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PACKAGE INSERT (Catalogue No: HAV003SCP)

Lot No: 20040268

Hepatitis A (HAV) Seroconversion Panel

PRODUCT DESCRIPTION

The HAV Seroconversion Panel consists of 13 members with each member containing 1 vial of 1.0 mL of human plasma. Panel members collected in this longitudinal series are from a single donor during the progression of an early HAV infection. This panel illustrates the onset and decline of IgM and Ig total Hepatitis A virus antibodies and RNA titer over a period of 108 days. Panel members are undiluted, naturally occurring plasma samples collected in 4% sodium citrate. Units were aseptically filtered. No preservative have been added. All panel members are ready to use.

INTENDED USE

This Seroconversion Panel (SCP) is intended for use by diagnostic manufacturers and researchers during assay development, evaluation, troubleshooting HAV test methods.

STORAGE AND STABILITY

Panel members should be stored at -20°C or colder. Thaw samples at room temperature and mix gently by inversion before usage. Avoid foaming, contamination and repeated freeze and thaw cycles. After usage, return immediately to storage conditions.

WARNINGS AND PRECAUTIONS

All blood products should be treated as potentially infectious. All human source materials used in the manufacture of this SCP, were tested and found negative for all US FDA required relevant transfusion-transmitted infections as described in 21 CFR 610.40. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents; appropriate care should be taken in the use of this product. These materials should be disposed in accordance to applicable local or national regulations. Waste must be disposed in a secured manner.

It is of the utmost importance that proper biosafety guidelines are followed by clinical laboratories when handling samples from HAV patients. Follow Universal Precautions[1].

DONOR INFORMATION

All panel members used in the preparation of this product have been tested and found negative by tests for antibodies to HIV 1/2, HCV and non-reactive for HBsAg. Pooled samples were found non-reactive for HIV-1 RNA, HBV DNA and HCV RNA by Nucleic Acid Test. All testing is performed with kits approved by the FDA.

The donor has been tested and found negative for syphilis according to FDA guidelines. All samples are collected under informed consent at an FDA licensed donor center within the US.

Donor Profile
Gender: Male
Age: 31
Race: Hispanic

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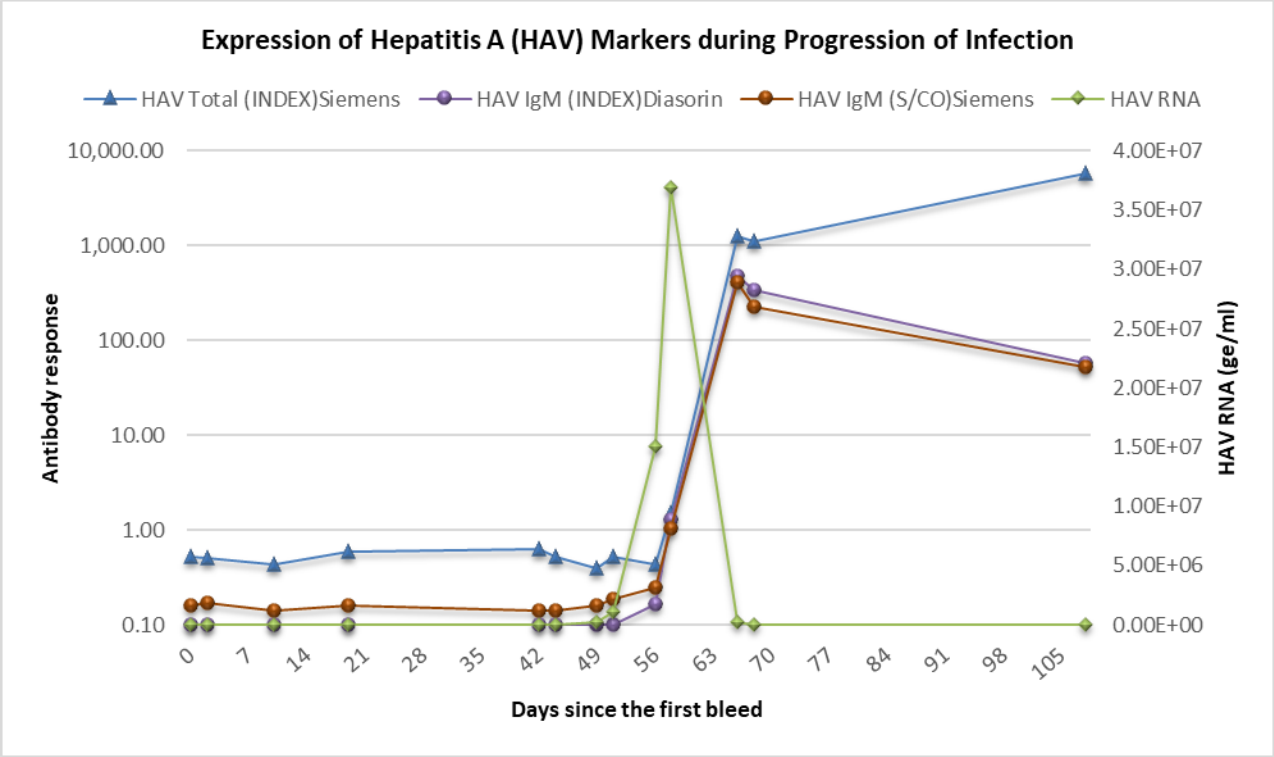
DETECTION METHODS

