

# HCV Ag Linearity Panel Max

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

The Biomex GmbH HCV Antigen Linearity Panel Max consists of 100 members (Genotypes 1a, 1b, 2b, 2c, 3a) with each member containing 1.0 mL of human plasma. This panel spans the upper (97,243 fmol/L) and lower limit (4.0 fmol/L) of quantification over a wide range, enabling developers to challenge their HCV Ag assays.

## 1. Intended Use

This Linearity Panel (LP) 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 LP at  $-20^{\circ}\text{C}$  to  $-80^{\circ}\text{C}$ . 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<sup>®</sup>, anti-HCV with Siemens ENZYGNOST<sup>®</sup> and Roche COBAS<sup>®</sup> e411, HCV Ag/Ab with DiaSorin MUREX<sup>®</sup> and Bio-Rad MONOLISA<sup>®</sup>, as well as qualitative testing is performed for the direct detection of HCV RNA with Roche COBAS<sup>®</sup> MPX 6800/8800. Viral load determination is performed with the Abbott m2000 System. Testing is carried out with CE marked test.

## 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 LP 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

HCV Ag Linearity Panel Max, Catalogue No: LPL-HCVAg-001

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	178683772	0091033256	21.02.2012	0.04	14.56	0.07	0.10	0.41	0.20	Reactive	2052
7	592564615	0011226679	03.05.2013	0.06	16.70	0.06	0.02	0.46	0.28	Reactive	1368
8	399848211	0011211829	04.01.2013	0.06	19.08	0.07	0.02	0.40	0.33	Reactive	21953
9	399848211	0011209986	18.12.2012	0.06	23.41	0.07	0.02	0.44	0.33	Reactive	29240
10	13923932	0011207199	27.11.2012	0.06	54.32	0.07	0.03	0.42	0.26	Reactive	9161
11	192709990	0091057313	10.09.2012	0.06	57.29	0.07	0.03	0.44	0.28	Reactive	10800
12	589684478	0800540521	04.10.2011	0.07	59.81	0.07	0.07	0.44	0.23	Reactive	7746
13	399848211	0011210731	26.12.2012	0.11	60.51	0.07	0.03	0.41	0.30	Reactive	90119
14	594346769	41472508	02.03.2012	0.05	73.65	0.08	0.01	0.46	0.24	Reactive	20046
15	50629067	0280980165	26.12.2012	0.09	81.34	0.07	0.05	0.50	0.78	Reactive	22418
16	524693959	360114120	12.10.2012	0.05	82.29	0.07	0.02	0.38	0.21	Reactive	24724
17	594346769	41471961	28.02.2012	0.05	101.18	0.06	0.01	0.52	0.26	Reactive	26887
18	185662561	0091119454	21.10.2013	0.07	121.91	0.07	0.03	0.45	0.24	Reactive	19860
19	44641609	0041487248	29.05.2012	0.09	122.79	0.06	0.05	0.37	0.30	Reactive	16598
20	178683772	0091034868	10.03.2012	0.04	132.74	0.07	0.06	0.53	0.22	Reactive	34825
21	589684478	0800541629	10.10.2011	0.07	133.75	0.07	0.07	0.55	0.27	Reactive	3262
22	13923932	0011208115	04.12.2012	0.07	149.80	0.06	0.03	0.46	0.25	Reactive	15050
23	178683772	0091034470	06.03.2012	0.05	154.37	0.07	0.08	0.46	0.21	Reactive	40332
24	44641609	0041491450	22.06.2012	0.07	168.24	0.07	0.03	0.41	0.28	Reactive	29652
25	450436900	6011074056	23.01.2014	0.04	190.26	0.07	0.00	0.52	0.27	Reactive	55631

