

Parvovirus B19 Mixed Titer Performance Panel

PVP201

DATA SHEET

OVERVIEW

SeraCare's Parvovirus B19 Mixed Titer Performance Panel PVP201 is the world's first commercially available Performance Panel of naturally occurring plasma samples characterized for IgM and IgG antibodies to parvovirus and for parvovirus B19 DNA. This Data Sheet provides test results from fourteen commercially available Parvovirus B19 IgG, IgM, and DNA assays. Results vary among different assays, indicating differing sensitivities, specificities, and calibrations for the included assays.

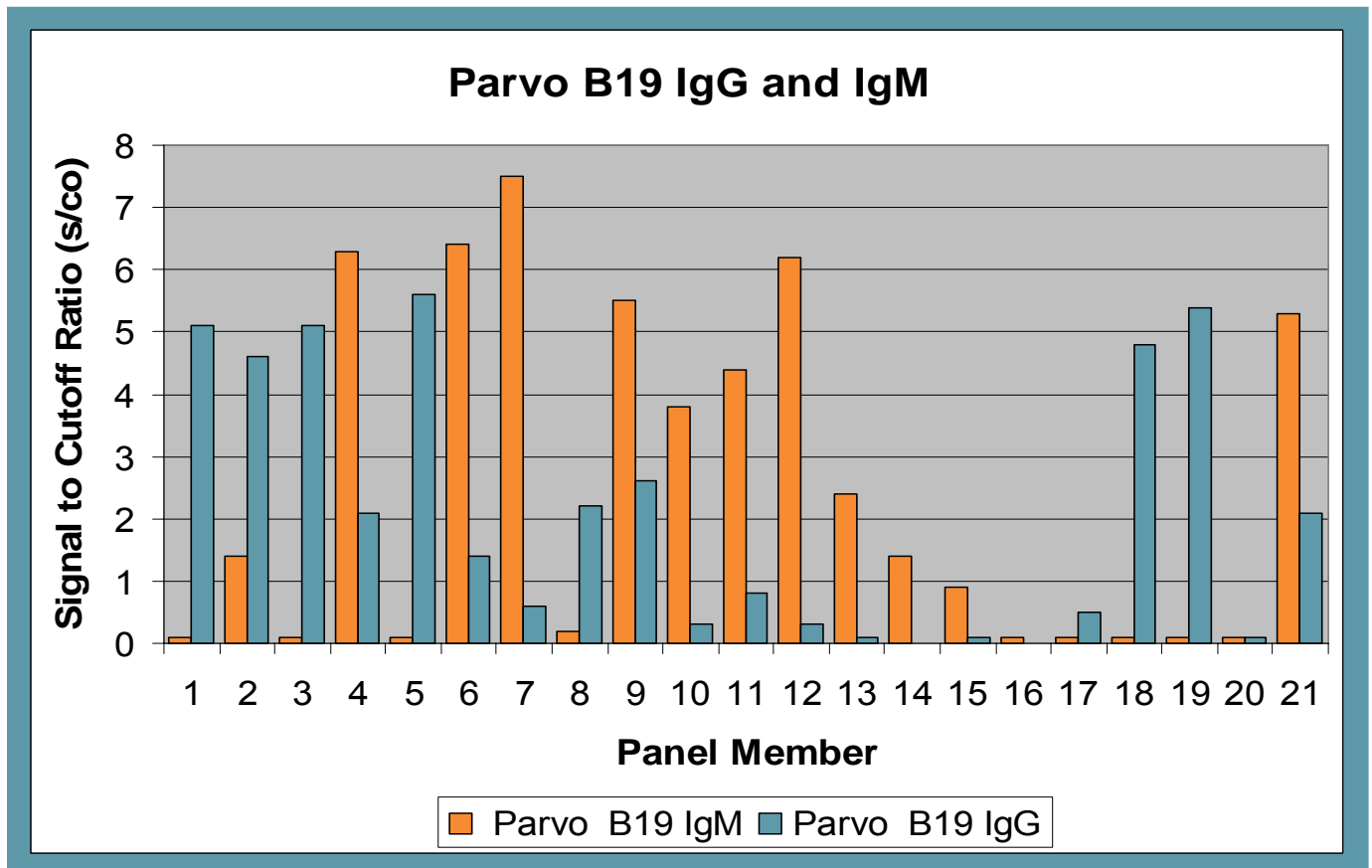
PVP201 is a 21 member, 1.2 mL per member panel of undiluted aliquots from plasma units. No preservatives were added.