HAV antibody reactivity is measured for each panel member with Siemens ADVIA Centaur Anti-HAV total and IgM antibody assays and LIAISON HAV IgM assay-DiaSorin, Inc. HAV RNA is measured with quantitative real-time PCR analysis "In-house"; HAV isolated from the donor has been genotyped (performed at Banc de Sang i Teixits [Spain])

LIMITATIONS AND RESTRICTIONS

This panel is for Research Use Only and not intended for human or animal diagnostics, or for therapeutic purposes. Each laboratory has the responsibility to ascertain the suitability of the SCP for its particular application and to establish their own guidelines for interpretation of results. Data is provided for informational purposes only. Access Biologicals does not claim that others can duplicate these test results exactly.



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HAV Seroconversion Panel, HAV003SCP

Panel member	Days since the first bleed	Bleed date	Siemens ADVIA Centaur		Diasorin Liaison	Roche HAV RNA (ge/ml)[d]
			Anti-HAV total (Index value)[a]	Anti-HAV Ig M (S/CO)[b]	Anti-HAV IgM (Index value)[c]	
1	0	6/3/2019	0.52	0.16	0.1	0.00E+00
2	2	6/5/2019	0.50	0.17	0.1	0.00E+00
3	10	6/13/2019	0.44	0.14	0.1	0.00E+00
4	19	6/22/2019	0.59	0.16	0.1	0.00E+00
5	42	7/15/2019	0.63	0.14	0.1	1.58E+03
6	44	7/17/2019	0.52	0.14	0.1	3.34E+03
7	49	7/22/2019	0.39	0.16	0.1	1.80E+05
8	51	7/24/2019	0.53	0.19	0.1	1.08E+06
9	56	7/29/2019	0.44	0.25	0.166	1.50E+07
10	58	7/31/2019	1.51	1.03	1.31	3.69E+07
11	66	8/8/2019	1,276.10	41.38	484.00	2.53E+05
12	68	8/10/2019	1,104.82	22.31	339.60	4.23E+04
13	108	9/19/2019	5,776.13	52.74	58.60	1.30E+03

[a] The system reports HAV Total results in Index Values, units < 1.00 is considered non-reactive for antibodies to HAV, ≥ 1.00 is considered reactive for antibodies to HAV.

[b] (S/CO) Signal-to-cutoff values; units < 0.80 is considered non-reactive for Ig M antibodies to HAV, units ≥ 0.80 and <1.20 is considered equivocal; units ≥ 1.20 is considered reactive for Ig M antibodies to HAV.