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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		
26	13923932	0011207930	02.12.2012	0.06	195.43	0.06	0.03	0.52	0.22	Reactive	32022
27	178683772	0091033531	23.02.2012	0.04	195.89	0.07	0.09	0.43	0.19	Reactive	19042
28	592564615	0011225849	28.04.2013	0.06	232.67	0.07	0.02	0.55	0.33	Reactive	11502
29	592564615	0011225657	26.04.2013	0.06	260.57	0.07	0.03	0.73	0.33	Reactive	21051
30	591505373	0041496370	23.07.2012	0.06	333.06	0.06	0.03	0.71	0.28	Reactive	10724
31	594508445	0041508316	02.10.2012	0.06	345.95	0.19	0.02	0.50	0.35	Reactive	51513
32	283800332	0451262650	07.08.2012	0.06	414.73	0.07	0.02	0.57	0.30	Reactive	251854
33	50629067	0280979950	22.12.2012	0.10	430.60	0.07	0.07	0.59	0.90	Reactive	84034
34	399848211	0011210597	22.12.2012	0.06	434.54	0.07	0.02	0.51	0.32	Reactive	191952
35	13923932	0011209140	11.12.2012	0.07	436.58	0.06	0.02	0.65	0.27	Reactive	56810
36	50629067	0280981318	02.01.2013	0.10	454.27	0.26	0.11	0.50	0.72	Reactive	103644
37	594508445	0041506940	24.09.2012	0.07	504.53	0.28	0.02	0.50	0.35	Reactive	92030
38	450436900	6011075809	30.01.2014	0.04	535.93	0.07	0.03	0.55	0.30	Reactive	86404
39	44641609	0041488005	02.06.2012	0.10	551.74	0.06	0.04	0.43	0.24	Reactive	101493
40	594346769	41473127	07.03.2012	0.05	717.38	0.91	0.00	0.50	0.24	Reactive	105118
41	13923932	0011209916	18.12.2012	0.06	766.09	0.06	0.04	0.61	0.30	Reactive	91388
42	594508385	0011199753	29.09.2012	0.25	849.28	0.07	0.03	0.51	0.34	Reactive	162130
43	50629067	0280981069	30.12.2012	0.10	1136.54	0.12	0.11	0.72	0.87	Reactive	59618
44	594065945	0011212786	12.01.2013	0.04	1294.74	0.07	0.01	0.84	0.34	Reactive	198571
45	594508385	0011200971	09.10.2012	0.24	1528.30	0.06	0.02	0.56	0.33	Reactive	155586
46	594508445	0041508713	04.10.2012	0.06	1645.94	0.19	0.02	0.67	0.47	Reactive	163204
47	589127115	0800613258	17.01.2013	0.06	2132.20	0.07	0.01	0.80	0.36	Reactive	299954
48	283800332	0451261936	02.08.2012	0.06	2175.02	0.07	0.01	1.23	0.57	Reactive	1540060
49	283800332	0451263937	14.08.2012	0.05	2307.87	0.07	0.02	1.08	0.50	Reactive	991411
50	283800332	0451263096	09.08.2012	0.06	2439.57	0.07	0.02	1.25	0.48	Reactive	1048441