CAUTION: Potentially infectious materials. Follow Universal Precautions. All panel members were found non-reactive for HBsAg, Anti-HIV and Anti-HCV.

For Research Use Only. Not for use in diagnostic procedures.

Data are offered for informational purposes only. SeraCare Life Sciences does not claim these results can be duplicated exactly.

For assistance, contact SeraCare Technical Support at 508.244.6400



This graph demonstrates IgG and IgM concentrations among PVP201 panel members with the Biotrin Parvo B19 IgG and IgM test.

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Parvo IgM

Panel Member	Biotrin Parvo B19 IgM s/co ¹	Diasorin LIAISON Parvo B19 IgM Index ²	DRG [®] International Parvo B19 IgM s/co ¹	Focus Diagnostics Parvo B19 IgM s/co ¹	r-Biopharm AG RIDASCREEN [®] Parvo IgM IU/mL ³	Virion-SERION Parvo B19 IgM s/co ¹
PVP201-01	0.1	<0.1	0.4	0.2	6.0	0.5
PVP201-02	1.4	1.2	0.4	0.1	2.0	0.2
PVP201-03	0.1	<0.1	0.2	0.1	4.0	0.3
PVP201-04	6.3	6.7	3.5	1.3	85.0	1.1
PVP201-05	0.1	<0.1	0.4	0.4	6.0	0.3
PVP201-06	6.4	2.6	4.7	5.2	76.0	5.5
PVP201-07	7.5	>48.0	5.2	1.7	>200.0	1.7
PVP201-08	0.2	<0.1	0.2	0.1	3.0	0.2
PVP201-09	5.5	33.9	2.9	7.5	>200.0	>10.4
PVP201-10	3.8	27.7	1.0	7.0	191.0	7.1
PVP201-11	4.4	24.6	0.9	0.7	28.0	0.8
PVP201-12	6.2	>48.0	0.7	6.4	>200.0	>10.4
PVP201-13	2.4	10.3	0.4	0.2	12.0	0.4
PVP201-14	1.4	3.5	0.3	2.3	13.5	1.1
PVP201-15	0.9	3.0	0.4	0.3	8.0	0.3
PVP201-16	0.1	<0.1	0.1	0.0	12.0	0.2
PVP201-17	0.1	<0.1	0.1	0.1	1.0	0.1
PVP201-18	0.1	<0.1	0.4	0.1	3.0	0.5
PVP201-19	0.1	<0.1	0.2	0.1	2.0	0.3
PVP201-20	0.1	<0.1	0.3	0.4	12.0	0.8
PVP201-21	5.3	38.4	2.7	3.6	41.0	2.9
Test Date	13-Sep-11	05-Sep-11	14-Sep-11	12-Sep-11	12-Sep-11	09-Nov-11
Test Site	SC	RL	SC	SC	SC	SC
Kit Part Code	V619IMUS	317010	EIA-3504	EL0100M	K6031	ESR122M
Kit Lot No.	36KT255US	129007	123M/K071	X110481	13041C	SMA.AQ
Kit Exp Date	29-Feb-12	21-Feb-12	31-Jul-12	31-May-12	31-Oct-12	30-Apr-12

1 Results are means of duplicates expressed as signal to cutoff ratios (s/co). Ratios ≥1.0 are considered reactive and are noted in red.

2 Results are means of duplicates expressed as Index values. Results ≥1.0 are considered reactive and are noted in red.

3 Results are means of duplicates expressed in IU/mL. Results >12.0 are considered reactive and are noted in red. Values between 10-12 IU/mL are considered equivocal.

