

HIV Seroconversion Panel

REF Catalogue No: **SCP-HIV-005**, Old Catalogue No: RP-018

The Biomex GmbH HIV Seroconversion Panel is a 25 member panel for Human Immunodeficiency Virus. This panel depicts the onset of immune system response to HIV from one individual over a period of 133 days.

1. Intended Use

The HIV Seroconversion Panel can be used for various research and investigation applications. It has been developed to aid diagnostic assay manufacturers and researchers during assay development, evaluation, troubleshooting and post-market surveillance of HIV test systems and methods. Moreover, it can be used for validation of diagnostic assay specificity. This panel is for Research Use Only.

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-HCV, HBsAg and Syphilis with FDA approved tests.

Donor profile

- Sex: Male
- Age: 49
- Ethnicity: Caucasian
- Residence: U.S. West coast

Medical background

- Homosexual
- No known IV drug use
- No history of alcoholism or drug addiction
- No history of Hepatitis, liver or venereal diseases
- No history of transfusions, surgeries or tattoos

5. Detection Methods

Each panel member is assayed for HIV Ag/Ab with Abbott ARCHITECT®, DiaSorin MUREX® HIV 1.2.O and Roche ELECSYS® HIV Ag. 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

REF	LOT	i	Manufactured by	2°C - 8°C
Catalog Number	Lot Number	Consult Instructions for Use		Temperature Limitation

HIV Seroconversion Panel, Catalogue No: SCP-HIV-005

Panel Member	Day	Bleed date	1. Replica Abbott Architect HIV Ag/ Ab combo S/CO	2. Replica Abbott Architect HIV Ag/ Ab combo S/CO	Roche Elecsys HIV Ag COI	Diasorin Murex HIV 1.2.O S/CO	Diasorin Murex HIV 1.2.O Valuation
			cut off 1.0 S/CO	cut off 1.0 S/CO	cut off 1.0 COI		
1	0	20.01.1998	0.42	0.16	0.266	0.19	negative
2	3	23.01.1998	0.17	0.15	0.287	0.19	negative
3	9	29.01.1998	0.15	0.17	0.379	0.18	negative
4	13	02.02.1998	0.47	0.46	0.566	0.24	negative
5	16	05.02.1998	26.38	27.33	35.24	0.76	negative
6	20	09.02.1998	4.05	4.08	5.90	0.26	negative
7	29	18.02.1998	40.69	42.49	17.46	8.95	positive
8	51	12.03.1998	15.49	15.65	0.463	9.02	positive
9	56	17.03.1998	16.07	25.95	0.428	8.91	positive
10	58	19.03.1998	30.22	31.46	0.439	8.79	positive
11	63	24.03.1998	40.75	41.95	0.385	8.83	positive
12	65	26.03.1998	46.76	46.51	0.455	8.91	positive
13	70	31.03.1998	61.48	60.78	0.379	9.00	positive
14	72	02.04.1998	56.94	58.23	0.397	9.16	positive
15	77	07.04.1998	54.71	62.47	0.392	8.96	positive
16	79	09.04.1998	60.05	65.14	0.436	8.94	positive
17	84	14.04.1998	50.22	69.93	0.277	8.95	positive
18	86	16.04.1998	55.20	42.90	0.311	8.73	positive
19	91	21.04.1998	49.18	67.79	0.351	8.77	positive
20	93	23.04.1998	71.62	71.80	0.333	8.81	positive
21	98	28.04.1998	79.98	77.60	0.361	8.86	positive
22	100	30.04.1998	27.24	80.70	0.267	8.86	positive
23	112	12.05.1998	94.99	92.99	0.338	8.69	positive
24	114	14.05.1998	87.83	92.19	0.365	8.67	positive
25	133	02.06.1998	125.41	93.61	0.331	8.74	positive

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Assay information:

Abbott Architect HIV Ag/ Ab combo assay; Lot: 72331HN00; Test Date: 15.07.2009

Roche Elecsys HIV Ag assay; Lot: 154634-01; Test Date: 11.03.2010

Diasorin Murex HIV 1.2.O assay; Lot:L373410; Test Date: 21.01.2010

