

# HCV Ag Linearity Panel Min

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

The Biomex GmbH HCV Antigen Linearity Panel Min consists of 50 members (Genotypes 1a, 1b, 2b, 2c, 3a) with each member containing 1.0 mL of human plasma. This panel spans the upper (49,941 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°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

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®, 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 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

REF	LOT	i		2°C - 8°C
Catalog Number	Lot Number	Consult Instructions for Use	Manufactured by	Temperature Limitation

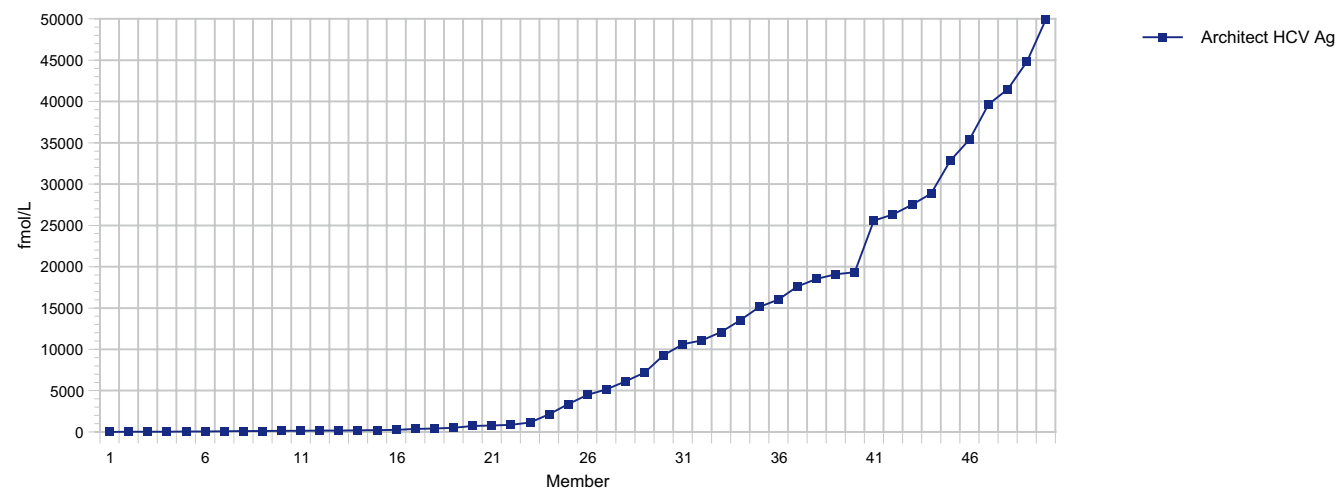
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Panel member	Donor	Lot#	Bleed Date	Anti-HCV Abbott Architect S/CO	HCV Ag Abbott Architect fmol/L	Roche Cobas e411 HCV Ab COI	Siemens Enzygnost Anti-HCV 4.0 S/CO	DiaSorin Murex HCV Ag/Ab S/CO	Bio-Rad Monolisa HCV Ag-Ab Ultra Assay S/CO	HCV MPX Qualitativ Roche Cobas 6800/8800	HCV viral load Abbott m2000 System IU/mL
				cut off $\geq 1$ 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		
1	204704243	0091128943	20.12.2013	0.05	4.00	0.06	0.01	0.37	0.22	Reactive	282
2	202647608	91116603	03.10.2013	0.07	11.48	0.06	0.01	0.43	0.23	Reactive	3744
3	592564615	0011226679	03.05.2013	0.06	16.70	0.06	0.02	0.46	0.28	Reactive	1368
4	399848211	0011209986	18.12.2012	0.06	23.41	0.07	0.02	0.44	0.33	Reactive	29240
5	13923932	0011207199	27.11.2012	0.06	54.32	0.07	0.03	0.42	0.26	Reactive	9161
6	399848211	0011210731	26.12.2012	0.11	60.51	0.07	0.03	0.41	0.30	Reactive	90119
7	50629067	0280980165	26.12.2012	0.09	81.34	0.07	0.05	0.50	0.78	Reactive	22418
8	594346769	41471961	28.02.2012	0.05	101.18	0.06	0.01	0.52	0.26	Reactive	26887
9	185662561	0091119454	21.10.2013	0.07	121.91	0.07	0.03	0.45	0.24	Reactive	19860
10	178683772	0091034868	10.03.2012	0.04	132.74	0.07	0.06	0.53	0.22	Reactive	34825
11	13923932	0011208115	04.12.2012	0.07	149.80	0.06	0.03	0.46	0.25	Reactive	15050
12	178683772	0091034470	06.03.2012	0.05	154.37	0.07	0.08	0.46	0.21	Reactive	40332
13	44641609	0041491450	22.06.2012	0.07	168.24	0.07	0.03	0.41	0.28	Reactive	29652
14	450436900	6011074056	23.01.2014	0.04	190.26	0.07	0.00	0.52	0.27	Reactive	55631
15	592564615	0011225849	28.04.2013	0.06	232.67	0.07	0.02	0.55	0.33	Reactive	11502
16	592564615	0011225657	26.04.2013	0.06	260.57	0.07	0.03	0.73	0.33	Reactive	21051
17	594508445	0041508316	02.10.2012	0.06	345.95	0.19	0.02	0.50	0.35	Reactive	51513
18	283800332	0451262650	07.08.2012	0.06	414.73	0.07	0.02	0.57	0.30	Reactive	251854
19	594508445	0041506940	24.09.2012	0.07	504.53	0.28	0.02	0.50	0.35	Reactive	92030
20	594346769	41473127	07.03.2012	0.05	717.38	0.91	0.00	0.50	0.24	Reactive	105118
21	13923932	0011209916	18.12.2012	0.06	766.09	0.06	0.04	0.61	0.30	Reactive	91388
22	594508385	0011199753	29.09.2012	0.25	849.28	0.07	0.03	0.51	0.34	Reactive	162130
23	50629067	0280981069	30.12.2012	0.10	1136.54	0.12	0.11	0.72	0.87	Reactive	59618
24	589127115	0800613258	17.01.2013	0.06	2132.20	0.07	0.01	0.80	0.36	Reactive	299954
25	316664732	0011189187	16.07.2012	0.08	3372.15	0.07	0.03	0.63	0.36	Reactive	321675