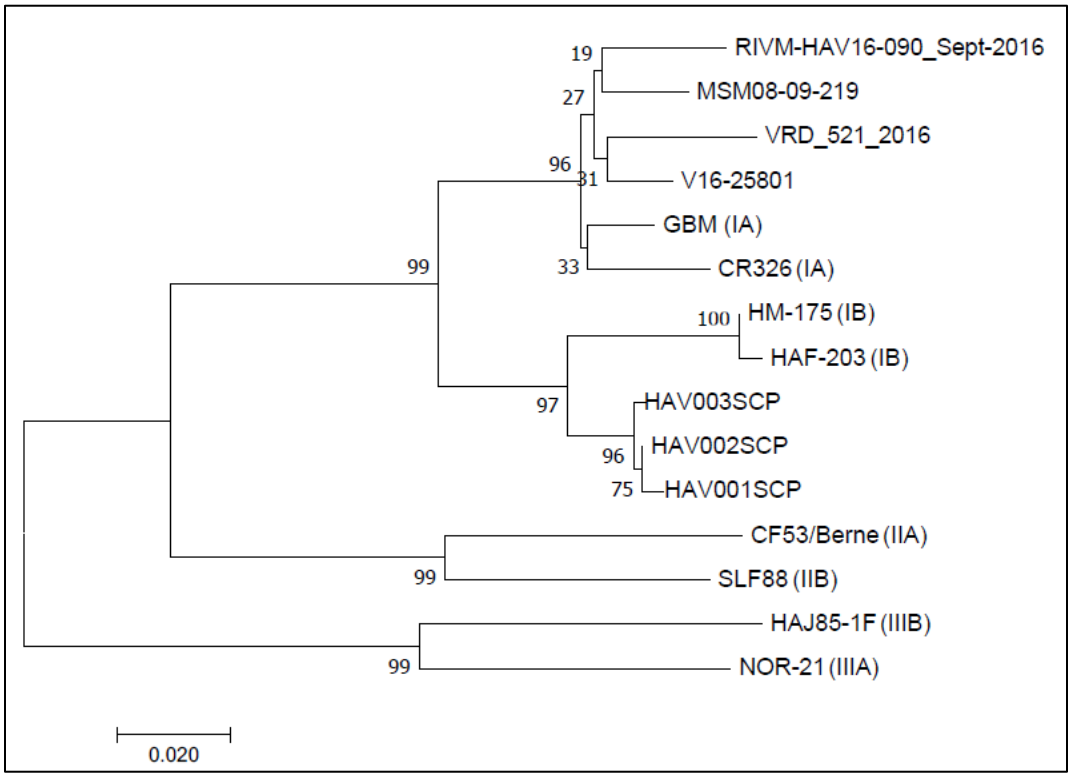
[c] The system reports HAV IgM results in Index Values, units < 0.90 is considered negative for IgM antibodies to HAV, units ≥ 0.90 and <1.10 is considered equivocal ≥ 1.10 is considered reactive for IgM antibodies to HAV.

[d] ge/mL: genome equivalents/milliliter plasma.

HAV GENOTYPING

HAV003SCP is the HAV isolated of the present panel. HAV genotype was determined by sequence analysis of the complete VP1/2A region of the HAV genome using the primers published by Sánchez et al., 2002[2]. Sequences were obtained with the 3130XL Genetic Analyzer (Applied Biosystems) and analyzed with FinchTV software. Phylogenetic analysis was performed using MEGA v7.0.26 software with the Neighbor-Joining method.

Phylogenetic tree according to the reference HAV IB strain HM-175 showing the relationship between the seroconversion panel HAV isolates



References:

1 Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7119119/pdf/main.pdf

2 Sánchez G, Pintó RM, Vanaclocha H, Bosch A. Molecular Characterization of Hepatitis A Virus Isolates from a Transcontinental Shellfish-Borne Outbreak. 2002. Journal of Clinical Microbiology 40(11):4148–4155.