

Anti-Epstein-Barr Virus Mixed Titer Performance Panel

PME202

DATA SHEET

OVERVIEW

This Data Sheet contains test results specific for Anti-Epstein Barr Virus (EBV) Mixed Titer Performance Panel PME202. Panel members are undiluted aliquots from plasma units collected from donors in the United States, Central and South America and Mexico. Test results for rapid assays that detect heterophile antibodies, tests for IgM and IgG antibodies to Epstein-Barr nuclear antigen (EBNA) and viral capsid antigen (VCA), and tests for IgG antibodies to early antigen (EA) are included. No preservatives were added.

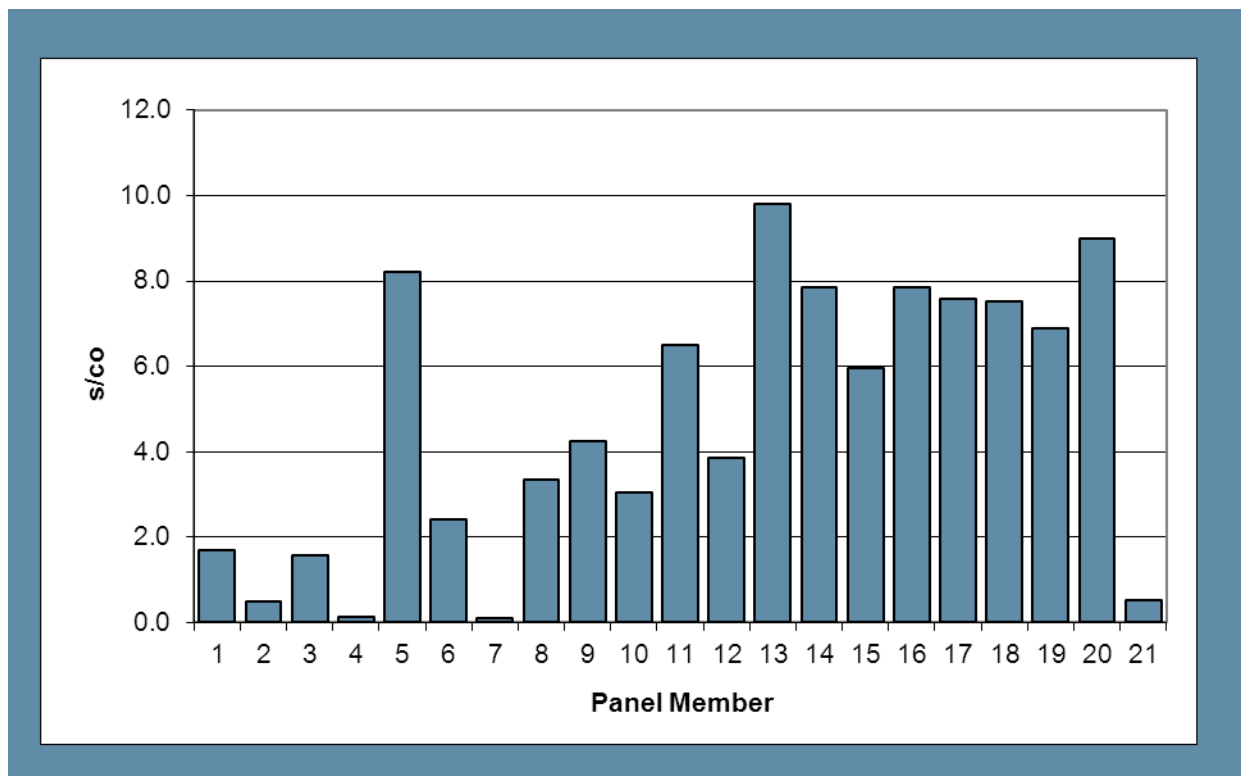
CAUTION: Follow Universal Precautions. All panel members were found non-reactive for HBsAg, anti-HIV and anti-HCV. This does not ensure the absence of these or other human pathogens.

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.

For assistance, contact SeraCare Technical Support at 508.244.6400.

