BOSTON BIOMEDICA, INC.

Anti-Rubella Mixed Titer Performance Panel

(PTR201)

INTENDED USE

This panel of naturally occurring serum and plasma specimens is provided for research use only. Our purpose in making available this Performance Panel is to enable manufacturers and diagnostic laboratories to evaluate their Anti-Rubella tests with characterized samples and to provide comprehensive data for comparative analysis.

PRODUCT DESCRIPTION

Boston Biomedica, Inc. (BBI) has assembled from its repository of frozen serum and plasma units a set of 25 aliquots with Anti-Rubella reactivity ranging from negative to strongly positive using a variety of currently available test methodologies. Samples have been selected to demonstrate IgG and/or IgM reactivity; in addition, one negative serum and one negative plasma have been included as nonreactive controls. Specimens are undiluted aliquots from plasma and serum units collected in 1994 and 1995. The units were processed by sterile filtration. No preservatives were added.

INTERPRETATION OF RESULTS

The attached data sheet provides the results from test kits commercially available in the United States. Product numbers are indicated for identification of each method. Testing was performed at BBI and an independent reference laboratory. EIA results are the means of duplicate tests. Results on page 1 are expressed as signal to cutoff ratios (s/co) to facilitate comparisons among kits; ratios $\geq$1.0 are considered reactive. Page 2 shows results expressed according to each manufacturer's instructions. Interpretive criteria for the methods are listed below each column of data. Latex agglutination results are reported as positive/reactive or negative. Hemaglutination inhibition results are expressed as endpoint titers. Titers $\geq$8 are considered reactive.

PRECAUTIONS

These materials have not been inactivated and should be handled, like all blood products, as if potentially biohazardous, following good laboratory safety practice.

Panel members have been tested and found negative for HBsAg, anti-HCV and anti-HIV 1/2. This does not ensure the absence of these or other human pathogens.

Never pipette by mouth. Do not smoke, eat or drink in areas where specimens are handled.

These materials should be disposed of in a manner that will inactivate pathogenic agents.

STORAGE

Panel members should be stored frozen. BBI recommends dividing the samples into smaller aliquots to avoid repeated freeze-thaw cycles.

LIMITATIONS

This Performance Panel is offered for research use only. Data are provided for informational purposes. Boston Biomedica, Inc. does not claim that others can duplicate these results exactly.

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Anti-Rubella Mixed Titer PERFORMANCE Panel (PTR201)

