

HCV Seroconversion Panel

REF Catalogue No: SCP-HCV-009

Old Catalogue No: RP-038

The Biomex GmbH HCV Seroconversion Panel consists of 8 members with each member containing 0.5 mL of human plasma. This panel illustrates the onset and decline of immune system response to HCV from one individual over a period of 60 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 HCV 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

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

4. Donor Information

All panel members have been tested and found negative/non-reactive for anti-HIV 1/2, HIV 1 Ag, HBsAg and Syphilis with FDA approved tests.

Donor profile

- Sex: Male
- Age: 34
- Ethnicity: Caucasian
- Residence: U.S. South West

Medical background

- No history of alcohol abuse
- No history of drug addiction
- No history of IV drug use
- No history of surgeries
- No history of blood transfusions
- No history of Hepatitis, liver or venereal diseases
- No tattoos

5. Detection Methods

Each panel member is assayed for HCV Ag and anti-HCV antibodies with Abbott ARCHITECT®. Testing is performed with CE marked test, anti-HCV antibodies with Roche cobas® e801 and anti-HCV with Diasorin Liaison® XL

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 Anti-HCV S/CO	Abbott Architect HCV Ag fmol/L	Roche Elecsys Anti-HCV COI	Diasorin Liaison XL Anti-HCV S/CO
			cut off 1.0 S/CO	cut off 3.0 fmol/L	cut off 1.0 COI	cut off 1.0 S/CO
1	0	27.10.2000	0.05	0	0.05	0.043
2	28	24.11.2000	0.06	7412.19	0.05	0.039
3	30	26.11.2000	0.05	5227.46	0.05	0.037
4	45	11.12.2000	0.08	4098.06	0.05	0.074
5	47	13.12.2000	0.22	7367.77	0.06	0.11
6	52	18.12.2000	1.16	5486.74	4.70	0.54
7	55	21.12.2000	3.73	4793.75	59.07	2.9
8	60	26.12.2000	6.81	5290.2	96.57	4.5

Assay information:

Abbott Architect Anti-HCV assay; Lot: 54814LI00; Exp. Date: 16.04.2016; Test Date: 13.11.2015

Abbott Architect HCV Ag assay; Lot: 79061LP05; Test Date: 18.08.2009

Roche Elecsys Anti-HCV assay; Lot: N/A; Test Date: 20.02.2018

Diasorin Liaison XL MUREX HCV Ab assay; Lot: N/A; Test Date: 14.02.2018