VIRAL CAPSID ANTIGEN (VCA) IgG –RESULTS for PME202 PANEL MEMBERS



This graph demonstrates the breadth of Epstein-Barr Virus VCA results for PME202 panel members.



Rapid Heterophile Antibodies and Nuclear Antigen (EBNA) Assays

Panel Member	Fisher Sure-Vue	Quidel QuickVue + Mono	DiaSorin Liaison NA IgG ²	Trinity Bio CAPTIA NA-1 IgG ¹	Trinity Bio CAPTIA EBNA-1 IgM ¹
PME202 - 01	Pos	Pos	<3	0.1	4.3
PME202 - 02	Pos	Pos	<3	0.2	1.7
PME202 - 03	Pos	Pos	<3	0.2	0.3
PME202 - 04	Pos	Pos	<3	0.1	0.6
PME202 - 05	Pos	Neg	>600	2.1	0.3
PME202 - 06	Pos	Neg	<3	0.2	2.8
PME202 - 07	Neg	Neg	3.55	0.1	0.2
PME202 - 08	Pos	Pos	43.35	1.6	4.2
PME202 - 09	Neg	Neg	33.15	1.4	0.5
PME202 - 10	Neg	Neg	>600	2.8	0.2
PME202 - 11	Pos	Pos	32.05	1.9	1.3
PME202 - 12	Neg	Neg	>600	2.4	0.2
PME202 - 13	Neg	Neg	>600	2.5	0.1
PME202 - 14	Neg	Neg	>600	2.7	1.9
PME202 - 15	Neg	Neg	151	1.7	2.8
PME202 - 16	Neg	Neg	>600	2.7	0.3
PME202 - 17	Neg	Neg	>600	2.7	0.2
PME202 - 18	Neg	Neg	>600	2.8	0.2
PME202 - 19	Neg	Neg	532	2.7	0.3
PME202 - 20	Neg	Neg	>600	2.9	0.2
PME202 - 21	Pos	Pos	<3	0.1	3.6
Test Date	08-Oct-2012	08-Oct-2012	09-Oct-2012	04-Oct-2012	04-Oct-2012
Test Site	SC	SC	RL	SC	SC
Kit Part Code	23-038006	20121	310520	2325800	2325860
Kit Lot No.	F-0512	708268	025023	2325800-549	2325860-043
Kit Exp. Date	28-Sep-2013	30-Apr-2014	27-Feb-2013	31-Aug-2013	31-May-2013
Kit Regulatory Status	IVD	CE-IVD	IVD	CE-IVD FDA-IVD Canadian Licensed	CE-IVD FDA-IVD Canadian Licensed

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

²Diasorin Liaison results are presented in units of U/mL. Values greater than 21.9 are considered reactive and noted in red.

POS = positive; NEG = negative;

RL = Reference Lab; SC = SeraCare

ASR = analyte specific reagent; CE = Conformité Européenne or CE Mark; FDA IVD = in vitro diagnostic use (U.S.)



