

## HIV Seroconversion Panel

**REF** Catalogue No: SCP-HIV-002, Old Catalogue No: RP-002

The Biomex GmbH HIV Seroconversion Panel is a 20 member panel for Human Immunodeficiency Virus. This panel depicts the onset of immune system response to HIV from one individual over a period of 106 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.

The plasma has been defibrinated and filtered. Sodium azide (0.095%) was added as preservative. All panel members are ready to use.

### 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.

 **WARNING: contains sodium azide.**

H302: Harmful if swallowed.

H413: May cause long lasting harmful effects to aquatic life.







### 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

Declaration of used symbols

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

### Reaction:

P330: Rinse mouth.

P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

### Disposal:

P501: Dispose of waste in accordance to applicable local or national regulations. Waste must be disposed in a secured manner.

### 4. Donor Information

#### Donor profile

- Sex: Male
- Age: 23
- Ethnicity: African-American
- Residence: U.S. South West

#### Medical background

- History of Hepatitis
- History of liver disease
- History of venereal diseases
- Allergies: milk, eggs, cats
- Non-smoker

### 5. Detection Methods

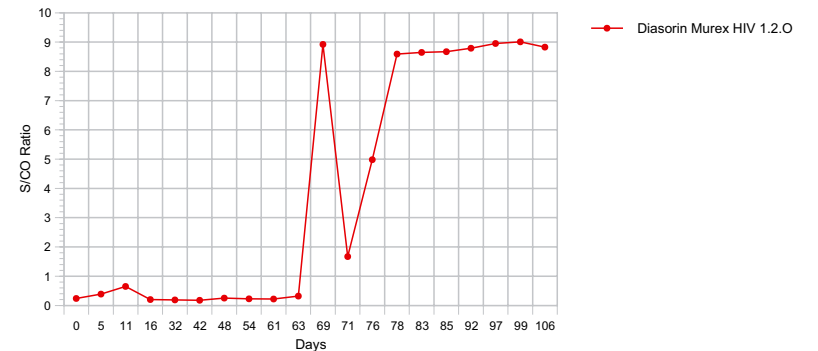
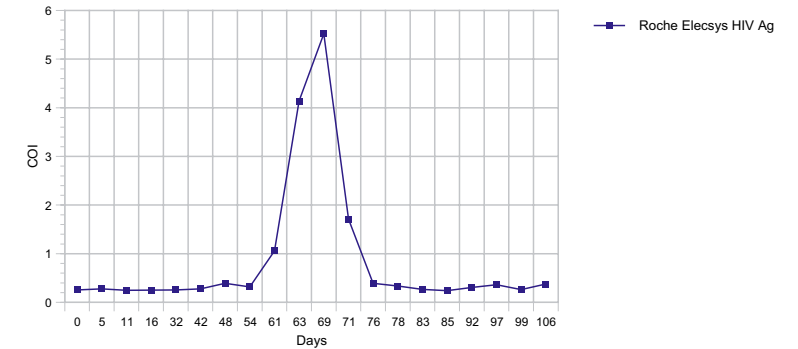
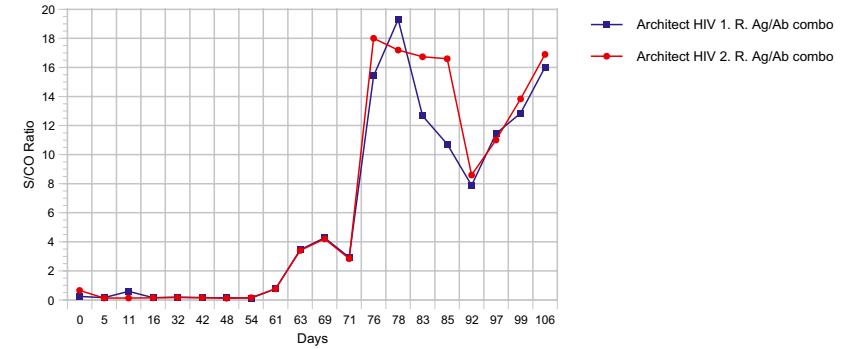
Each panel member is assayed for HIV Ag/Ab with Abbott ARCHITECT®, DiaSorin MUREX® HIV 1.2.O and Roche ELECSYS® HIV Ag. Testing is performed with CE marked test.

### 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.

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Panel Member	Day	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	0.24	0.66	0.253	0.24	negative
2	5	0.16	0.13	0.277	0.39	negative
3	11	0.59	0.13	0.246	0.65	negative
4	16	0.15	0.14	0.251	0.20	negative
5	32	0.19	0.17	0.253	0.19	negative
6	42	0.15	0.15	0.277	0.18	negative
7	48	0.14	0.12	0.391	0.25	negative
8	54	0.13	0.15	0.318	0.23	negative
9	61	0.77	0.77	1.060	0.22	negative
10	63	3.45	3.40	4.140	0.32	negative
11	69	4.28	4.20	5.520	8.92	positive
12	71	2.93	2.84	1.710	1.67	positive
13	76	15.42	18.00	0.391	4.98	positive
14	78	19.30	17.19	0.337	8.59	positive
15	83	12.66	16.73	0.265	8.65	positive
16	85	10.72	16.60	0.241	8.67	positive
17	92	7.88	8.60	0.305	8.79	positive
18	97	11.45	11.01	0.362	8.95	positive
19	99	12.85	13.83	0.261	9.01	positive
20	106	16.01	16.89	0.375	8.83	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