

Hepatitis B Seroconversion Panel PHM934(M)

Subtype ad

INTENDED USE

This Hepatitis B Seroconversion Panel PHM934(M) is a group of serial bleeds from an individual plasma donor during seroconversion for markers of Hepatitis B (HBV). This panel is intended for use by diagnostic manufacturers and other laboratories in evaluating their HBV test systems with well-characterized specimens, and to provide comprehensive data for comparative analysis. For Research Use Only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION

PHM934(M) consists of a set of 5 undiluted plasma samples from a single plasma donor collected during a period of Hepatitis B seroconversion. All units were maintained in a frozen state, except for the interval of dispensing into vials. No preservatives were added.

REAGENTS

Cat No. PHM934(M)-1.5 1 vial per member
5 members, 1.5 mL per vial

PRECAUTIONS

BIOHAZARD CAUTION: Potentially infectious materials. Use the Centers for Disease Control (CDC) recommended universal precautions for handling this product.¹ These materials have not been treated and should be considered biohazardous. Panel members were tested and some were found positive by tests for HBsAg.

The plasma units that make up this panel were tested and found negative for 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 at -10°C or colder. SeraCare recommends dividing the samples into smaller aliquots if necessary to avoid repeated freeze-thaw cycles. If turbidity of particulate matter is observed, the samples should be centrifuged in accordance with each test kit manufacturer's instructions for sample preparation.

INTERPRETATION OF RESULTS

The attached data sheet lists results for panel members generated using commercially available HBsAg screening tests and the results of tests for other relevant markers. All tests were performed in the laboratories of SeraCare Life Sciences and at internationally recognized reference laboratories (RL) by individuals who routinely use these test procedures. All EIA results are means of duplicates, and expressed as either specimen absorbance to cutoff ratios (s/co) or as a ratio of cutoff to specimen absorbance (co/s). Ratios ≥ 1.0 are considered reactive. HBV DNA was detected using the Roche Amplicor HBV Monitor™ test. Results are single observations expressed as DNA copies/mL. The quantitative range of detection for this assay is from 400 - 40,000,000 copies/mL.

LIMITATIONS

PHM934(M) is offered 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.

REFERENCES

1. CDC recommendations for prevention of HIV transmission in health care settings. MMWR 36 (suppl. 2) 1987.

For assistance, contact SeraCare Life Sciences Technical Support

Phone (508) 244-6400 or US Toll Free (800) 676-1881

Visit our website at www.seracare.com



25 Birch Street
Milford, MA 01757 USA

SeraCare Life Sciences
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----- HBsAg Test Results -----

----- Other HBV Tests -----

Member I.D. #	Bleed Dates	Days Since 1st Bleed	Abbott	Abbott	Abbott	Siemens	Ortho	DiaSorin	Ortho	DiaSorin	DiaSorin
			AxSYM	ARCHITECT®	PRISM®	ADVIA Centaur®	VITROS®	ETI-AB-COREK	HBc	ETI-EBK	ETI-CORE-IgMK
			s/co	s/co	s/co	s/co	s/co	co/s	s/co	s/co	s/co
			<u>SeraCare</u>	<u>RL53</u>	<u>RL54</u>	<u>RL55</u>	<u>RL48</u>	<u>SeraCare</u>	<u>SeraCare</u>	<u>SeraCare</u>	<u>SeraCare</u>
PHM934-01	13-Jan-98	0	1.3	1.3	1.9	1.0	0.8	0.2	0.1	0.2	0.1
PHM934-02	16-Jan-98	3	2.2	2.7	4.5	2.7	2.3	0.3	0.1	0.2	0.1
PHM934-03	20-Jan-98	7	6.3	8.9	16.1	11.8	9.8	0.2	0.1	0.5	0.1
PHM934-04	23-Jan-98	10	NA	NA	NA	NA	NA	NA	NA	NA	NA
PHM934-05	27-Jan-98	14	39.6	84.8	108.3	100.5	94.8	0.2	0.1	2.2	0.1
PHM934-06	7-Apr-98	84	144.9	1608.0	1410.4	>1000	1245.0	3.0	5.7	>45.5	10.3
Run Date:			22-MAR-10	29-MAR-10	26-MAR-10	29-MAR-10	30-MAR-10	22-MAR-10	25-MAR-10	22-MAR-10	23-MAR-10
Kit Lot #:			82103M100	85548LF00	80419M100	51170147	6830	9910420A	CHK538	0600330A/2	0270260A
Exp. Date:			16-MAY-10	14-Sep-10	2-JUN-10	27-OCT-10	28-SEP-10	21-SPE-10	31-AUG-10	8-SEP-10	15-JUN-10
Product #:			9B01-20	01L80	6D19	03393362	6801322	P001927	933245	P001930	P001928

Panel Member 4 is no longer available. Data are provided for informational purposes.

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

Panel members were tested and found to be negative for the following Hepatitis B markers: anti-HBe and anti-HBs.

