

SeraCare Life Sciences
Hepatitis B Seroconversion Panel
PHM926

INTENDED USE

This Hepatitis B Seroconversion Panel PHM926 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 manufacturers and laboratories to evaluate their HBV marker assays using well-characterized specimens and to provide comprehensive data for comparative analysis.

PRODUCT DESCRIPTION

SeraCare Life Sciences has assembled this set of undiluted plasma samples from a group of serial bleeds 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. This panel is provided as 1.5 ml volume per vial.

INTERPRETATION OF RESULTS

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

PRECAUTIONS

BIOHAZARD CAUTION: Potentially infectious materials. Follow Universal Precautions. Panel members were tested and some were found positive by tests for HBsAg. Panel members were tested and found negative for anti-HCV and anti-HIV 1.

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. Avoid repeated freeze-thaw cycles.

LIMITATIONS

This panel 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 these results exactly.

For assistance, contact SeraCare Technical Support (800) 676-1881



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October 2008
11873-04
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SeraCare Life Sciences
Hepatitis B Seroconversion Panel (PHM926), Subtype Indeterminate
Data Sheet

| Member I.D. # | Bleed Dates | Days Since 1st Bleed | ----- HBsAg EIA Tests, results expressed as s/co ----- | | | | | |
|-------------------|----------------|-------------------------|--------------------------------------------------------|-----------------------------|--------------------------------------------|---------------------------|---------------------------------------------|-------------------------------------------------|
| | | | HBV DNA Roche PCR copies/ml SeraCare | Abbott AxSYM SeraCare | Abbott Auszyme ¹ SeraCare | Abbott IMx SeraCare | Gen. Sys. HBsAg ² SeraCare | Ortho Test System 2 ¹ SeraCare |
| PHM926-01 | 17 APR 97 | 0 | <4 x 10 ² | 0.6 | 0.2 | 0.5 | 0.3 | 0.0 |
| PHM926-02 | 19 APR 97 | 2 | <4 x 10 ² | 0.7 | 0.1 | 0.5 | 0.4 | 0.0 |
| PHM926-03 | 26 APR 97 | 9 | 2 x 10 ³ | 1.0 | 0.3 | 0.6 | 0.8 | 0.1 |
| PHM926-04 | 30 APR 97 | 13 | 6 x 10 ³ | 1.5 | 0.7 | 0.7 | 1.5 | 0.4 |
| PHM926-05 | 02 MAY 97 | 15 | 1 x 10 ⁴ | 2.3 | 1.0 | 0.8 | 2.6 | 0.6 |
| PHM926-06 | 07 MAY 97 | 20 | 6 x 10 ⁴ | 4.9 | 3.0 | 1.3 | 4.6 | 1.5 |
| PHM926-07 | 10 MAY 97 | 23 | 1 x 10 ⁵ | 7.2 | 4.9 | 1.4 | 5.5 | 2.2 |
| PHM926-08 | 14 MAY 97 | 27 | 6 x 10 ⁵ | 16.9 | 10.3 | 3.1 | 11.0 | 5.8 |
| Run Date: | | | 15 JUL 98 | 06 AUG 08 | 20 APR 98 | 02 MAY 98 | 20 MAR 98 | 29 APR 98 |
| Kit Lot #: | | | 9707 | 63209m200 | 38039M300 | 37146M401 | 260PM1-05 | 2HB451 |
| Exp. Date: | | | JAN 99 | 19 OCT 08 | 19 AUG 98 | 21 JUN 98 | 07 JUL 98 | 29 APR 98 |
| Product #: | | | 87521 | 9b01-20 | 1980 | 2228 | 255 | 933540 |

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: HBeAg, anti-HBe, anti-HBc IgM, anti-HBc Total and anti-HBs.

For research use only. Not for use in diagnostic procedures. Data are offered for informational purposes. SeraCare Life Sciences does not claim that others can duplicate these test results exactly. EIA results were generated using commercially available testing, performed at SeraCare and at internationally recognized referee laboratories (RL) by individuals who routinely use these procedures. All EIA results are means of duplicates expressed as specimen signal to cutoff ratios (s/co). Ratios ≥ 1.0 are considered reactive. Specimens are undiluted aliquots of plasma units collected from a single donor in 1997. No preservatives were added.

