

New Panels

We have new Panels for those who want to develop or evaluate their HCV Ag/Ab or HCV Ab Assays

These panels are intended for use by in-vitro diagnostic manufacturers and researchers during assay development, evaluation, verification, troubleshooting and post-marked surveillance of assays for the detection of Hepatitis C antibodies as well as Hepatitis C core antigen and Ag/Ab (combi) test systems.



Three Validation Panels and two Linearity Panels:

The linearity panels can be used as a validation tool to estimate the limit of detection (LOD) and limit of quantification (LOQ) or for the identification of cut-off values.

- VAP-HCVAg-001** Low HCV Ag: Range from 4.0 – 1,645 fmol/L (Abbott Architect)
Lowest viral load 282 IU/mL – highest viral load 198,571 IU/mL
- VAP-HCVAg-002** Medium HCV Ag: Range from 430 – 18,537 fmol/L (Abbott Architect)
Lowest viral load 77,272 IU/mL – highest viral load 2,409,118 IU/mL
- VAP-HCVAg-003** High HCV Ag: Range from 1,136 – 80,197 fmol/L (Abbott Architect)
Lowest viral load 59,618 IU/mL – highest viral load 18,684,452 IU/mL

Each panel is prepared from 20 different donors.

- LPS-HCVAg-001** Comprised of 50 samples with a HCV Ag range from 4.0-49,941 fmol/L (Abbott Architect);
Lowest viral load 282 IU/mL – highest viral load 9,483,393 IU/mL
- LPL-HCVAg-001** Comprised of 100 samples with a HCV Ag range from 4.0-97,243 fmol/L (Abbott Architect);
Lowest viral load 282 IU/mL – highest viral load 19,080,473 IU/mL

Nine Seroconversion Panels:

Seroconversion panels are used for the validation of diagnostic sensitivity or the identification of cut-off values.

Four classical Seroconversion Panels with a negative to positive HCV Ab response.

- SCP-HCV-004** 5 Member collected from Aug 12 – Sep 12
- SCP-HCV-010** 9 Member collected from Feb 12 – Mar 12
- SCP-HCV-011** 5 Member collected from Mar 12 – Apr 12
- SCP-HCV-012** 4 Member collected in Oct 13

Five Seroconversion Panels with a negative to positive HCV Ag only response.

- SCP-HCV(Ag)-003** 5 Member collected from Sep 13 – Oct 13
- SCP-HCV(Ag)-005** 7 Member collected from Jul 12 – Aug 12
- SCP-HCV(Ag)-006** 6 Member collected in Jan 14
- SCP-HCV(Ag)-007** 18 Member collected from Jul 12 – Nov 12
- SCP-HCV(Ag)-008** 11 Member collected from Dec 12 – Jan 13

Each panel member has a volume of 1.0 mL and 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 performed for the direct detection of HCV RNA with Roche COBAS® MPX 6800/8800. Viral load determination is performed with the Abbott m2000 System.

For more information please visit our website www.biomex.de or send an email to info@biomex.de