

Hepatitis A Virus (HAV) Seroconversion Panel

PHT903

INTENDED USE

PHT903 is a panel of undiluted serial bleeds from an individual plasma donor, collected during the evolution of the donor's immune response to Hepatitis A infection. This Panel is intended for use by diagnostics manufacturers, researchers, and other laboratories to evaluate their assays for markers of Hepatitis A infection or to study the humoral immune response to this infection.

PRODUCT DESCRIPTION

Seroconversion Panel PHT903 contains ten plasma samples collected from an individual over 108 days during the development of an immune response to Hepatitis A infection. The plasma was maintained frozen except during sterile filtration and dispensing into vials. No preservatives were added.

REAGENTS

Cat No. PHT903-1.0 1 vial per member
10 members, 1.0 mL per vial

INTERPRETATION OF RESULTS

The PHT903 data sheet provides results from test methods commercially available in the United States. Product numbers are indicated for identification of each method. Tests were performed at SeraCare Life Sciences and at internationally recognized referee laboratories. Numeric results are the means of duplicate tests and are expressed as signal to cutoff ratios (s/co) or cutoff to signal ratios (co/s) to facilitate comparisons among kits; ratios ≥ 1.0 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 at -10°C or colder. SeraCare Life Sciences recommends dividing the samples into smaller aliquots if necessary to avoid repeated freeze-thaw cycles.

LIMITATIONS

Seroconversion Panel PHT903 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.

For assistance, contact SeraCare Life Sciences, Inc. Technical Support

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

Visit our website at www.seracare.com



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SeraCare Life Sciences
Hepatitis A Seroconversion Panel PHT903
Data Sheet

-----Anti-HAV Total (IgG & IgM), results expressed as co/s-----

Member I.D. #	Bleed Dates	Days Since 1st Bleed	HAV RNA UltraQual™ RL49	Abbott	Abbott	DiaSorin	Ortho	Siemens
				AxSYM® HAVAB® 2.0 SeraCare	HAVAB® EIA SeraCare	ETI-AB-HAVK PLUS SeraCare	VITROS® ECiQ Anti-HAV Total RL48	ADVIA Centaur® HAV Total RL50
PHT903-01	26-Oct-05	0	POS	0.5	0.6	0.7	0.5	0.0
PHT903-02	29-Oct-05	3	POS	0.5	0.5	0.6	0.5	0.0
PHT903-03	03-Dec-05	38	POS	9.1	31.7	>49.5	>50.0	>5.0
PHT903-04	12-Dec-05	47	POS	10.5	32.5	48.1	>50.0	>5.0
PHT903-05	16-Dec-05	51	POS	9.8	29.8	33.6	41.5	>5.0
PHT903-06	19-Dec-05	54	POS	11.5	26.9	>49.5	>50.0	>5.0
PHT903-07	14-Jan-06	80	POS	12.7	31.4	46.7	>50.0	>5.0
PHT903-08	04-Feb-06	101	NEG	12.1	32.3	32.5	>50.0	>5.0
PHT903-09	08-Feb-06	105	NEG	10.7	35.4	48.1	41.6	>5.0
PHT903-10	11-Feb-06	108	NEG	13.9	28.9	44.3	>50.0	>5.0

Run Date:	02 Aug 08	20-Oct-08	18-Jun-08	1-Aug-08	5-Aug-08	5-Aug-08
Kit Lot #:	NA	66169M100	61823M100	9570300A/2	NA	NA
Exp. Date:	NA	22-Jan-09	14-Aug-08	4-Nov-08	NA	NA
Product #:	NA	8D21-20	7895-24	P001926	NA	NA

BIOHAZARD CAUTION: Potentially infectious materials. Follow Universal Precautions. Panel members were tested and found to be negative for the following HBsAg, anti-HIV-1/2, and anti-HCV.

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POS = positive; NEG = negative; NA = not available

-----Anti-HAV IgM, results expressed as s/co-----

Member I.D. #	Days Since 1st Bleed	Abbott	Abbott	DiaSorin	Ortho	Siemens
		AxSYM® HAVAB®-M 2.0 SeraCare	HAVAB®-M EIA SeraCare	ETI-HA-IgMK PLUS SeraCare	VITROS® ECiQ Anti-HAV IgM RL48	ADVIA Centaur® HAV IgM RL50
PHT903-01	0	0.1	0.3	0.0	0.1	0.2
PHT903-02	3	0.1	0.3	0.0	0.1	0.2
PHT903-03	38	4.8	6.6	6.7	7.8	6.9
PHT903-04	47	4.8	5.2	6.7	6.5	6.4
PHT903-05	51	4.8	4.8	5.9	6.0	6.3
PHT903-06	54	4.1	3.0	5.7	5.8	6.0
PHT903-07	80	2.0	1.3	3.5	3.8	3.6
PHT903-08	101	1.4	1.3	2.6	2.4	2.7
PHT903-09	105	1.2	1.0	2.0	2.8	2.6
PHT903-10	108	1.3	0.9	2.1	3.0	2.4

Run Date:	5-Aug-08	13-Jul-08	4-Aug-08	5-Aug-08	5-Aug-08
Kit Lot #:	54148M100	64959M100	9850270A	NA	NA
Exp. Date:	16-Aug-08	6-Oct-08	21-Dec-08	NA	NA
Product #:	5e20-20	9843	P001925	NA	NA

For additional information, please contact SeraCare Life Sciences Technical Support. Telephone (508)244-6400 or US Toll Free (800) 676-1881
Visit our website at www.seracare.com or email us at info@seracare.com