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The donor is a 58 year old male. Medical history, risk factor and mode of transmission for this donor are unknown.

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Member I.D. #	Bleed Dates	Days Since 1st Bleed	HBV DNA Roche PCR copies/ml SeraCare	----- HBsAg Tests, results expressed as s/co -----				
				Abbott AxSYM SeraCare	Abbott Auszyme ¹ SeraCare	Abbott IMx SeraCare	Gen. Sys. HBsAg ² SeraCare	Ortho Test System 2 ¹ SeraCare
PHM934-01	13 JAN 98	0	4 x 10 ³	1.5	0.6	0.5	1.5	0.3
PHM934-02	16 JAN 98	3	1 x 10 ⁴	2.5	1.1	0.8	3.7	1.0
PHM934-03	20 JAN 98	7	4 x 10 ⁴	7.4	3.8	2.4	11.2	3.8
PHM934-04	23 JAN 98	10	1 x 10 ⁵	14.7	8.9	3.2	16.4	8.1
PHM934-05	27 JAN 98	14	2 x 10 ⁵	39.8	31.4	8.8	23.6	30.0
PHM934-06	07 APR 98	84	>4 x 10 ⁷	143.2	>35.7	37.3	29.8	>60.0
Run Date:			03 MAY 99	14 AUG 08	10 AUG 99	23 AUG 99	12 AUG 99	11 AUG 99
Kit Lot #:			9803A	63209M200	53333M300	5519M101	116RM1-05	2HB475-5
Exp. Date:			MAY 99	19 OCT 08	26 NOV 99	22 OCT 99	10 FEB 00	17 AUG 99
Product #:			87521	9B01-20	1980	2228	0255	931540

Member I.D. #	-----HBeAg Results expressed as s/co-----			----HbC IgM results expressed as s/co----			HbC Total results expressed as co/s	
	Abbott HBe (rDNA) SeraCare	DiaSorin ETI-EBK SeraCare	Abbott Corzyme-M SeraCare	Abbott IMx SeraCare	DiaSorin ETI-CORE-IgM SeraCare	Ortho Vitros Eci RL12	Abbott Corzyme SeraCare	DiaSorin ETI-AB-COREK SeraCare
PHM934-01	0.2	0.2	0.2	0.1	0.1	0.0	0.5	0.2
PHM934-02	0.2	0.2	0.3	0.0	0.1	0.0	0.4	0.2
PHM934-03	0.3	0.3	0.3	0.1	0.1	0.0	0.4	0.2
PHM934-04	0.4	0.5	0.2	0.1	0.1	0.0	0.5	0.2
PHM934-05	0.7	1.3	0.2	0.0	0.1	0.1	0.5	0.2
PHM934-06	14.6	23.1	>6.6	2.8	5.5	3.5	45.6	15.5
Run Date:	16 JUL 99	13 AUG 99	16 JUL 99	18 AUG 99	11 AUG 99	10 SEP 99	12 AUG 99	12 AUG 99
Kit Lot #:	52185M400	4920410A	51543M300	55537M100	4860360A	32	54795M200	4530830A
Exp. Date:	06 NOV 99	19 OCT 99	09 SEP 99	10 MAY 00	08 FEB 00	03 DEC 99	19 JAN 00	14 MAR 00
Product #:	1235	P8020	1236	2260	P8015	8577413	9977	P8010

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¹ Day Procedure; ² Shaker Incubation

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----- INTERNATIONAL HBsAg Tests, results expressed as s/co -----

Member I.D. #	Days Since 1st Bleed	Abbott AxSYM v.2 RL23	Abbott PRISM RL33	Diag. Past. Access RL33
PHM934-01	0	0.7	1.9	0.4
PHM934-02	3	1.2	4.0	0.5
PHM934-03	7	3.3	14.7	1.2
PHM934-04	10	6.8	36.9	2.6
PHM934-05	14	22.3	105.7	8.1
PHM934-06	84	166.7	886.2	238.6

Run Date:	16 AUG 99	25 AUG 99	09 SEP 99
Kit Lot #:	55240LU01	52100HP00	992136
Exp. Date:	19 JAN 00	07 APR 00	15 MAR 00
Product #:	7A40-22	3A47	34220

Member I.D. #	Org. Tek Uni-Form II RL23	Ortho Vitros Eci RL12	Roche Cobas Core II RL23	Roche Elecsys RL23
PHM934-01	0.7	0.7	0.7	1.3
PHM934-02	1.4	2.5	1.6	2.5
PHM934-03	4.2	11.4	4.5	8.1
PHM934-04	9.1	30.1	10.0	19.9
PHM934-05	25.4	110.5	22.8	69.4
PHM934-06	>25.4	1255.0	71.0	585.0

Run Date:	14 SEP 99	02 SEP 99	30 AUG 99	14 SEP 99
Kit Lot #:	99021903	90	B1632	19845801
Exp. Date:	31 JUL 00	29 JAN 00	28 FEB 01	30 SEP 00
Product #:	80281/80252	843 5307	753505	1288 989

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