¹Day Procedure; ²Shaker Incubation

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

| Member I.D. # | Days Since 1st Bleed | Abbott Dynamic | Abbott AxSYM | Abbott PRISM | Biotest HBsAg | Boeh. Mann. Enzymun | Boeh. Mann. Elecsys |
|------------------|-------------------------|-------------------|-----------------|-----------------|------------------|------------------------|------------------------|
| | | <u>RL23</u> | <u>RL19</u> | <u>RL23</u> | <u>RL23</u> | <u>RL23</u> | <u>RL23</u> |
| PHM926-01 | 0 | 0.2 | 0.5 | 0.5 | 0.6 | 0.0 | 0.7 |
| PHM926-02 | 2 | 0.3 | 0.6 | 0.4 | 0.6 | 0.0 | 0.7 |
| PHM926-03 | 9 | 0.6 | 0.6 | 1.2 | 0.8 | 0.2 | 0.9 |
| PHM926-04 | 13 | 1.4 | 0.8 | 2.2 | 1.0 | 0.5 | 1.2 |
| PHM926-05 | 15 | 3.1 | 1.1 | 4.0 | 1.3 | 0.9 | 1.5 |
| PHM926-06 | 20 | 6.3 | 1.9 | 8.3 | 2.4 | 2.3 | 2.8 |
| PHM926-07 | 23 | 10.4 | 2.4 | 11.0 | 2.8 | 3.7 | 4.3 |
| PHM926-08 | 27 | 26.1 | 5.2 | 23.4 | 6.0 | 9.2 | 5.1 |
| Run Date: | | 18 MAY 98 | 19 MAY 98 | 12 MAY 98 | 19 MAY 98 | 12 MAY 98 | 12 MAY 98 |
| Kit Lot #: | | 37117HP00 | 40007LU00 | 39024HP00 | D-0398 | 194359-02 | 194565-01 |
| Exp. Date: | | 02 SEP 98 | 18 OCT 98 | 02 FEB 99 | 03 APR 99 | 31 DEC 98 | 31 MAY 98 |
| Product #: | | 7B17 | 7A40 | 3A47 | 807340 | 1288 989 | 1820 532 |

| Member I.D. # | Diag. Past. Monolisa 2 Gen | Murex Version II | Org. Tek. Uniform II | Ortho Test System 3 | Roche Cobas Core II | Sorin ETI MAK III |
|------------------|-------------------------------|---------------------|-------------------------|------------------------|------------------------|----------------------|
| | <u>RL23</u> | <u>RL33</u> | <u>RL23</u> | <u>RL23</u> | <u>RL23</u> | <u>RL23</u> |
| PHM926-01 | 0.4 | 0.2 | 0.4 | 0.1 | 0.4 | 0.1 |
| PHM926-02 | 0.5 | 0.2 | 0.3 | 0.1 | 0.2 | 0.1 |
| PHM926-03 | 0.5 | 0.2 | 0.5 | 0.4 | 0.5 | 0.3 |
| PHM926-04 | 0.5 | 0.3 | 0.8 | 1.3 | 0.7 | 0.8 |
| PHM926-05 | 0.7 | 0.3 | 1.2 | 2.1 | 1.2 | 1.3 |
| PHM926-06 | 1.3 | 0.6 | 2.4 | 5.4 | 2.7 | 2.3 |
| PHM926-07 | 1.4 | 0.7 | 3.1 | 8.0 | 3.3 | 3.3 |
| PHM926-08 | 2.4 | 1.2 | 5.7 | 18.9 | 9.0 | 7.2 |
| Run Date: | 18 MAY 98 | 10 JUN 98 | 12 MAY 98 | 12 MAY 98 | 14 MAY 98 | 12 MAY 98 |
| Kit Lot #: | 7F180X | F489310 | 97062311 | HBT180 | P0242 | 7840690A |
| Exp. Date: | 31 MAY 98 | 28 OCT 98 | 28 NOV 98 | 18 MAY 98 | 30 NOV 99 | 18 NOV 98 |
| Product #: | 7220 | GE14/15 Ver II | 80251/80252 | 940825 | 753505 | P3142 |