

## HCV Ag Validation Panel Low

**REF** Catalogue No: VAP-HCVAg-001

The Biomex GmbH HCV Ag Validation Panel Low consists of 20 members (Genotypes 1a, 1b, 2b, 2c, 3a) with each member containing 1.0 mL of human plasma. This panel spans the lower limit of quantification (4.00 – 1,645.94 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 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) or the identification of cut-off values.

### 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 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.

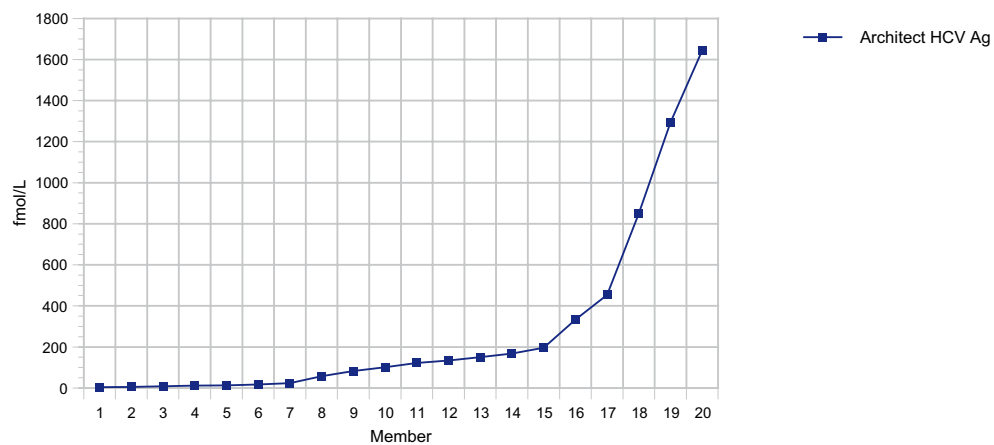
Declaration of used symbols

 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	204704243	0091128943	20.12.2013	0.05	4.00	0.06	0.01	0.37	0.22	Reactive	282
2	399848211	0011212091	07.01.2013	0.06	5.13	0.06	0.01	0.39	0.31	Reactive	5655
3	146789763	0011173340	06.03.2012	0.10	8.26	0.07	0.02	0.37	0.24	Reactive	2677
4	202647608	91116603	03.10.2013	0.07	11.48	0.06	0.01	0.43	0.23	Reactive	3744
5	450436900	6011075170	28.01.2014	0.05	13.34	0.07	0.02	0.42	0.26	Reactive	2081
6	592564615	0011226679	03.05.2013	0.06	16.70	0.06	0.02	0.46	0.28	Reactive	1368
7	283800332	0451261534	31.07.2012	0.06	23.46	0.07	0.02	0.42	0.25	Reactive	19222
8	192709990	0091057313	10.09.2012	0.06	57.29	0.07	0.03	0.44	0.28	Reactive	10800
9	524693959	360114120	12.10.2012	0.05	82.29	0.07	0.02	0.38	0.21	Reactive	24724
10	594346769	41471961	28.02.2012	0.05	101.18	0.06	0.01	0.52	0.26	Reactive	26887
11	185662561	0091119454	21.10.2013	0.07	121.91	0.07	0.03	0.45	0.24	Reactive	19860
12	589684478	0800541629	10.10.2011	0.07	133.75	0.07	0.07	0.55	0.27	Reactive	3262
13	13923932	0011208115	04.12.2012	0.07	149.80	0.06	0.03	0.46	0.25	Reactive	15050
14	44641609	0041491450	22.06.2012	0.07	168.24	0.07	0.03	0.41	0.28	Reactive	29652
15	178683772	0091033531	23.02.2012	0.04	195.89	0.07	0.09	0.43	0.19	Reactive	19042
16	591505373	0041496370	23.07.2012	0.06	333.06	0.06	0.03	0.71	0.28	Reactive	10724
17	50629067	0280981318	02.01.2013	0.10	454.27	0.26	0.11	0.50	0.72	Reactive	103644
18	594508385	0011199753	29.09.2012	0.25	849.28	0.07	0.03	0.51	0.34	Reactive	162130
19	594065945	0011212786	12.01.2013	0.04	1294.74	0.07	0.01	0.84	0.34	Reactive	198571
20	594508445	0041508713	04.10.2012	0.06	1645.94	0.19	0.02	0.67	0.47	Reactive	163204

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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