DATA SHEET

Panel I.D. #	Matrix	Abbott EIA Rubella-IgM s/co	BioWhittaker EIA Rubella-IgM s/co	Abbott EIA Rubella-IgG s/co	Abbott IMX Rubella-IgG s/co	BioWhittaker EIA Rubella-IgG s/co	Bect. Dick. Rubella-Total Latex Aggl.	Murex Rubella-Total Latex Aggl.	Seradyn Rubella-Total Latex Aggl.	HAI[1] Rubella-Total Titer
PTR201-01	S	0.2	0.1	1.1	2.5	1.4	Reactive	Positive	2+	<8
PTR201-02	S	0.5	0.4	2.4	21.7	6.7	Reactive	Positive	3+	64
PTR201-03*	P	>2.3	1.6	3.1	32.2	5.9	Reactive	Positive	2+	64
PTR201-04	S	0.2	0.1	2.8	48.7	8.9	Reactive	Positive	1+	256
PTR201-05	P	0.1	0.1	0.1	0.0	0.0	Non-Reactive	Negative	Negative	<8
PTR201-06	S	0.1	0.1	1.2	3.1	2.6	Reactive	Positive	2+	8
PTR201-07	P	1.2	0.3	2.5	9.2	2.2	Reactive	Positive	2+	16
PTR201-08	S	0.2	0.3	1.7	4.9	2.0	Reactive	Positive	3+	8
PTR201-09	S	0.1	0.1	2.7	29.1	7.3	Reactive	Positive	3+	128
PTR201-10	P	0.1	0.1	3.0	27.6	4.1	Reactive	Positive	3+	64
PTR201-11	P	>2.3	8.4	2.7	12.1	8.6	Reactive	Positive	4+	16
PTR201-12	S	0.2	0.1	2.7	49.7	8.9	Reactive	Positive	1+	128
PTR201-13*	P	0.7	0.1	3.2	45.8	7.4	Reactive	Positive	4+	64
PTR201-14	P	0.1	0.1	2.4	4.6	1.7	Reactive	Positive	2+	32
PTR201-15	P	0.1	0.1	3.3	83.3	6.8	Reactive	Positive	3+	256
PTR201-16	S	0.2	0.1	0.1	0.3	0.1	Non-Reactive	Negative	Negative	<8
PTR201-17	S	0.2	0.1	2.0	8.3	5.4	Reactive	Positive	3+	32
PTR201-18	S	0.9	1.4	1.1	2.9	2.1	Reactive	Positive	2+	32
PTR201-19	P	2.1	0.2	1.7	4.0	0.5	Reactive	Positive	3+	8
PTR201-20	P	0.1	0.1	>3.4	34.2	6.1	Reactive	Positive	3+	128
PTR201-21	S	0.2	0.9	2.2	15.2	4.2	Reactive	Positive	3+	64
PTR201-22	P	0.1	0.1	1.4	2.1	0.8	Reactive	Positive	2+	<8
PTR201-23	S	0.1	0.1	2.2	13.9	4.7	Reactive	Positive	3+	64
PTR201-24	P	1.0	0.2	1.3	3.3	0.6	Reactive	Positive	2+	<8
PTR201-25	S	0.3	0.2	2.5	34.8	5.9	Reactive	Positive	3+	128
Run Date:		07/13/95	07/01/95	07/13/95	06/08/95	06/08/95	06/09/95	07/05/95	06/11/95	07/28/95
Kit Lot #:		06143M100	4E8570	02790M100	02893M200	4E2319	1000E5FERY	UK4	5B4M	NA
Exp Date:		10/06/95	12/12/95	09/01/95	09/08/95	11/17/95	10/01/95	03/01/96	02/24/96	NA
Product #:		7205-22	30-347U	7870-24	2247-20	30-336U	4961701	68152	0369579	NA

This Panel is provided for research use only. Data are offered for informational purposes. BBI does not claim that others can duplicate these test results exactly. Above results except HAI were generated using commercially available FDA approved Anti-Rubella screening tests, performed at BBI by individuals who routinely use these procedures. EIA results are means of duplicate expressed on this page as signal to cutoff ratios (s/co). Ratios $\geq$1.0 are considered reactive. Latex agglutination results were run in duplicate and reported per manufacturer's instructions. Specimens are undiluted aliquots from serum (S) or plasma (P) units collected between 1994 and 1995. Processing consisted of sterile filtration.

[1]HAI = Hemagglutination Inhibition performed by an inhouse method at an independent reference laboratory, NA = not available

All samples are nonreactive for rheumatoid factor except member 02 (13 IU/ml). Samples $\geq$9 IU/ml are considered reactive for rheumatoid factor.

*Member 13 was collected 14 days later from the same naturally infected individual as member 03. Members 07, 19 and 24 were collected from recently immunized individuals.

