Boston Biomedica, Inc.
Hepatitis B Seroconversion Panel (Subtype ad)
Data Sheet - PHM921

Member I.D. #	Bleed Dates	Days Since 1st Bleed	HBV DNA[1] Detection PCR	HBsAg conc. ng/ml[2]	HBsAg Tests, results expressed as s/co: Abbott RIA Proc. B[3]	Abbott EIA Proc. B[3]	Abbott EIA IMx	Gen. Sys. EIA Proc. B[5]	Ortho EIA Proc. A[4]
PHM921-01	26 OCT 90	0	+	0.7	2.7	3.5	1.3	7.5	2.0
PHM921-02	31 OCT 90	5	+	>2.7	5.5	27.1	2.5	13.2	5.3
PHM921-03	02 NOV 90	7	+	>2.7	9.2	20.9	4.0	16.2	8.6
PHM921-04	07 NOV 90	12	+	>2.7	30.4	>37.7	16.4	19.3	40.4
PHM921-05	09 NOV 90	14	+	>2.7	49.2	>37.7	21.9	20.0	60.0
PHM921-06	14 NOV 90	19	+	>2.7	90.6	>37.7	40.7	22.3	60.0
Run Date:			30 JUN 94		27 AUG 91	12 JUN 92	12 APR 96	18 DEC 95	07 DEC 95
Kit Lot #:			NA		55457M200	64848M103	10511M103	223MM2	2HB393
Exp. Date:			NA		16 SEP 91	31 JUL 92	29 APR 96	23 MAY 96	15 DEC 95
Product #:			NA		7802	1980	2228	0255	933540

BIOHAZARD CAUTION: Potentially infectious materials. Follow Universal Precautions. Panel members were tested and some were found positive by a test for HBsAg.

PHM921 has tested negative by U.S. FDA-licensed tests for anti-HIV, anti-HTLV, and anti-HCV.

For research use only. Data are offered for informational purposes. BBI does not claim that others can duplicate these test results exactly. EIA and RIA results on pages 1 and 2 were generated using commercially available FDA approved tests, performed at BBI by individuals who routinely use these procedures. All numeric results are means of duplicates expressed as specimen signal to cutoff ratios (s/co), except for anti-HBc and anti-HBe, which are expressed as cutoff to specimen signal ratios (co/s). Ratios $\geq$1.0 are considered reactive. Specimens are undiluted aliquots of plasma units collected from a single donor in 1990. No preservatives were added.

[1]HBV DNA in plasma samples was detected at BBI with Southern blot analysis after PCR amplification; the detection limit for the HBV DNA assay is 100 copies.

[2]HBsAg concentrations were determined by testing the Seroconversion Panel in duplicate in the same run with BBI HBsAg Sensitivity Panel PHA802 and reading HBsAg concentrations from the PHA802 standard curve.

[3]Overnight Procedure; [4]Day Procedure; [5]Shaker Incubation

		Other HBV Tests				
Member I.D. #	Days Since 1st Bleed	HBeAg Abbott RIA s/co	anti-HBe Abbott EIA co/s	anti-HBc IgM Abbott EIA s/co	anti-HBc Org. Tek. EIA co/s	anti-HBs Abbott EIA s/co
PHM921-01	0	0.6	0.6	0.2	0.6	0.4
PHM921-02	5	0.5	0.5	0.2	0.5	0.3
PHM921-03	7	0.6	0.5	0.2	0.5	0.3
PHM921-04	12	0.7	0.5	0.2	0.6	0.2
PHM921-05	14	1.0	0.5	0.1	0.4	0.4
PHM921-06	19	1.7	0.5	0.4	0.5	0.3
	Run Date:	23 NOV 91	12 OCT 91	06 MAR 92	26 AUG 91	31 JAN 92
	Kit Lot #:	56767M100	57293M100	60743M201	10207578	60887M100
	Exp. Date:	27 OCT 91	04 MAR 92	28 MAY 92	28 JAN 92	30 MAR 92
	Product #:	1237	1235	1236	80236	9006

Member I.D. #	Days Since 1st Bleed	EUROPEAN HBsAg EIA Tests, results expressed as s/co: Abbott Auszyme	Abbott IMx	ADI	Behring	Biokit	BioMerieux	Kodak
PHM921-01	0	3.7	1.3	1.6	1.7	2.6	2.0	2.7
PHM921-02	5	10.8	2.5	3.1	4.5	7.6	6.2	8.3
PHM921-03	7	16.9	3.3	4.0	7.8	12.8	10.2	15.1
PHM921-04	12	42.6	11.3	21.9	30.2	34.4	32.3	78.4
PHM921-05	14	38.5	15.0	27.8	48.6	48.3	56.9	32.6
PHM921-06	19	42.6	21.2	26.1	51.0	57.4	106.0	446.2
Kit Lot #:		87898M100	00719141J	3K000090	26068	C5594	940711-0	80
Exp. Date:		28 SEP 94	11 NOV 94	21 JUL 94	13 SEP 94	19 OCT 94	11 JUL 94	31 OCT 94

Member I.D. #	Murex	Org. Tek.	Ortho	Roche	Sanofi/ Diag. Past.	Sorin	Syva
PHM921-01	1.9	1.4	5.9	3.3	4.6	3.2	0.3
PHM921-02	4.0	3.4	9.1	9.4	10.6	10.4	0.9
PHM921-03	7.4	5.3	15.2	16.3	16.5	17.0	1.5
PHM921-04	21.7	11.0	73.2	58.5	73.4	44.4	6.1
PHM921-05	26.8	16.2	79.6	68.6	69.8	58.8	10.9
PHM921-06	24.8	28.6	93.8	68.6	73.2	55.6	21.6
Kit Lot #:	K360510	93070802	HBT103	N2535	3J129.V	7840230B	81500601
Exp. Date:	28 AUG 94	28 DEC 94	07 JUL 94	MAY 95	15 JUL 94	19 JAN 94	31 DEC 94

As part of a large study by RL12 of HBsAg methods available in Europe, duplicate samples from several seroconversion series were randomized and tested by each method. One kit lot was used for each manufacturer, but several runs were required. Numeric EIA results are means of duplicate specimen absorbance to cutoff ratios (s/co).

Test methods used are described in the PHM900 Panels package insert.