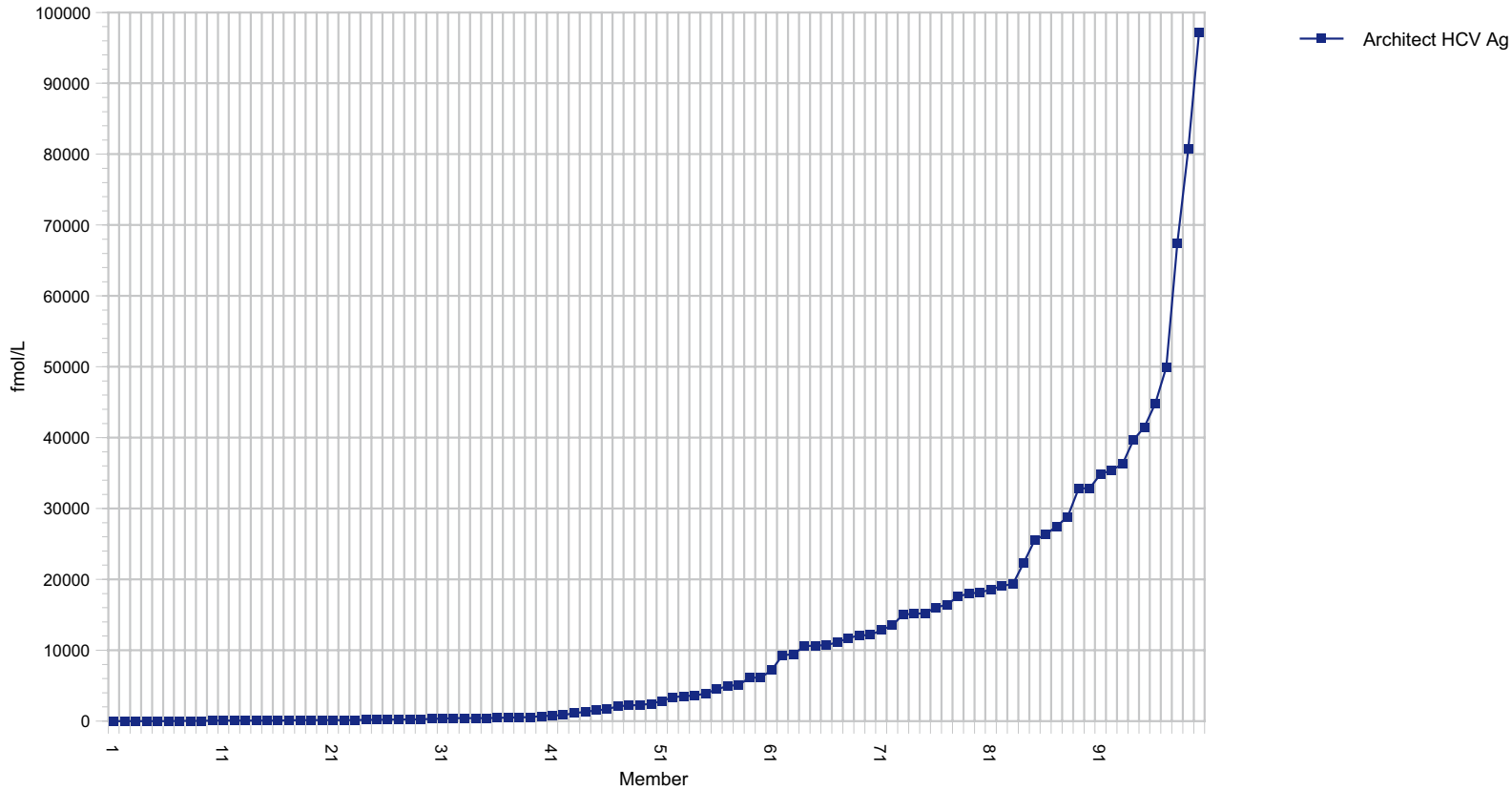
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Panel member	Donor	Lot#	Bleed Date	Anti-HCV Abbott Architect S/CO	HCV Ag Abbott Architect fmol/L	Roche Cobas e411 HCV Ab COI	Siemens Enzygnost Anti-HCV 4.0 S/CO	DiaSorin Murex HCV Ag/Ab S/CO	Bio-Rad Monolisa HCV Ag-Ab Ultra Assay S/CO	HCV MPX Qualitativ Roche Cobas 6800/8800	HCV viral load Abbott m2000 System IU/mL
				cut off $\geq 1$ s/co	cut off $\geq 3$ fmol/L	cut off $\geq 1$ COI	cut off $\geq 1$ s/co	cut off $\geq 1$ s/co	cut off $\geq 1$ s/co		
51	13923932	0011210273	20.12.2012	0.06	2858.28	0.06	0.03	1.02	0.52	Reactive	97344
52	316664732	0011189187	16.07.2012	0.08	3372.15	0.07	0.03	0.63	0.36	Reactive	321675
53	175720405	0091118134	12.10.2013	0.07	3540.98	0.06	0.05	0.92	0.45	Reactive	342565
54	44641609	0041488416	05.06.2012	0.09	3614.63	0.06	0.04	0.63	0.35	Reactive	246982
55	175720405	0091118244	14.10.2013	0.05	3927.89	0.21	0.05	0.87	0.34	Reactive	77272
56	524693959	360114461	15.10.2012	0.06	4471.16	0.07	0.02	0.84	0.25	Reactive	1048441
57	237411634	0280977338	11.12.2012	0.04	4949.50	0.06	0.04	3.03	0.48	Reactive	428453
58	316664732	0011190165	23.07.2012	0.07	5138.13	0.06	0.03	0.72	0.43	Reactive	420502
59	237411634	0280977832	13.12.2012	0.04	6122.99	0.06	0.04	2.68	0.56	Reactive	815152
60	283800332	0451264430	16.08.2012	0.05	6159.13	0.07	0.01	1.90	0.66	Reactive	2149244
61	594065945	0011214615	26.01.2013	0.04	7188.20	0.06	0.02	3.09	1.17	Reactive	957354
62	137921545	0800605062	19.11.2012	0.04	9304.42	0.06	0.02	3.13	1.57	Reactive	908368
63	594065945	0011213989	22.01.2013	0.04	9421.55	0.06	0.01	4.96	1.26	Reactive	2199818
64	467274467	6010936012	01.05.2012	0.09	10604.63	0.06	0.03	3.30	1.09	Reactive	886490
65	243559211	0280935968	19.06.2012	0.04	10628.94	0.07	0.02	1.17	0.48	Reactive	2169273
66	467274467	6010937319	08.05.2012	0.07	10728.34	0.07	0.02	2.96	1.07	Reactive	1214242
67	146789763	0011176403	02.04.2012	0.19	11094.76	0.85	0.25	4.23	1.46	Reactive	3588595
68	594065945	0011215069	30.01.2013	0.04	11715.55	0.06	0.00	4.23	1.54	Reactive	1758841
69	467274467	6010936424	03.05.2012	0.08	12087.58	0.06	0.03	3.40	1.53	Reactive	1899439
70	594065945	0011213642	19.01.2013	0.04	12148.76	0.06	0.01	3.93	1.21	Reactive	1594847
71	146789763	0011174074	13.03.2012	0.08	12815.97	0.07	0.03	3.95	0.99	Reactive	2409118
72	237411634	0280976201	06.12.2012	0.04	13512.72	0.06	0.02	5.48	0.79	Reactive	1089742
73	524693959	360116639	30.10.2012	0.05	15036.30	0.07	0.02	2.43	0.68	Reactive	4813347
74	467274467	6010938592	15.05.2012	0.07	15114.00	0.06	0.02	4.13	1.25	Reactive	1783607
75	594065945	0011213087	15.01.2013	0.04	15224.30	0.07	0.00	6.66	1.98	Reactive	2046444