Early Antigen (EA) and Viral Capsid Antigen (VCA) IgG Assays¹

Panel Member	DiaSorin Liaison EA IgG ²	Trinity Bio CAPTIA EA-D IgG	Wampole EA IgG	Gold Standard Diagnostics VCA IgG	Trinity Bio CAPTIA p18 IgG	Wampole VCA ELISA II IgG
PME202 - 01	52.7	3.3	0.5	Pending	1.7	0.6
PME202 - 02	79.6	2.8	0.4	Pending	0.5	0.8
PME202 - 03	51.5	1.3	0.4	Pending	1.6	1.3
PME202 - 04	107	2.6	0.5	Pending	0.1	1.2
PME202 - 05	<5	0.8	1.3	Pending	8.2	3.5
PME202 - 06	79.9	4.7	1.3	Pending	2.4	1.4
PME202 - 07	<5	0.3	0.2	Pending	0.1	0.2
PME202 - 08	39.1	1.1	0.6	Pending	3.4	2.8
PME202 - 09	46.9	1.1	0.9	Pending	4.3	3.3
PME202 - 10	51.3	3.3	1.6	Pending	3.0	3.6
PME202 - 11	134.5	3.6	0.6	Pending	6.5	2.0
PME202 - 12	>150	4.3	2.0	Pending	3.8	6.6
PME202 - 13	96.7	3.9	3.3	Pending	9.8	6.6
PME202 - 14	>150	4.9	2.5	Pending	7.8	6.5
PME202 - 15	<5	0.6	0.6	Pending	5.9	3.6
PME202 - 16	64.1	3.1	2.1	Pending	7.9	6.8
PME202 - 17	81	3.0	1.8	Pending	7.6	6.2
PME202 - 18	29.0	0.9	0.7	Pending	7.5	2.7
PME202 - 19	<5	0.6	1.0	Pending	6.9	2.6
PME202 - 20	<5	1.1	1.6	Pending	9.0	3.6
PME202 - 21	44.7	1.2	0.4	Pending	0.5	0.4
Test Date	09-Oct-2012	04-Oct-2012	05-Oct-2012	Pending	04-Oct-2012	05-Oct-2012
Test Site	RL	SC	SC	Pending	SC	SC
Kit Part Code	310540	2325000	425000CE	Pending	2324700	424700CE
Kit Lot No.	102017	2325000-534	12060141	Pending	2324700-549	12050181
Kit Exp. Date	31-Dec-2012	31-Mar-2013	30-Oct-2013	Pending	31-Jul-2013	31-Jul-2013
Kit Regulatory Status	IVD	CE-IVD FDA-IVD Canadian Licensed	CE-IVD	Pending	CE-IVD FDA-IVD Canadian Licensed	CE-IVD

¹ Unless otherwise noted, results are expressed as signal to cutoff ratios (s/co). Ratios ≥1.0 are considered reactive and noted in red.

² DiaSorin Liaison results are presented in units of U/mL. Values greater than 10.9 are considered reactive and noted in red.

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Viral Coat Antigen (VCA) IgM Assays¹

Panel Member	DiaSorin Liaison VCA IgM ²	Gold Standard Diagnostics VCA IgM	Trinity Bio CAPTIA VCA IgM	Wampole VCA IgM
PME202 - 1	71.6	Pending	5.8	6.3
PME202 - 2	76.7	Pending	2.8	5.9
PME202 - 3	>160	Pending	2.7	5.5
PME202 - 4	>160	Pending	4.6	6.3
PME202 - 5	<10	Pending	0.1	0.0
PME202 - 6	>160	Pending	6.9	6.3
PME202 - 7	<10	Pending	0.1	0.0
PME202 - 8	40.6	Pending	1.0	2.9
PME202 - 9	26.6	Pending	0.2	0.0
PME202 - 10	<10	Pending	0.1	0.1
PME202 - 11	60.8	Pending	2.4	5.8
PME202 - 12	<10	Pending	0.2	0.0
PME202 - 13	<10	Pending	0.0	0.0
PME202 - 14	<10	Pending	0.3	0.1
PME202 - 15	19.6	Pending	0.2	0.1
PME202 - 16	<10	Pending	0.0	0.0
PME202 - 17	<10	Pending	0.0	0.0
PME202 - 18	<10	Pending	0.1	0.0
PME202 - 19	<10	Pending	0.1	0.0
PME202 - 20	<10	Pending	0.1	0.0
PME202 - 21	>160	Pending	3.2	6.3
Test Date	09-Oct-2012	Pending	08-Oct-2012	05-Oct-2012
Test Site	RL	Pending	SC	SC
Kit Part Code	310500	Pending	2325760	425760CE
Kit Lot No.	028024	Pending	2325760-098	12070246
Kit Exp. Date	09-May-2013	Pending	31-May-2013	31-Jan-2014
Kit Regulatory Status	IVD	Pending	CE-IVD FDA-IVD Canadian Licensed	CE-IVD

¹ Unless otherwise noted, results are expressed as signal to cutoff ratios (s/co). Ratios ≥1.0 are considered reactive and noted in red.

² DiaSorin Liaison results are presented in units of U/mL. Values greater than 43.9 are considered reactive and noted in red.

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CE = Conformité Européenne or CE Mark; FDA IVD = in vitro diagnostic use (U.S.)

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