

DATA SHEET

OVERVIEW

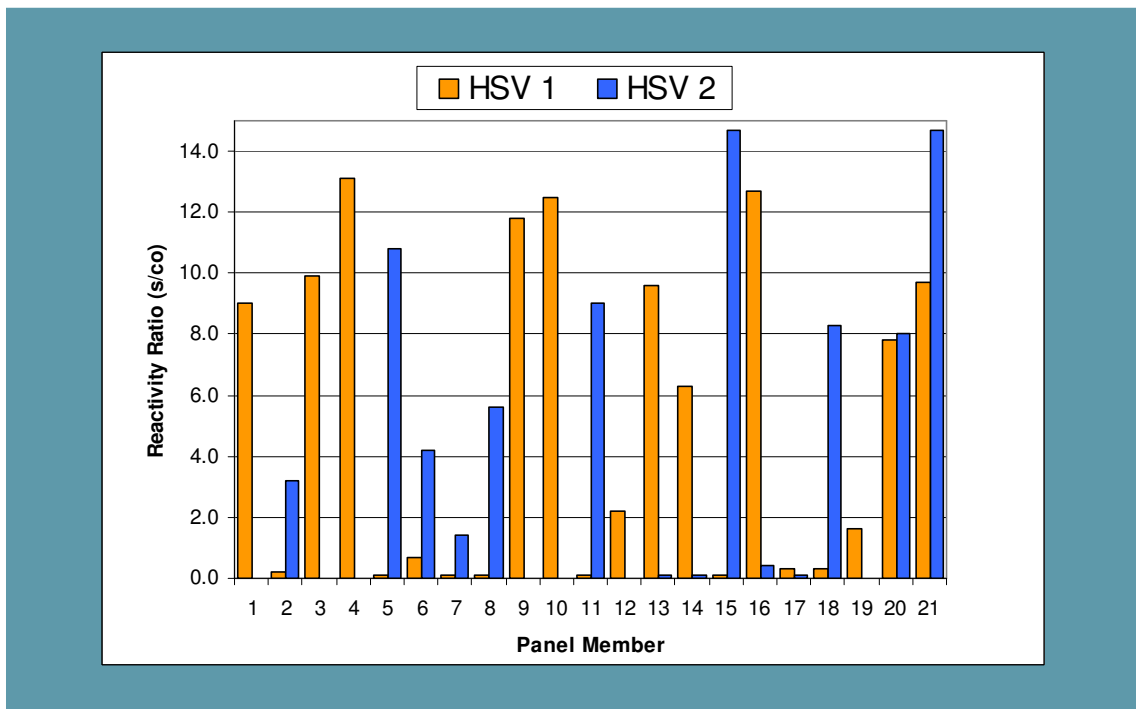
This Data Sheet contains test results specific for Anti-Herpes Simplex (HSV 1/2) Mixed Titer Performance Panel PTH202. Panel members are undiluted aliquots from plasma units collected from donors in the United States. This Panel contains very challenging samples for HSV 2 IgG. No preservatives were added.

CAUTION: Follow Universal Precautions. All panel members were found non-reactive for HBsAg, anti-HIV and anti-HCV. This does not ensure the absence of these or other human pathogens.

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

Data are provided for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

ANTI-HERPES MIXED TITER PERFORMANCE PANEL PTH202



This graph demonstrates the breadth of antibody reactivity among PTH202 panel members using Focus HERPES SELECT® ELISA.

