



**PACKAGE INSERT (Catalogue No: B19V001SCP)**

**Lot No: 20100840**

Human parvovirus B19 (B19V) Seroconversion Panel

**PRODUCT DESCRIPTION**

The B19V Seroconversion Panel consists of 6 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 parvovirus B19 infection. This panel illustrates the profile of IgM and IgG parvovirus B19 antibodies and DNA titer over a period of 19 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 parvovirus B19 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 parvovirus B19 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 at an FDA licensed donor center within the US.

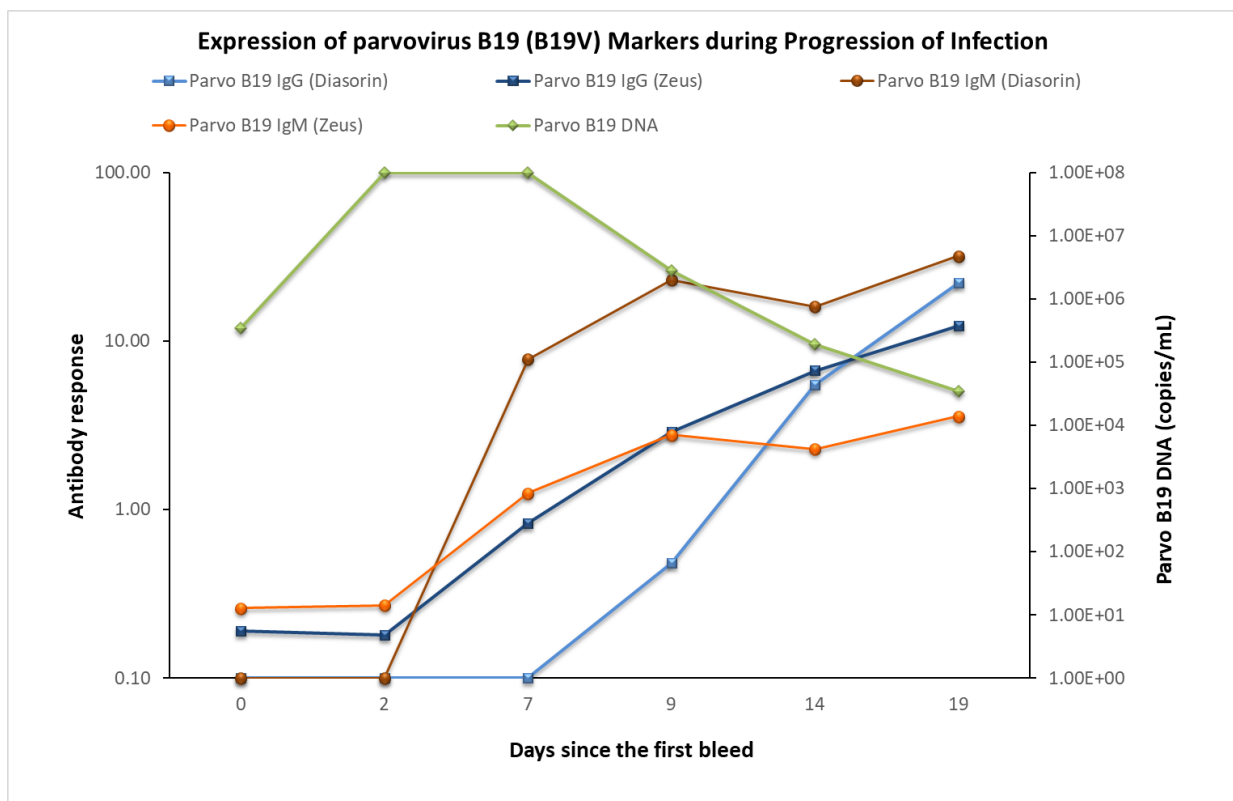
Donor Profile: The donor was un-treated and asymptomatic throughout the collection period.

## DETECTION METHODS

Parvo B19 antibody reactivity is measured for each panel member using the Liaison Biotrin Parvovirus B19 IgG assay, Liaison Biotrin Parvovirus B19 IgM assay by Diasorin, ZEUS ELISA Parvovirus B19 IgG test system and ZEUS ELISA Parvovirus B19 IgM test system. B19V DNA is measured with quantitative real-time PCR analysis performed at Quest Diagnostic Infections Disease, Inc.

## 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.



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Panel member	Days since the first bleed	Bleed date	Diasorin Liaison <sup>a</sup>		Zeus <sup>b</sup>		B19V DNA (copies/mL) <sup>c</sup>
			Anti-B19V IgG	Anti-B19V IgM	Anti-B19V IgG	Anti-B19V IgM	
1	0	2/19/2014	<0.10	<0.10	0.19	0.26	3.45E+05
2	2	2/21/2014	<0.10	<0.10	0.18	0.27	>1.00E+08
3	7	2/26/2014	<0.10	7.8	0.83	1.25	>1.00E+08
4	11	2/28/2014	0.48	23	2.89	2.78	2.80E+06
5	14	3/5/2014	5.5	16	6.65	2.29	1.89E+05
6	19	3/10/2014	22	32	12.30	3.58	3.39E+04

<sup>a</sup> The system reports IgG and IgM antibodies to parvovirus in Index Values, units < 0.9 are considered negative for IgG and IgM antibodies to parvovirus, units ≥ 0.9 and ≤ 1.1 are considered equivocal, units > 1.1 are considered positive for IgG and IgM antibodies to parvovirus B19.

<sup>b</sup> The system reports IgG and IgM antibodies to parvovirus results in Index Values/OD ratios, units ≤ 0.90 are considered negative for IgG and IgM antibodies to parvovirus B19, units = 0.91 and 1.09 are considered equivocal, units ≥ 1.10 are considered positive for IgG and IgM antibodies to parvovirus B19.

<sup>c</sup> B19V DNA copies / milliliter

**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.**

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