

HAV Seroconversion Panel

REF Catalogue No: SCP-HAV-002

Old Catalogue No: RP-013

The Biomex GmbH HAV IgM Seroconversion Panel consists of 15 members with each member containing 0.3 mL of human plasma. This panel illustrates the onset and decline of IgM and IgG Hepatitis A virus antibodies from one individual over a period of 190 days.

1. Intended Use

This Seroconversion Panel (SCP) is intended for standard testing by diagnostic manufacturers and researchers during assay development, evaluation, troubleshooting and post-marked surveillance of IgM/IgG antibody test systems and methods. Moreover, it serves as validation tool for diagnostic sensitivity, determination of analytical sensitivity, identification of cut-off values or to study the humoral immune response to this infection.

2. Storage and Stability

Store the SCP at -20°C to -80°C. 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.

3. Warnings and Precautions

Potentially infectious materials. Handle the product as if capable of transmitting infectious diseases. Do not pipette by mouth.

Prevention:

P264: Wash hands thoroughly after handling.

P270: Do not eat, drink or smoke when using this product

P273: Avoid the release to the environment

Disposal:

P501: Dispose of waste in accordance to applicable local or national regulations. Waste must be disposed in a secured manner.

4. Donor Information

All panel members have been tested and found negative/non-reactive for anti-HIV, anti-HCV, HBsAg and Syphilis with FDA approved tests.

Donor profile

- Sex: Male
- Age: 36
- Ethnicity: African/American
- Residence: U.S. South West

Medical background

- No history of drug or alcohol abuse
- No history of heart or lung diseases
- No history of venereal diseases
- No current medication
- No history of Hepatitis
- No history of surgical procedures
- No history of blood transfusions

5. Detection Methods

Each panel member is assayed for IgM and IgG antibodies with Abbott ARCHITECT®. Testing is performed with CE marked test.

6. Limitations and Restrictions

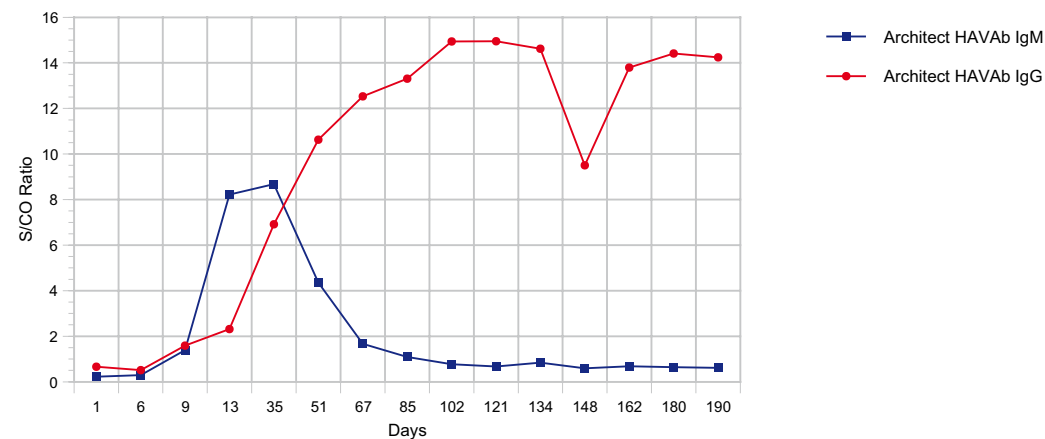
This panel is for Research Use Only and not intended for human or animal diagnostics, or for therapeutic purposes. Each laboratory has the responsibility to ascertain the suitability of the SCP for its particular application and to establish their own guidelines for interpretation of results. Data is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

Declaration of used symbols

Catalog Number	Lot Number	Consult Instructions for Use	Manufactured by	Temperature Limitation

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Panel Member	Day	Bleed date	Abbott Architect HAVAb IgM S/CO cut off 1.2 S/CO	Abbott Architect HAVAb IgG S/CO cut off 1.0 S/CO
1	1	04.04.1996	0.22	0.66
2	6	09.04.1996	0.29	0.51
3	9	12.04.1996	1.39	1.59
4	13	16.04.1996	8.22	2.32
5	35	08.05.1996	8.68	6.92
6	51	24.05.1996	4.36	10.63
7	67	09.06.1996	1.67	12.53
8	85	27.06.1996	1.09	13.31
9	102	14.07.1996	0.77	14.94
10	121	02.08.1996	0.67	14.95
11	134	15.08.1996	0.84	14.62
12	148	29.08.1996	0.59	9.50
13	162	12.09.1996	0.68	13.80
14	180	30.09.1996	0.64	14.41
15	190	10.10.1996	0.61	14.24



Assay information:

Abbott Architect HAVAb IgM assay; Lot: 45350LI00; Exp. Date: 06.11.2015; Test Date: 24.09.2015

Abbott Architect HAVAb IgG assay; Lot: 54149LI00; Exp. Date: 26.12.2015; Test Date: 24.09.2015 and 02.12.2015