Anti-Herpes Mixed Titer Performance Panel PTH202

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Anti-HSV-1 IgG Assays (s/co)¹

Panel Member	Bleed Date	Focus Diagnostics HerpeSelect [®] 1 ELISA IgG HSV 1 IgG	Roche Elecsys HSV 1 IgG	Trinity Biotech CAPTIA [™] HSV 1 IgG
PTH202-01	05 May 05	9.0	Pending	3.5
PTH202-02	25 Jan 10	0.2	Pending	1.2
PTH202-03	28 Apr 06	9.9	Pending	4.7
PTH202-04	03 Jul 01	13.1	Pending	4.9
PTH202-05	28 Jun 12	0.1	Pending	3.0
PTH202-06	NA	0.7	Pending	1.8
PTH202-07	19 May 05	0.1	Pending	1.1
PTH202-08	27 Apr 05	0.1	Pending	2.3
PTH202-09	06 May 04	11.8	Pending	5.3
PTH202-10	10 Mar 05	12.5	Pending	4.4
PTH202-11	30 Nov 05	0.1	Pending	1.6
PTH202-12	NA	2.2	Pending	3.7
PTH202-13	17 Oct 06	9.6	Pending	5.5
PTH202-14	26 Sep 02	6.3	Pending	5.0
PTH202-15	29 Aug 02	0.1	Pending	2.5
PTH202-16	09 May 05	12.7	Pending	5.4
PTH202-17	16 Apr 05	0.3	Pending	0.3
PTH202-18	29 Oct 05	0.3	Pending	2.2
PTH202-19	14 Nov 05	1.6	Pending	1.8
PTH202-20	23 Jan 10	7.8	Pending	5.0
PTH202-21	NA	9.7	Pending	5.9
Test Date		07 Feb 13		14 Feb 13
Test Site		SC		SC
Kit Part Code		EL0910G		2325400
Kit Lot No.		123451		2325400-528
Kit Exp. Date		30 Nov 13		31 Jan 14
Kit Regulatory Status		IVD/CE		CE

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

SC = SeraCare; NA = not available

CE = Conformité Européenne or CE Marking; IVD = in vitro diagnostic use

Anti-Herpes Mixed Titer Performance Panel PTH202

DATA SHEET

Anti-HSV-2 IgG Assays (s/co)¹

Panel Member	Focus Diagnostics HerpeSelect [®] 2 ELISA IgG HSV 2 IgG	Bio-Rad Platelia [™] HSV 2 IgG	Trinity Biotech CAPTIA [™] HSV 2 IgG
PTH202-01	0.0	0.2	0.7
PTH202-02	3.2	4.8	1.4
PTH202-03	0.0	0.3	1.7
PTH202-04	0.0	0.1	1.6
PTH202-05	10.8	2.9	4.5
PTH202-06	4.2	1.6	2.3
PTH202-07	1.4	0.8	1.6
PTH202-08	5.6	2.6	3.6
PTH202-09	0.0	0.3	1.5
PTH202-10	0.0	0.2	1.3
PTH202-11	9.0	4.0	1.9
PTH202-12	0.0	0.2	0.9
PTH202-13	0.1	0.3	2.2
PTH202-14	0.1	0.3	1.4
PTH202-15	14.7	6.4	4.5
PTH202-16	0.4	0.8	2.3
PTH202-17	0.1	0.3	0.2
PTH202-18	8.3	4.1	3.5
PTH202-19	0.0	0.2	0.4
PTH202-20	8.0	2.2	2.9
PTH202-21	14.7	6.4	5.1
Test Date	07 Feb 13	26 Feb 13	14 Feb 13
Test Site	SC	SC	SC
Kit Part Code	EL0920G	72821	2325500
Kit Lot No.	123449	2D0018	2325500-527
Kit Exp. Date	31 Dec 13	30 Sep 13	31 Jan 14
Kit Regulatory Status	IVD/CE	IVD/CE	CE

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

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Anti-Herpes Mixed Titer Performance Panel PTH202

