

HBV Seroconversion Panel

REF Catalogue No: SCP-HBV-005

Old Catalogue No: RP-027

The Biomex GmbH HBV Seroconversion Panel consists of 7 members with each member containing 0.5 mL of human plasma. This panel depicts the onset and decline of immune system response to HBV from one individual over a period of 42 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 HBV 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.

Declaration of used symbols

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

4. Donor Information

All panel members have been tested and found negative/non-reactive for anti-HIV, HIV 1 Ag, anti-HCV and Syphilis with FDA approved tests.

Donor profile

- Sex: Male
- Age: 46
- Ethnicity: African/American
- Residence: U.S. South West

Medical background

- No history of alcohol or drug abuse
- No history of venereal diseases
- No known food allergies
- No history of heart disease
- No history of Hepatitis, jaundice or liver disease
- No history of blood transfusions
- No history of surgery
- In general good health

5. Detection Methods

Each panel member is assayed for HBsAg, anti-HBs, anti-HBc, anti-HBc IgM, HBeAg and anti-HBe 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.

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Panel Member	Day	Bleed date	Abbott Architect HBsAg qualitative II S/CO cut off 1.0 S/CO	Abbott Architect Anti-HBs mIU/mL cut off 10 mIU/mL	Abbott Architect Anti-HBc II S/CO cut off 1.0 S/CO	Abbott Architect Anti-HBc IgM S/CO cut off 1.0 S/CO	Abbott Architect Anti-HBe S/CO cut off 1.0 S/CO (competitive)	Abbott Architect HBeAg S/CO cut off 1.0 S/CO
1	0	22.11.1997	0.47	0.00	0.60	0.14	2.29	0.335
2	20	12.12.1997	16.78	0.00	0.41	0.16	2.26	0.325
3	25	17.12.1997	24.71	0.00	0.39	0.12	2.30	0.352
4	27	19.12.1997	26.74	0.00	0.28	0.09	2.21	0.383
5	35	27.12.1997	166.94	0.00	0.35	0.11	2.25	0.480
6	38	30.12.1997	264.12	0.00	0.30	0.10	2.29	0.624
7	42	03.01.1998	426.47	0.55	0.60	0.11	2.32	0.810

Assay information:

Abbott Architect HBsAg qualitative II assay; Lot: 57152LH00; Exp. Date: 18.09.2016; Test Date: 04.12.2015

Abbott Architect Anti-HBs assay; Lot: 56237LH00; Exp. Date: 21.08.2016; Test Date: 04.12.2015

Abbott Architect Anti- HBc II assay; Lot: 55959LI00; Exp. Date: 28.07.2016; Test Date: 04.12.2015

Abbott Architect Anti-HBc IgM assay; Lot: 56556LI00; Exp. Date: 20.08.2016; Test Date: 04.12.2015

Abbott Architect Anti-HBe assay; Lot: 58201LI00; Exp. Date: 14.09.2016; Test Date: 04.12.2015

Abbott Architect HBeAg assay; Lot: 58368LI00; Exp. Date: 22.09.2016; Test Date: 04.12.2015