Rubella Antibody Results - Manufacturer's Units and Interpretation

Panel I.D. #	Abbott EIA Rubella-IgM Index		BioWhittaker EIA Rubella-IgM Value		Abbott EIA Rubella-IgG Index		Abbott IMX Rubella-IgG IU/ml		BioWhittaker EIA Rubella-IgG PIV		Bect. Dick. Rubella-Total Latex Aggl.	Murex Rubella-Total Latex Aggl.	Seradyn Rubella-Total Latex Aggl.	HAI[1] Rubella-Total Titer
PTR201-01	0.159	N	0.02	N	1.086	P	24.5	P	1.38	LP	Reactive	Positive	2+	<8
PTR201-02	0.518	N	0.10	N	2.357	P	217.4	P	6.66	HP	Reactive	Positive	3+	64
PTR201-03*	>2.543	P	0.44	P	3.148	P	321.8	P	5.90	MP	Reactive	Positive	2+	64
PTR201-04	0.174	N	0.03	N	2.782	P	487.0	P	8.92	HP	Reactive	Positive	1+	256
PTR201-05	0.103	N	0.03	N	0.089	N	0.0	N	0.00	N	Non-Reactive	Negative	Negative	<8
PTR201-06	0.146	N	0.02	N	1.204	P	30.6	P	2.60	LP	Reactive	Positive	2+	8
PTR201-07	1.319	P	0.08	N	2.451	P	91.7	P	2.23	LP	Reactive	Positive	2+	16
PTR201-08	0.230	N	0.07	N	1.650	P	48.7	P	2.00	LP	Reactive	Positive	3+	8
PTR201-09	0.137	N	0.04	N	2.711	P	291.3	P	7.32	HP	Reactive	Positive	3+	128
PTR201-10	0.082	N	0.03	N	2.997	P	275.8	P	4.10	MP	Reactive	Positive	3+	64
PTR201-11	>2.543	P	2.35	P	2.738	P	121.4	P	8.60	HP	Reactive	Positive	4+	16
PTR201-12	0.241	N	0.02	N	2.652	P	496.6	P	8.92	HP	Reactive	Positive	1+	128
PTR201-13*	0.766	N	0.03	N	3.199	P	458.2	P	7.43	HP	Reactive	Positive	4+	64
PTR201-14	0.096	N	0.03	N	2.441	P	45.7	P	1.74	LP	Reactive	Positive	2+	32
PTR201-15	0.114	N	0.02	N	3.254	P	832.8	P	6.76	HP	Reactive	Positive	3+	256
PTR201-16	0.185	N	0.03	N	0.088	N	3.1	N	0.10	N	Non-Reactive	Negative	Negative	<8
PTR201-17	0.238	N	0.04	N	1.995	P	83.0	P	5.40	MP	Reactive	Positive	3+	32
PTR201-18	0.944	EQ	0.39	P	1.127	P	29.4	P	2.08	LP	Reactive	Positive	2+	32
PTR201-19	2.334	P	0.05	N	1.664	P	40.4	P	0.48	N	Reactive	Positive	3+	8
PTR201-20	0.086	N	0.02	N	>3.390	P	342.3	P	6.12	MP	Reactive	Positive	3+	128
PTR201-21	0.186	N	0.25	EQ	2.234	P	151.6	P	4.22	MP	Reactive	Positive	3+	64
PTR201-22	0.120	N	0.04	N	1.385	P	20.5	P	0.80	EQ	Reactive	Positive	2+	<8
PTR201-23	0.120	N	0.02	N	2.194	P	139.3	P	4.68	MP	Reactive	Positive	3+	64
PTR201-24	1.111	P	0.05	N	1.300	P	33.2	P	0.56	N	Reactive	Positive	2+	<8
PTR201-25	0.268	N	0.06	N	2.511	P	347.9	P	5.92	MP	Reactive	Positive	3+	128
Interpretation:	>1.090 positive 0.910-1.090 EQ		≥0.28 positive 0.24-0.27 EQ positive 0.2-0.23 EQ negative		≥1.000 positive		≥10 positive		≥6.60 high positive 2.9-6.59 mod. positive 1-2.89 low positive 0.8-0.99 EQ				≥1+ positive	≥8 positive

EIA results are means of duplicates, expressed in units specified in manufacturers' instructions.

N = Negative, P = Positive, MP = Moderate Positive, HP = High Positive, LP = Low Positive, EQ = Equivocal, IU = International units, PIV = Predictive Index Value

[1]HAI = Hemagglutination Inhibition performed by an inhouse method at a commercial reference laboratory.

All samples are nonreactive for rheumatoid factor except member 02 (13 IU/ml). Samples ≥9 IU/ml are considered reactive for rheumatoid factor.

*Member 13 was collected 14 days later from the same naturally infected individual as member 03. Members 07, 19 and 24 were collected from recently immunized individuals.

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