

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 plasma. This panel illustrates the onset of the Hepatitis C virus (Genotype 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 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.

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 |

HCV Ag Only Seroconversion Panel, Catalogue No: SCP-HCV(Ag)-003

| 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 |
| Roche cobas® MPX assay | 209572 | 31.10.2016 | 18.04.2016 |
| Abbott RealTime HCV Amplification kit | 466744 | 15.08.2017 | 14.11.2016 |

HCV Ag Only Seroconversion Panel, Catalogue No: SCP-HCV(Ag)-003

