

HIV Seroconversion Panel

REF Catalogue No: **SCP-HIV-004**, Old Catalogue No: RP-034

The Biomex GmbH HIV Seroconversion Panel is a 7 member panel for Human Immunodeficiency Virus. This panel depicts the onset of immune system response to HIV from one individual over a period of 64 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: 33
- Ethnicity: African-American
- Residence: U.S. West coast

Medical background

- No history of Hepatitis, jaundice or liver disease
- No history of alcoholism or drug addiction
- No history of surgery or blood transfusion
- No history of heart disease
- No history of venereal disease

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

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Panel Member	Day	Bleed date	1. Replica Abbott Architect HIV Ag/ Ab combo S/CO cut off 1.0 S/CO	2. Replica Abbott Architect HIV Ag/ Ab combo S/CO cut off 1.0 S/CO	Roche Elecsys HIV Ag COI cut off 1.0 COI	Diasorin Murex HIV 1.2.O S/CO	Diasorin Murex HIV 1.2.O Valuation
1	0	17.04.1997	0.16	0.14	0.369	0.17	negative
2	5	22.04.1997	0.14	0.15	0.498	0.19	negative
3	7	24.04.1997	0.15	0.14	0.373	0.25	negative
4	25	12.05.1997	0.16	0.17	0.353	0.26	negative
5	56	12.06.1997	22.68	23.09	0.589	8.85	positive
6	62	18.06.1997	41.43	41.29	0.413	8.97	positive
7	64	20.06.1997	33.93	23.95	0.360	9.01	positive

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