DATA SHEET

Anti-HSV-1/2 IgM/IgG Assays (s/co)¹

Panel Member	Trinity Biotech CAPTIA™ HSV 1 IgM	Trinity Biotech CAPTIA™ HSV 2 IgM	Siemens IMMULITE® HSV 1 & 2 IgG	Bio-Rad Platelia™ HSV 1 & 2 IgM	DiaSorin LIAISON® HSV 1 & 2 ²
PTH202-01	0.3	0.3	9.3	0.2	8.7
PTH202-02	1.3	1.8	3.3	0.7	0.9
PTH202-03	1.3	0.5	26.4	0.4	16.5
PTH202-04	0.1	0.2	36.7	0.3	6.5
PTH202-05	0.1	0.2	25.6	0.4	6.8
PTH202-06	1.2	1.4	12.4	0.4	3.0
PTH202-07	0.4	0.6	3.9	0.3	0.7
PTH202-08	0.7	1.0	7.4	1.5	1.1
PTH202-09	0.4	0.3	20.8	0.2	16.6
PTH202-10	0.1	0.4	16.9	1.2	8.2
PTH202-11	0.7	1.1	7.0	0.3	2.6
PTH202-12	0.5	0.3	13.7	0.3	<0.5
PTH202-13	0.5	0.5	35.6	0.3	25.8
PTH202-14	1.1	0.6	14.1	0.7	1.3
PTH202-15	0.3	0.6	31.6	0.4	11.7
PTH202-16	0.2	0.3	26.5	0.5	14.7
PTH202-17	0.1	0.1	0.4	0.1	<0.5
PTH202-18	0.5	0.7	9.1	0.2	2.2
PTH202-19	1.5	0.5	4.2	0.8	0.7
PTH202-20	0.6	0.7	29.9	0.7	15.0
PTH202-21	0.4	0.3	42.4	3.2	24.8
Test Date	14 Feb 13	14 Feb 13	01 Mar 13	26 Feb 13	19 Feb 13
Test Site	SC	SC	SC	SC	RL
Kit Part Code	2325460	2325560	LKHS1	72822	3108000
Kit Lot No.	2325460-038	2325560-042	LKHS1-0314	2K0017	73054
Kit Exp. Date	30 Nov 13	31 May 13	30 Jun 13	30 Oct 13	15 Oct 13
Kit Regulatory Status	CE	CE	CE	IVD/CE	IVD/CE

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

² DiaSorin LIAISON® HSV 1 & 2 results are single point data.

RL = Reference Lab; SC = SeraCare

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Rapid Test/Immunoblot

Panel Member	Fisher Sure-Vue HSV-2 Rapid Test	Focus Diagnostics HerpeSelect® 1 & 2 Immunoblot IgG
PTH202-01	Neg	HSV 1
PTH202-02	Pos	Neg
PTH202-03	Neg	HSV 1
PTH202-04	Neg	HSV 1
PTH202-05	Pos	HSV 2
PTH202-06	Pos	HSV 2
PTH202-07	Neg	Neg
PTH202-08	Pos	HSV 2
PTH202-09	Neg	HSV 1
PTH202-10	Neg	HSV 1
PTH202-11	Pos	HSV 2
PTH202-12	Neg	EQ
PTH202-13	Neg	HSV 1
PTH202-14	Neg	HSV 1
PTH202-15	Pos	HSV 2
PTH202-16	Neg	HSV 1
PTH202-17	Neg	Neg
PTH202-18	Pos	HSV 2
PTH202-19	Neg	Neg
PTH202-20	Pos	HSV 1
PTH202-21	Pos	HSV 1
Test Date	13 Feb 13	14 Feb 13
Test Site	SC	SC
Kit Part Code	23-046395	IB0900G
Kit Lot No.	M743, D2933	122057
Kit Exp. Date	30 Apr 13, 31 Oct 13	30 Sep 13
Kit Regulatory Status	IVD	IVD/CE

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

SC = SeraCare
 CE = Conformité Européenne or CE Marking; IVD = in vitro diagnostic use
 Pos = positive; Neg = Negative; EQ = Equivocal

For assistance, contact SeraCare Technical Support at 508.244.6400.

The Package Insert for this panel in PDF form can be found at www.seracarecatalog.com

A printed copy of the Package Insert or Data Sheet may be requested by email at info@seracare.com, or by phone at 508.244.6400

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