

HCV Ag Validation Panel High

REF Catalogue No: VAP-HCVAg-003

The Biomex GmbH HCV Ag Validation Panel High consists of 20 members (Genotypes 1a, 1b, 2b, 3a) with each member containing 1.0 mL of human sodium citrate plasma. This panel spans the upper range of quantification (1,136 – 80,197 fmol/L), enabling developers to challenge their HCV Ag assays.

1. Intended Use

This Validation Panel (VAP) is intended for standard testing by diagnostic manufacturers and re-researchers during assay development, evaluation, troubleshooting and post-marked surveillance of Hepatitis C core antigen test systems and methods. Moreover, it serves as validation tool to estimate the limit of detection (LOD) and limit of quantification (LOQ).

2. Storage and Stability

Store the VAP 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

Potentially infectious materials. Handle the product as if capable of transmitting infectious disease. 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 VAP 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.

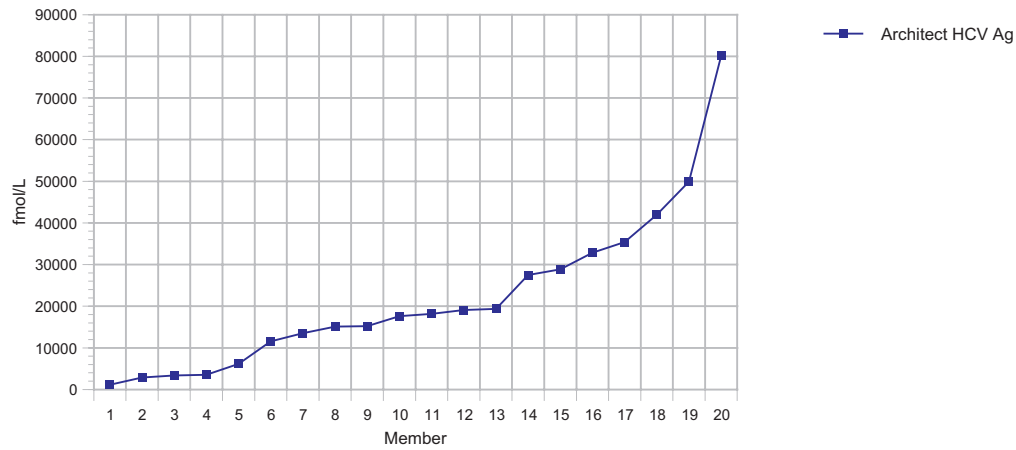
Declaration of used symbols

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

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Panel member	Donor	Lot#	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	Genotype
				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	50629067	0280981069	30.12.2012	0.10	1136.54	0.12	0.11	0.72	0.87	Reactive	59618	1a
2	13923932	0011210273	20.12.2012	0.06	2858.28	0.06	0.03	1.02	0.52	Reactive	97344	1a
3	316664732	0011189187	16.07.2012	0.08	3372.15	0.07	0.03	0.63	0.36	Reactive	321675	3a
4	175720405	0091118134	12.10.2013	0.07	3540.98	0.06	0.05	0.92	0.45	Reactive	342565	2b
5	283800332	0451264430	16.08.2012	0.05	6159.13	0.07	0.01	1.90	0.66	Reactive	2149244	1a
6	592455343	0041535302	18.03.2013	0.05	11563.50	0.06	0.02	4.23	3.58	Reactive	934168	1a
7	237411634	0280976201	06.12.2012	0.04	13512.72	0.06	0.02	5.48	0.79	Reactive	1089742	1b
8	467274467	6010938592	15.05.2012	0.07	15114.00	0.06	0.02	4.13	1.25	Reactive	1783607	2b
9	594065945	0011213087	15.01.2013	0.04	15224.30	0.07	0.00	6.66	1.98	Reactive	2046444	1a
10	524693959	360116025	25.10.2012	0.04	17605.32	0.07	0.02	1.81	0.44	Reactive	4069837	3a
11	589164868	0011198104	18.09.2012	0.06	18161.25	0.06	0.03	5.33	1.48	Reactive	18295558	1b
12	485178982	0080170944	17.02.2012	0.09	19084.85	0.07	0.03	4.97	1.62	Reactive	1908056	2b
13	146789763	0011174356	15.03.2012	0.09	19335.49	0.07	0.02	6.20	1.55	Reactive	3816236	1b
14	594088435	0041461315	22.12.2011	0.11	27504.80	0.08	0.03	7.22	3.84	Reactive	252224	1a
15	299709168	0451300031	12.03.2013	0.03	28847.25	0.07	-0.01	8.50	3.22	Reactive	1557424	1a
16	281887437	11195069	28.08.2012	0.69	32816.30	0.47	0.87	10.50	2.07	Reactive	7321876	1b
17	202647608	91118609	16.10.2013	0.08	35418.65	0.06	0.02	9.17	3.26	Reactive	9483393	2b
18	294601579	0451314309	03.06.2013	0.04	41937.80	0.08	0.02	9.05	3.68	Reactive	1868396	1a
19	179743038	0091045298	15.06.2012	0.16	49941.25	0.07	0.03	9.57	3.83	Reactive	5932100	1a
20	589127115	0800616111	06.02.2013	0.05	80197.70	0.06	0.02	10.86	6.23	Reactive	18684452	1a

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Assay information:

Assay	Lot#	Exp. Date	Test Date
Abbott Architect Anti-HCV assay	59391LI00	17.08.2016	Feb-Apr2016
Abbott Architect Anti HCV assay	62999LI01	13.10.2016	Mar-Apr2016
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