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				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		
26	524693959	360114461	15.10.2012	0.06	4471.16	0.07	0.02	0.84	0.25	Reactive	1048441
27	316664732	0011190165	23.07.2012	0.07	5138.13	0.06	0.03	0.72	0.43	Reactive	420502
28	237411634	0280977832	13.12.2012	0.04	6122.99	0.06	0.04	2.68	0.56	Reactive	815152
29	594065945	0011214615	26.01.2013	0.04	7188.20	0.06	0.02	3.09	1.17	Reactive	957354
30	137921545	0800605062	19.11.2012	0.04	9304.42	0.06	0.02	3.13	1.57	Reactive	908368
31	467274467	6010936012	01.05.2012	0.09	10604.63	0.06	0.03	3.30	1.09	Reactive	886490
32	146789763	0011176403	02.04.2012	0.19	11094.76	0.85	0.25	4.23	1.46	Reactive	3588595
33	467274467	6010936424	03.05.2012	0.08	12087.58	0.06	0.03	3.40	1.53	Reactive	1899439
34	237411634	0280976201	06.12.2012	0.04	13512.72	0.06	0.02	5.48	0.79	Reactive	1089742
35	467274467	6010938592	15.05.2012	0.07	15114.00	0.06	0.02	4.13	1.25	Reactive	1783607
36	299709168	0451299355	07.03.2013	0.03	16030.40	0.07	0.01	5.01	1.66	Reactive	2409118
37	524693959	360116025	25.10.2012	0.04	17605.32	0.07	0.02	1.81	0.44	Reactive	4069837
38	467274467	6010937987	11.05.2012	0.08	18537.00	0.07	0.03	4.90	1.62	Reactive	309008
39	485178982	0080170944	17.02.2012	0.09	19084.85	0.07	0.03	4.97	1.62	Reactive	1908056
40	146789763	0011174356	15.03.2012	0.09	19335.49	0.07	0.02	6.20	1.55	Reactive	3816236
41	281887437	11194172	21.08.2012	0.07	25585.90	0.06	0.03	9.58	1.80	Reactive	6058024
42	179743038	0091045936	20.06.2012	0.18	26338.55	0.07	0.02	6.75	2.55	Reactive	4488328
43	594088435	0041461315	22.12.2011	0.11	27504.80	0.08	0.03	7.22	3.84	Reactive	252224
44	299709168	0451300031	12.03.2013	0.03	28847.25	0.07	-0.01	8.50	3.22	Reactive	1557424
45	281887437	11195069	28.08.2012	0.69	32816.30	0.47	0.87	10.50	2.07	Reactive	7321876
46	202647608	91118609	16.10.2013	0.08	35418.65	0.06	0.02	9.17	3.26	Reactive	9483393
47	524693959	360117573	06.11.2012	0.04	39679.15	0.07	0.01	4.86	1.08	Reactive	4036100
48	179743038	0091044069	06.06.2012	0.18	41469.15	0.07	0.03	9.68	3.82	Reactive	5978208
49	179743038	0091044971	13.06.2012	0.18	44809.50	0.07	0.02	10.13	4.15	Reactive	9286563
50	179743038	0091045298	15.06.2012	0.16	49941.25	0.07	0.03	9.57	3.83	Reactive	5932100

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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