

HCV Ag Only Seroconversion Panel

REF Catalogue No: SCP-HCV(Ag)-003

The Biomex GmbH HCV Ag Only Seroconversion Panel consists of 5 members with each member containing 1.0 mL of human sodium citrate plasma. This panel illustrates the onset of the Hepatitis C virus (Ge-notype 2b) core antigen from one individual over a period of 21 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 Hepatitis C core antigen and Ag/Ab test systems and methods. Moreover, it serves as validation tool for diagnostic sensitivity, determination of analytical sensitivity or the identification of cut-off values.

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.

3. Warnings and Precautions

Infectious material. This product is 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 were collected in the USA and have been tested and found negative/non-reactive for anti-HIV 1/2, anti-HCV and HBsAg by CE marked tests. Furthermore the members were tested non-reactive for HIV RNA and HBV DNA.

5. Detection Methods

Each panel member is assayed for HCV Ag with Abbott ARCHITECT®, anti-HCV with Abbott ARCHITECT®, Siemens ENZYGNOST® and Roche COBAS® e411, HCV Ag/Ab with DiaSorin MUREX® and Bio-Rad MONOLISA®, as well as qualitative testing is performed for the direct detection of HCV RNA with Roche COBAS® MPX 6800/8800. Viral load determination is performed with the Abbott m2000 System. Testing is carried out with CE marked tests. Genotyping was performed with an accredited IVDR compliant validated inhouse test on ABI 3730XL DNA Analyzer.

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	Donor	Lot#	Day	Bleed Date	Anti-HCV Abbott Architect S/CO	HCV Ag Abbott Architect fmol/L	Roche Cobas e411 HCV Ab COI	Siemens Enzygnost Anti-HCV 4.0 S/CO	DiaSorin Murex HCV Ag/Ab S/CO	Bio-Rad Monolisa HCV Ag-Ab Ultra Assay S/CO	HCV MPX Qualitativ Roche Cobas 6800/8800	HCV viral load Abbott m2000 System IU/mL
					cut off ≥ 1 s/co	cut off ≥ 3 fmol/L	cut off ≥ 1 COI	cut off ≥ 1 s/co	cut off ≥ 1 s/co	cut off ≥ 1 s/co		
1	202647608	91115329	0	25.09.2013	0.08	0.85	0.06	0.02	0.40	0.22	Non Reactive	<12
2	202647608	91116255	6	01.10.2013	0.08	0.42	0.06	0.02	0.43	0.24	Reactive	20
3	202647608	91116603	8	03.10.2013	0.07	11.48	0.06	0.01	0.43	0.23	Reactive	3744
4	202647608	91118063	17	12.10.2013	0.08	34835.15	0.06	0.01	10.07	3.76	Reactive	3897244
5	202647608	91118609	21	16.10.2013	0.08	35418.65	0.06	0.02	9.17	3.26	Reactive	9483393

Assay information:

Assay	Lot#	Exp. Date	Test Date
Abbott Architect Anti-HCV assay	62999LI00	13.10.2016	16.03.2016
Abbott Architect HCV Ag assay	59161LP39	08.10.2016	25.04.2016
Roche Anti-HCV assay	131785-01	01.09.2016	26.04.2016
Siemens Enzygnost Anti-HCV 4.0	45981	09.12.2016	02.05.2016
DiaSorin Murex HCV Ag/Ab	C931010	28.02.2017	28.04.2016
Bio-Rad Monolisa HCV Ag-Ab Ultra assay	5J0022	30.08.2016	06.06.2016
Abbott Architect HIV Ag/Ab combo assay	62998LI00	22.10.2016	16.03.2016
Abbott Architect HBsAg qualitativ II assay	61151FN00	25.01.2017	16.03.2016

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