

HCV Ag Validation Panel Medium

REF Catalogue No: VAP-HCVAg-002

The Biomex GmbH HCV Ag Validation Panel Medium consists of 20 members (Genotypes 1a, 1b, 2b, 3a) with each member containing 1.0 mL of human plasma. This panel spans the medium range of quantification (430 – 18,537 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 researchers during assay development, evaluation, troubleshooting and post-marked surveillance of Hepatitis 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 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 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.

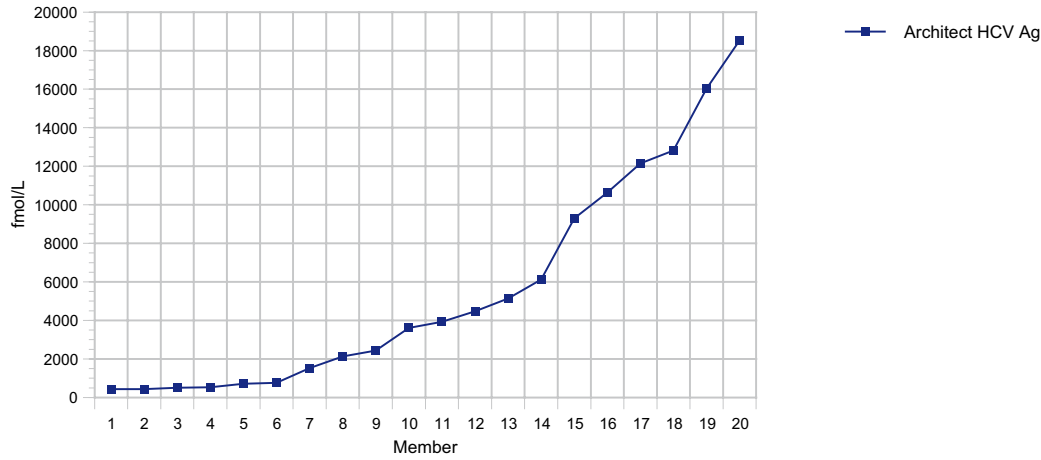
Declaration of used symbols

 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
				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	0280979950	22.12.2012	0.10	430.60	0.07	0.07	0.59	0.90	Reactive	84034
2	399848211	0011210597	22.12.2012	0.06	434.54	0.07	0.02	0.51	0.32	Reactive	191952
3	594508445	0041506940	24.09.2012	0.07	504.53	0.28	0.02	0.50	0.35	Reactive	92030
4	450436900	6011075809	30.01.2014	0.04	535.93	0.07	0.03	0.55	0.30	Reactive	86404
5	594346769	41473127	07.03.2012	0.05	717.38	0.91	0.00	0.50	0.24	Reactive	105118
6	13923932	0011209916	18.12.2012	0.06	766.09	0.06	0.04	0.61	0.30	Reactive	91388
7	594508385	0011200971	09.10.2012	0.24	1528.30	0.06	0.02	0.56	0.33	Reactive	155586
8	589127115	0800613258	17.01.2013	0.06	2132.20	0.07	0.01	0.80	0.36	Reactive	299954
9	283800332	0451263096	09.08.2012	0.06	2439.57	0.07	0.02	1.25	0.48	Reactive	1048441
10	44641609	0041488416	05.06.2012	0.09	3614.63	0.06	0.04	0.63	0.35	Reactive	246982
11	175720405	0091118244	14.10.2013	0.05	3927.89	0.21	0.05	0.87	0.34	Reactive	77272
12	524693959	360114461	15.10.2012	0.06	4471.16	0.07	0.02	0.84	0.25	Reactive	1048441
13	316664732	0011190165	23.07.2012	0.07	5138.13	0.06	0.03	0.72	0.43	Reactive	420502
14	237411634	0280977832	13.12.2012	0.04	6122.99	0.06	0.04	2.68	0.56	Reactive	815152
15	137921545	0800605062	19.11.2012	0.04	9304.42	0.06	0.02	3.13	1.57	Reactive	908368
16	243559211	0280935968	19.06.2012	0.04	10628.94	0.07	0.02	1.17	0.48	Reactive	2169273
17	594065945	0011213642	19.01.2013	0.04	12148.76	0.06	0.01	3.93	1.21	Reactive	1594847
18	146789763	0011174074	13.03.2012	0.08	12815.97	0.07	0.03	3.95	0.99	Reactive	2409118
19	299709168	0451299355	07.03.2013	0.03	16030.40	0.07	0.01	5.01	1.66	Reactive	2409118
20	467274467	6010937987	11.05.2012	0.08	18537.00	0.07	0.03	4.90	1.62	Reactive	309008

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Assay information:

Assay	Lot#	Exp. Date	Test Date
Abbott Architect Anti-HCV assay	59391LI00	17.08.2016	01.02.2016
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