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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 $\geq 1$ s/co	cut off $\geq 3$ fmol/L	cut off $\geq 1$ COI	cut off $\geq 1$ s/co	cut off $\geq 1$ s/co	cut off $\geq 1$ s/co		
76	299709168	0451299355	07.03.2013	0.03	16030.40	0.07	0.01	5.01	1.66	Reactive	2409118
77	524693959	360117013	01.11.2012	0.05	16443.75	0.07	0.02	3.37	0.69	Reactive	8905073
78	524693959	360116025	25.10.2012	0.04	17605.32	0.07	0.02	1.81	0.44	Reactive	4069837
79	243559211	0280936534	21.06.2012	0.04	17997.29	0.08	0.01	1.31	0.73	Reactive	2965956
80	589164868	0011198104	18.09.2012	0.06	18161.25	0.06	0.03	5.33	1.48	Reactive	18295558
81	467274467	6010937987	11.05.2012	0.08	18537.00	0.07	0.03	4.90	1.62	Reactive	309008
82	485178982	0080170944	17.02.2012	0.09	19084.85	0.07	0.03	4.97	1.62	Reactive	1908056
83	146789763	0011174356	15.03.2012	0.09	19335.49	0.07	0.02	6.20	1.55	Reactive	3816236
84	294601579	0451313974	31.05.2013	0.04	22361.10	0.08	0.02	7.55	3.08	Reactive	3742329
85	281887437	11194172	21.08.2012	0.07	25585.90	0.06	0.03	9.58	1.80	Reactive	6058024
86	179743038	0091045936	20.06.2012	0.18	26338.55	0.07	0.02	6.75	2.55	Reactive	4488328
87	594088435	0041461315	22.12.2011	0.11	27504.80	0.08	0.03	7.22	3.84	Reactive	252224
88	299709168	0451300031	12.03.2013	0.03	28847.25	0.07	-0.01	8.50	3.22	Reactive	1557424
89	281887437	11195069	28.08.2012	0.69	32816.30	0.47	0.87	10.50	2.07	Reactive	7321876
90	281887437	11194796	24.08.2012	0.08	32859.20	0.09	0.06	11.05	2.08	Reactive	8659493
91	202647608	91118063	12.10.2013	0.08	34835.15	0.06	0.01	10.07	3.76	Reactive	3897244
92	202647608	91118609	16.10.2013	0.08	35418.65	0.06	0.02	9.17	3.26	Reactive	9483393
93	299709168	0451301115	19.03.2013	0.03	36245.95	0.07	0.00	10.95	4.86	Reactive	8843032
94	524693959	360117573	06.11.2012	0.04	39679.15	0.07	0.01	4.86	1.08	Reactive	4036100
95	179743038	0091044069	06.06.2012	0.18	41469.15	0.07	0.03	9.68	3.82	Reactive	5978208
96	179743038	0091044971	13.06.2012	0.18	44809.50	0.07	0.02	10.13	4.15	Reactive	9286563
97	179743038	0091045298	15.06.2012	0.16	49941.25	0.07	0.03	9.57	3.83	Reactive	5932100
98	589127115	0800613878	22.01.2013	0.05	67386.60	0.06	0.02	10.95	4.40	Reactive	17061180
99	589127115	0800614948	29.01.2013	0.05	80764.50	0.06	0.01	10.03	6.65	Reactive	19080473
100	589127115	0800615345	31.01.2013	0.05	97243.40	0.06	0.01	10.31	7.67	Reactive	2352549

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Assay information:

Assay	Lot#	Exp. Date	Test Date
Abbott Architect Anti-HCV assay	62999LI00	13.10.2016	Feb-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