SC = SeraCare; RL = Reference Lab



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Parvo IgG

Panel Member	Biotrin Parvo B19 IgG s/co ¹	Diasorin LIAISON Parvo B19 IgG Index ²	DRG [®] International Parvo B19 IgG s/co ¹	Focus Diagnostics Parvo B19 IgG s/co ¹	r-Biopharm AG RIDASCREEN [®] Parvo IgG IU/mL ³	Virion-SERION Parvo B19 IgG s/co ¹
PVP201-01	5.1	32.3	1.0	6.6	40.0	4.8
PVP201-02	4.6	23.1	1.1	4.0	49.5	4.1
PVP201-03	5.1	24.2	0.6	5.5	59.5	4.3
PVP201-04	2.1	>48.0	0.5	1.7	14.0	3.1
PVP201-05	5.6	36.3	1.1	7.4	66.5	5.4
PVP201-06	1.4	46.3	1.2	2.8	7.7	3.4
PVP201-07	0.6	0.6	0.7	0.4	3.5	1.1
PVP201-08	2.2	7.6	0.3	1.0	11.0	2.3
PVP201-09	2.6	11.4	1.6	8.7	11.0	5.1
PVP201-10	0.3	0.6	0.8	0.3	<2.0	0.5
PVP201-11	0.8	2.9	0.4	1.2	3.1	1.5
PVP201-12	0.3	0.2	0.4	0.3	2.5	1.1
PVP201-13	0.1	<0.1	0.5	0.0	<2.0	0.3
PVP201-14	0.0	<0.1	0.1	0.0	<2.0	0.0
PVP201-15	0.1	<0.1	0.2	0.1	<2.0	0.1
PVP201-16	0.0	<0.1	0.5	0.0	<2.0	0.1
PVP201-17	0.5	<0.1	0.2	0.0	<2.0	0.1
PVP201-18	4.8	27.4	1.2	6.1	2.6	4.1
PVP201-19	5.4	36.6	1.9	11.0	49.5	4.7
PVP201-20	0.1	<0.1	0.4	0.0	<2.0	0.1
PVP201-21	2.1	7.9	1.2	3.2	6.5	3.2
Test Date	06-Sep-11	05-Sep-11	13-Sep-11	12-Sep-11	12-Sep-11	12-Sep-11
Test Site	SC	RL	SC	SC	SC	SC
Kit Part Code	V519IGUS	317000	EIA-3503	EL0100G	K6021	ESR122G
Kit Lot No.	35KT217US	127005	123G/K031	X111303	12121C	SBB.DL
Kit Exp Date	29-Feb-12	14-Feb-12	30-Apr-12	31-Jul-12	31-Jul-12	28-Feb-13

1 Results are means of duplicates expressed as signal to cutoff ratios (s/co). Ratios ≥ 1.0 are considered reactive and are noted in red.

2 Results are means of duplicates expressed as Index values. Values ≥ 1.0 are considered reactive and are noted in red.

3 Results are means of duplicates expressed in IU/mL. Results >5.0 are considered reactive and are noted in red. Values between 3.0-5.0 IU/mL are considered equivocal.

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Parvo DNA

Panel Member	Abbott <i>m2000</i> Parvo DNA	Roche LightCycler® Parvo DNA copies/mL	Real-Time PCR Parvo DNA copies/mL
PVP201-01	PENDING	BLD	BLD
PVP201-02	PENDING	BLD	BLD
PVP201-03	PENDING	BLD	1.3 x 10 ³
PVP201-04	PENDING	3.5 x 10 ⁴	1.9 x 10 ⁴
PVP201-05	PENDING	BLD	1.2 x 10 ³
PVP201-06	PENDING	7.8 x 10 ³	6.7 x 10 ³
PVP201-07	PENDING	1.1 x 10 ⁴	2.0 x 10 ⁴
PVP201-08	PENDING	BLD	BLD
PVP201-09	PENDING	4.9 x 10 ⁵	2.9 x 10 ⁵
PVP201-10	PENDING	9.0 x 10 ⁶	3.4 x 10 ⁶
PVP201-11	PENDING	3.7 x 10 ⁴	1.1 x 10 ⁴
PVP201-12	PENDING	2.5 x 10 ⁶	1.2 x 10 ⁶
PVP201-13	PENDING	2.3 x 10 ^{9*}	3.5 x 10 ^{6*}
PVP201-14	PENDING	2.7 x 10 ^{9*}	4.1 x 10 ^{7****}
PVP201-15	PENDING	2.9 x 10 ^{10**}	2.3 x 10 ^{6**}
PVP201-16	PENDING	4.4 x 10 ^{11***}	2.9 x 10 ^{6***}
PVP201-17	PENDING	8.6 x 10 ^{10**}	1.5 x 10 ^{7**}
PVP201-18	PENDING	1.4 x 10 ⁴	3.8 x 10 ²
PVP201-19	PENDING	1.0 x 10 ⁵	1.8 x 10 ⁵
PVP201-20	PENDING	4.0 x 10 ⁴	1.4 x 10 ³
PVP201-21	PENDING	1.5 x 10 ⁵	7.5 x 10 ³
Test Date	PENDING	15-Sep-11/30-Sep-11/12-Oct-11/ 21-Oct-11	07-Sep-11/19-Nov-11
Test Site	PENDING	SC	RL
Kit Part Code	PENDING	03246809001	NA
Kit Lot No.	PENDING	12035921	NA
Kit Exp Date	PENDING	31-Mar-13	NA

