

HBV Seroconversion Panel

REF Catalogue No: SCP-HBV-004

Old Catalogue No: RP-017

The Biomex GmbH HBV Seroconversion Panel consists of 30 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 188 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
- History of venereal disease (gonorrhoea)
- Known food allergies: peanuts, tomatoes
- 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.

HBV Seroconversion Panel, Catalogue No: SCP-HBV-004

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	23.01.1997	0.23	0.00	0.19	0.02	2.10	0.321
2	2	25.01.1997	0.21	0.00	0.18	0.02	2.08	0.303
3	7	30.01.1997	0.26	0.00	0.19	0.02	2.21	0.272
4	9	01.02.1997	0.28	0.00	0.12	0.02	2.17	0.333
5	18	10.02.1997	0.97	0.00	0.15	0.02	2.24	0.317
6	22	14.02.1997	2.13	0.00	0.17	0.02	2.13	0.325
7	26	18.02.1997	5.53	0.00	0.15	0.02	2.02	0.359
8	29	21.02.1997	8.14	0.00	0.14	0.02	1.98	0.357
9	33	25.02.1997	55.30	0.00	0.18	0.02	2.00	0.528
10	36	28.02.1997	66.36	0.00	0.14	0.02	2.17	0.608
11	40	04.03.1997	270.51	0.00	0.31	0.02	1.99	1.850
12	43	07.03.1997	560.76	0.00	0.19	0.02	2.13	3.695
13	65	29.03.1997	3768.32	0.00	0.45	0.10	30.16	682.860
14	71	04.04.1997	1161.6	0.00	3.56	0.50	59.99	1462.692
15	76	09.04.1997	989.23	0.00	6.91	1.02	56.33	1338.324
16	78	11.04.1997	1081.68	0.07	6.62	1.04	55.62	1257.783
17	140	12.06.1997	553.55	0.00	10.49	5.21	0.36	0.413
18	143	15.06.1997	257.54	0.00	10.45	4.10	0.34	0.388
19	147	19.06.1997	104.89	0.00	10.24	3.16	0.34	0.362
20	150	22.06.1997	46.65	0.15	10.48	2.45	0.33	0.358
21	158	30.06.1997	5.23	0.00	10.18	1.52	0.31	0.359
22	160	02.07.1997	3.42	0.00	9.98	1.27	0.31	0.320
23	165	07.07.1997	1.22	0.36	10.02	1.42	0.20	0.356
24	167	09.07.1997	1.16	0.09	9.96	0.95	0.25	0.331

HBV Seroconversion Panel, Catalogue No: SCP-HBV-004

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
25	172	14.07.1997	0.68	1.29	10.59	1.01	0.21	0.342
26	174	16.07.1997	0.32	0.46	10.01	0.75	0.27	0.346
27	179	21.07.1997	0.87	1.07	10.17	0.69	0.25	0.351
28	181	23.07.1997	0.47	1.78	10.11	0.56	0.25	0.370
29	186	28.07.1997	0.35	1.93	10.32	0.59	0.23	0.329
30	188	30.07.1997	0.36	2.06	9.96	0.49	0.24	0.331

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

HBV Seroconversion Panel, Catalogue No: SCP-HBV-004

