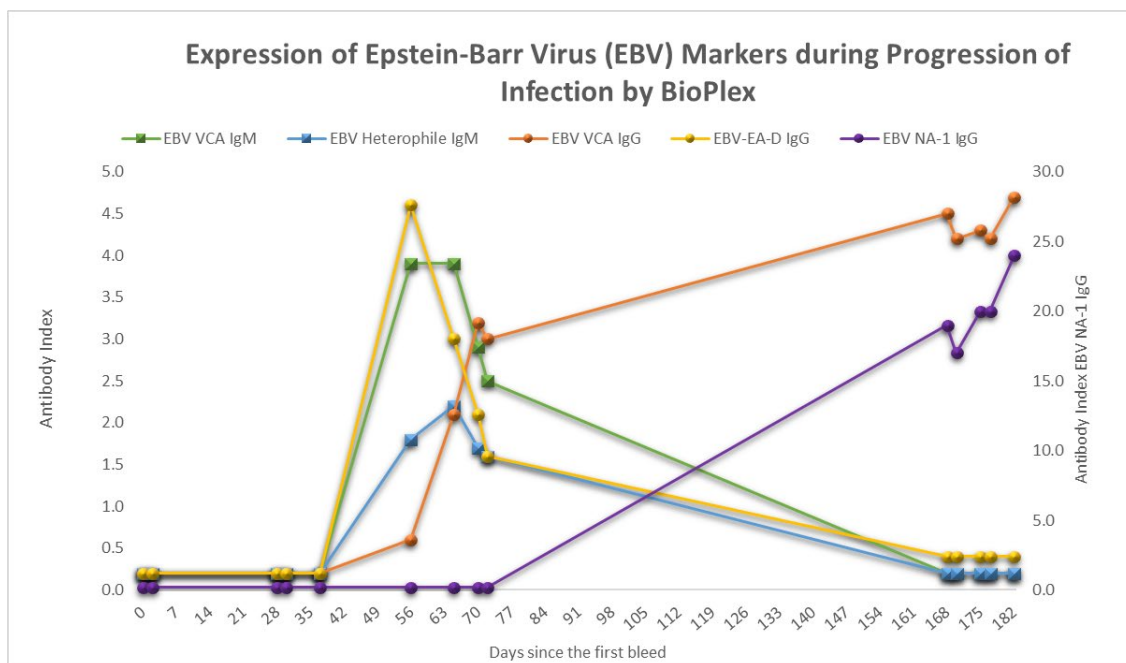
Donor Demographics: Donor was un-treated and asymptomatic throughout the collection period.

## DETECTION METHODS

EBV antibody reactivity is measured for each panel member with BioPlex® 2200 System IgM (two separate analytes; Epstein-Barr Virus Viral Capsid Antigen IgM [EBV VCA IgM] antibodies and Heterophile antibodies), BioPlex® 2200 System IgG (antibodies to three separate EBV antigens; EBV Nuclear Antigen-1 [EBV NA-1 IgG], Viral Capsid Antigen [EBV VCA IgG], and Early Antigen diffuse [EBV EA-D IgG] and ASI (Arlington Scientific, Inc.) Color Mono II Test for the detection of heterophil antibodies.

## 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. Access Biologicals does not claim that others can duplicate these test results exactly.



**EBV Seroconversion Panel, EBV001SCP**

| Panel member | Days since the first bleed | Bleed Date | BioPlex <sup>a</sup> |              |              |             |                     | ASI <sup>b</sup> |
|--------------|----------------------------|------------|----------------------|--------------|--------------|-------------|---------------------|------------------|
|              |                            |            | EBV VCA IgG          | EBV-EA-D IgG | EBV NA-1 IgG | EBV VCA IgM | EBV Heterophile IgM |                  |
| 1            | 0                          | 18/12/2008 | 0.2                  | 0.2          | 0.2          | 0.2         | 0.2                 | NR               |
| 2            | 2                          | 20/12/2008 | 0.2                  | 0.2          | 0.2          | 0.2         | 0.2                 | NR               |
| 3            | 28                         | 15/01/2009 | 0.2                  | 0.2          | 0.2          | 0.2         | 0.2                 | NR               |
| 4            | 30                         | 17/01/2009 | 0.2                  | 0.2          | 0.2          | 0.2         | 0.2                 | NR               |
| 5            | 37                         | 24/01/2009 | 0.2                  | 0.2          | 0.2          | 0.2         | 0.2                 | NR               |
| 6            | 56                         | 12/02/2009 | 0.6                  | 4.6          | 0.2          | 3.9         | 1.8                 | 1:8              |
| 7            | 65                         | 21/02/2009 | 2.1                  | 3.0          | 0.2          | 3.9         | 2.2                 | 1:8              |
| 8            | 70                         | 26/02/2009 | 3.2                  | 2.1          | 0.2          | 2.9         | 1.7                 | 1:8              |
| 9            | 72                         | 28/02/2009 | 3.0                  | 1.6          | 0.2          | 2.5         | 1.6                 | 1:4              |
| 10           | 168                        | 04/06/2009 | 4.5                  | 0.4          | 19.0         | 0.2         | 0.2                 | NR               |
| 11           | 170                        | 06/06/2009 | 4.2                  | 0.4          | 17.0         | 0.2         | 0.2                 | NR               |
| 12           | 175                        | 11/06/2009 | 4.3                  | 0.4          | 20.0         | 0.2         | 0.2                 | NR               |
| 13           | 177                        | 13/06/2009 | 4.2                  | 0.4          | 20.0         | 0.2         | 0.2                 | NR               |
| 14           | 182                        | 18/06/2009 | 4.7                  | 0.4          | 24.0         | 0.2         | 0.2                 | NR               |

<sup>a</sup> The system reports IgG and IgM antibodies to EBV as an antibody index (AI), units  $\leq 0.8$  are considered negative for IgG and IgM antibodies to EBV, units 0.9 and 1.0 are considered equivocal, units  $\geq 1.1$  are considered positive for IgG and IgM antibodies to EBV.

<sup>b</sup> NR: Nonreactive (no visible agglutination). The highest dilution in which visible agglutination occurs is considered the endpoint titer.

**References:**

1 Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7119119/pdf/main.pdf>

**This Product was manufactured under GMP guidelines in a facility which has a Quality Management System that is ISO 9001 certified.**

Access Biologicals • 995 Park Center Drive | Vista, CA 92081 • Tel 760- 931-8444 • Fax (760) 931-8456

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