SC = SeraCare; RL = Reference Lab

BLD = Below the limit of detection; ALR = Above the linear range

* = Tested at 1:1,000 dilution

** = Tested at 1:10,000 dilution

*** = Tested at 1: 100,000 dilution

**** = Tested at 1:10 dilution

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Parvo IgM and IgG Blot

Panel Member	r-Biopharm RIDA® Parvo IgG Band Pattern	r-Biopharm RIDA® Parvo IgG Result	r-Biopharm RIDA® Parvo IgM Band Pattern	r-Biopharm RIDA® Parvo IgM Result
PVP201-01	VP-N, VP-1S	Pos	VP-N, fVP-C	Pos
PVP201-02	NS-1, VP-N, fVP-C, VP-1S	Pos	fVP-N	Neg
PVP201-03	VP-N, VP-C, VP-1S	Pos	No Bands	Neg
PVP201-04	VP-N, VP-C, fVP-1S	Pos	VP-N, VP-C	Pos
PVP201-05	fNS-1, VP-N, VP-C, VP-1S	Pos	No Bands	Neg
PVP201-06	VP-N, VP-C, VP-1S	Pos	VP-N, VP-C, VP-1S	Pos
PVP201-07	VP-N, VP-C	Pos	VP-N, VP-C	Pos
PVP201-08	VP-N, fVP-1S	Pos	No Bands	Neg
PVP201-09	VP-N, VP-C, VP-1S	Pos	VP-N, VP-C, VP-1S	Pos
PVP201-10	fVP-N, VP-C	Pos	VP-N, VP-C	Pos
PVP201-11	VP-N, VP-C, VP-1S	Pos	VP-N, fVP-C	Pos
PVP201-12	fVP-N, fVP-C	Pos	VP-N, VP-C	Pos
PVP201-13	fVP-C	Neg	VP-C	Ind
PVP201-14	No Bands	Neg	fVP-N, VP-C	Ind
PVP201-15	fVP-C	Neg	VP-C	Ind
PVP201-16	No Bands	Neg	No Bands	Neg
PVP201-17	No Bands	Neg	No Bands	Neg
PVP201-18	VP-N, VP-C, VP-1S	Pos	VP-N	Ind
PVP201-19	NS-1, VP-N, VP-C, VP-1S	Pos	No Bands	Neg
PVP201-20	No Bands	Neg	VP-C	Ind
PVP201-21	VP-N, VP-C, VP-1S	Pos	VP-N, VP-C, VP-1S	Pos
Test Date	13-Sep-11		28-Nov-11	
Test Site	SC		SC	
Kit Part Code	L6003		L6003	
Kit Lot No.	13041		13041M	
Kit Exp Date	30-Jun-12		30-Jun-12	

Pos = Positive; Neg = Negative; f = Faint; Ind = Indeterminate
SC = SeraCare

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The Data Sheet for this panel in PDF form can be found at www.seracarepanels.com

The printed Data Sheet may be requested by email at info@seracare.com, or by phone at 508.244.6400

