

HBV Seroconversion Panel

REF Catalogue No: SCP-HBV-001

Old Catalogue No: RP-009

The Biomex GmbH HBV Seroconversion Panel consists of 20 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 202 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, anti-HCV and Syphilis with FDA approved tests.

Donor profile

- Sex: Male
- Age: 35
- Ethnicity: African/American

Medical background

- History of alcohol abuse
- Asymptomatic course of infection
- Heterosexual, monogamous
- No history of IV drug use
- History of cocaine and tobacco use
- History of incarceration
- No tattoos
- No medication (prescribed or OTC)
- No history of blood transfusions
- Routine plasma donor
- Frequent travel to U.S. SW
- No history of overseas travel
- No dental work in the last 1 – 2 years
- 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	1	18.07.1995	2.22	0.34	0.18	0.03	2.39	0.398
2	3	21.07.1995	22.40	0.92	0.17	0.03	2.45	0.719
3	11	29.07.1995	119.62	0.18	0.15	0.03	2.37	1.670
4	13	31.07.1995	181.04	0.11	0.15	0.03	2.53	2.315
5	29	16.08.1995	5884.44	0.00	3.46	0.05	24.34	464.626
6	31	18.08.1995	5123.55	0.00	3.75	0.06	35.36	687.466
7	36	23.08.1995	2569.59	0.27	4.89	0.33	63.89	1511.352
8	43	30.08.1995	946.87	0.95	6.70	2.48	69.33	1708.433
9	56	12.09.1995	1161.40	0.13	8.01	31.07	61.69	1364.262
10	69	25.09.1995	2523.99	0.00	8.90	30.91	20.63	437.017
11	81	07.10.1995	4699.14	0.00	10.51	29.40	1.65	30.107
12	88	14.10.1995	6247.58	0.00	10.64	27.30	0.28	0.843
13	98	24.10.1995	5654.19	0.00	10.56	20.10	0.34	0.573
14	109	04.11.1995	2335.09	0.00	10.13	10.71	0.34	0.409
15	123	18.11.1995	365.97	0.08	10.15	5.00	0.30	0.393
16	133	28.11.1995	92.03	0.12	10.13	2.91	0.32	0.357
17	152	16.12.1995	9.23	0.88	10.10	1.77	0.42	0.337
18	166	30.12.1995	1.73	3.36	10.06	1.39	0.41	0.320
19	186	19.01.1996	0.44	9.63	9.85	1.18	0.49	0.347
20	202	04.02.1996	0.93	33.22	10.40	1.27	0.40	0.335

Assay information:

Abbott Architect HBsAg qualitative II assay; Lot: 61151FN00; Exp. Date: 25.01.2017; Test Date: 15.03.2016

Abbott Architect Anti-HBs assay; Lot: 58705LH00; Exp. Date: 20.01.2017; Test Date: 15.03.2016

Abbott Architect Anti-HBc II assay ; Lot: 59017LI00; Exp. Date: 11.11.2016; Test Date: 15.03.2016

Abbott Architect Anti-HBc IgM assay; Lot: 56556LI00; Exp. Date: 20.08.2016; Test Date: 15.03.2016

Abbott Architect Anti-HBe assay; Lot: 58201LI00; Exp. Date: 14.09.2016; Test Date: 15.03.2016

Abbott Architect HBeAg assay; Lot: 58368LI00; Exp. Date: 22.09.2016; Test Date: 15.03.2016

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