

HCV Verification Panel

REF Catalogue No: VFP-HCV-001

The Biomex GmbH HCV Verification Panel consists of 10 members with each member containing 0.5 mL of human plasma. This panel demonstrates steady IgM and IgG values of Hepatitis C virus antibodies from one individual over a period of 35 days.

1. Intended Use

This VFP Panel (VFP) is intended for standard testing by diagnostic manufacturers and researchers during assay development, evaluation, troubleshooting and post-marked surveillance of IgM/IgG antibody test systems and methods. Moreover, it serves as validation tool for diagnostic sensitivity, determination of analytical sensitivity, for batch release verification and lab operator training.

2. Storage and Stability

Store the VFP 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-HIV, HIV 1 Ag and HBsAg with FDA approved tests.

Donor profile

- Sex: Male
- Age: 19
- Ethnicity: Caucasian
- Residence: U.S. South West

Medical background

- No history of Hepatitis, liver or venereal diseases
- No known IV drug use
- No history of drug addiction
- No history of blood transfusion or surgery
- 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.

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

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

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Panel Member	Day	Bleed date	Abbott Architect Anti-HCV S/CO cut off 1.0 S/CO	Abbott Architect HCV Ag fmol/L cut off 3.0 fmol/L
1	0	05.02.1998	11.82	1.35
2	5	10.02.1998	12.07	0.00
3	8	13.02.1998	11.74	0.00
4	13	18.02.1998	12.11	0.02
5	15	20.02.1998	11.62	0.00
6	20	25.02.1998	11.71	0.00
7	22	27.02.1998	11.49	0.61
8	28	05.03.1998	11.46	0.00
9	30	07.03.1998	12.72	0.00
10	35	12.03.1998	13.32	0.00

Assay information:

Abbott Architect Anti-HCV assay; Lot: 59391LI00; Exp. Date: 17.08.2016 ; Test Date: 01.03.2016

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

