

PhenoSense™ HIV Neutralization Assay

Background

Monogram Biosciences' PhenoSense™ HIV Neutralization, or "Neutralizing Antibody", Assay is available to pharmaceutical and vaccine companies and researchers involved in HIV vaccine and therapeutic antibody research. The assay is offered in 3 different formats:

- 1.) **CURVES: 10-point dilutions (full titers, "Curves"):**
Results provided as IC50s, IC80s, IC90s and IC95s with corresponding 10-point inhibition curves in PDF format.
- 2.) **CURVES PLUS: 10-point dilutions (full titers, "Curves Plus"):**
Results provided as IC50s, etc. with corresponding 10-point inhibition curves in PDF format PLUS a summary of the percent inhibition at each of the 10 concentrations (dilutions) tested in tabular format in a spreadsheet file.
- 3.) **HITS: 4-point dilutions (screening "hits"):**
Results provided as percent inhibition at each of 4 dilutions (example: 1:10, 1:30, 1:90 and 1:270) in tabular format in a spreadsheet file.

The 10-point "curves" or "curves plus" formats are the gold standard assay formats for assessing neutralizing antibody activity. The 10-dilution curves allow the most precise estimation of IC50 and % inhibitions at various dilutions. The 10-point formats ("curves" or "curves plus") are recommended for most projects.

For screening larger numbers of serum samples or antibodies, the 4-point "hits" format is available. This format may be used to economically screen serum samples or antibodies for overall activity prior to testing in the 10-point "curves" format. Please note that a minimum of 10 sera/antibodies per shipment, and a minimum of 1000 hits per year are required in the "hits" format.

Virus Envelope Library

Monogram Biosciences maintains a large library (virus pools and clones) of HIV-1 envelopes (gp160), including numerous non-subtype B viruses, which allows for virus panel customization. This library includes commonly available lab strain and repository viruses as well as thousands of primary patient isolates. Clients may also send their own viruses (e.g. a vaccine strain or HIV+ patient plasma) for testing. An additional one-time charge for virus set-up will apply. Please inquire for more details.

Minimum Testing Volume

In order to offer the best possible pricing, Monogram Biosciences requires a minimum testing volume of 10 antibody samples tested against 5 virus specimens (plus 3 control viruses) in "hits" format, or 5 antibody samples tested against 5 library specimens (plus 3 control viruses) in the "curves" or "curves plus" format per sample submission. The 3 control viruses (JRCSF, aMLV and NL4-3) are provided at no additional charge and do not count toward the minimum.

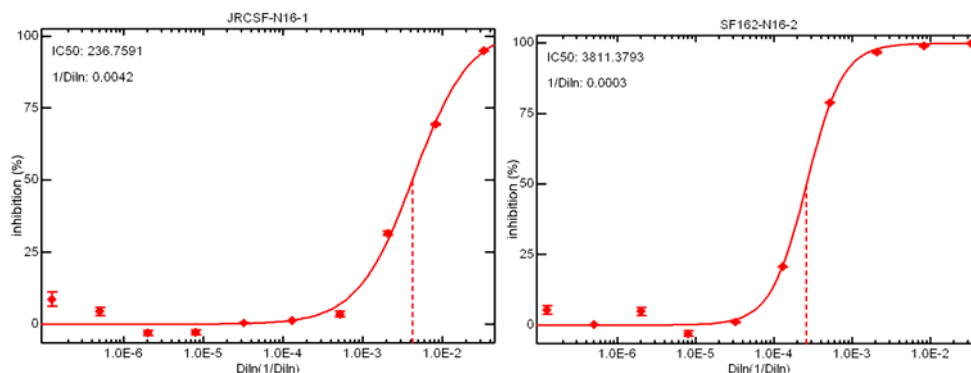
The HITS format requires a minimum commitment of 1000 “hits” using a standard, fixed virus panel (minimum of 5 viruses) in a 12-month period. This minimum is in addition to the minimum volume of 10 sera or antibodies tested per sample submission.

Pre-Screening Requirement

Monogram Biosciences pre-screens most plasma and sera for possible treatment to minimize interfering substances present in the sample prior to subsequent neutralization testing.

Monogram Biosciences requests submission of an additional volume of 300µl of sample to allow for this screening step.

Example of CURVES data:



Neutralizing Antibody Assay: CURVES Summary

Client: Monogram

Date: 00/00/2006

Virus	Sera	Unit	1/Diln	IC50	IC80	IC90	IC95	Toxicity	# Toxicity Affected Dilns	Overall
Virus 1	N16	Diln(1/Diln)	0.0146	68.6936	30.5192	<20.0000	<20.0000		1	P
Virus 2	N16	Diln(1/Diln)	0.0138	72.4469	36.6547	26.4294	21.0240		1	P
Virus 3	N16	Diln(1/Diln)	0.0046	218.7167	80.3774	47.4924	31.4976		1	P
Virus 4	N16	Diln(1/Diln)	0.0126	79.6281	25.4424	<20.0000	<20.0000		1	P
Virus 5	N16	Diln(1/Diln)	0.0150	66.7384	23.1343	<20.0000	<20.0000		1	P
Virus 6	N16	Diln(1/Diln)	0.0104	96.1900	31.8453	<20.0000	<20.0000		1	P
Virus 7	N16	Diln(1/Diln)	>0.0500	<20.0000	<20.0000	<20.0000	<20.0000		1	N
Virus 8	N16	Diln(1/Diln)	0.0182	54.8195	<20.0000	<20.0000	<20.0000		1	P
Virus 9	N16	Diln(1/Diln)	0.0288	34.7329	<20.0000	<20.0000	<20.0000		1	N
Virus 10	N16	Diln(1/Diln)	0.0061	164.0519	71.7909	46.1546	32.4416		1	P
Virus 11	N16	Diln(1/Diln)	0.0055	182.2798	56.6277	30.7761	<20.0000		1	P
Virus 12	N16	Diln(1/Diln)	0.0075	133.1779	40.3371	21.3119	<20.0000		1	P
Virus 13	N16	Diln(1/Diln)	0.0058	171.2768	58.5416	33.6621	22.0796		1	P
Virus 14	N16	Diln(1/Diln)	0.0125	80.2084	29.1598	<20.0000	<20.0000		1	P
Virus 15	N16	Diln(1/Diln)	0.0100	99.5349	44.0218	25.9884	<20.0000		1	P
JRCSF	N16	Diln(1/Diln)	0.0017	577.7882	245.7345	150.3425	96.9437		1	P
NL43	N16	Diln(1/Diln)	0.0005	1866.3062	1031.6978	721.5761	508.9267		1	P
AMP	N16	Diln(1/Diln)	>0.0500	<20.0000	<20.0000	<20.0000	<20.0000		1	N

Example of HITS data:



Neutralizing Antibody Assay: HITS

Client: Monogram

Date: 00/00/2006

Virus-Name	Sera-Name	Unit	Starting-Dilution	Fold-Dilution	Toxicity	Inhibition Starting Diln	Inhibition Diln 1:3	Inhibition Diln 1:9	Inhibition Diln 1:27	Overall
Virus 16	N16	Diln(1/Diln)	0.02	3		P 60.4%	N 28.1%	N 20.0%	N 3.4%	P
Virus 17	N16	Diln(1/Diln)	0.02	3		P 51.6%	N 32.9%	N 7.2%	N 12.2%	P
Virus 18	N16	Diln(1/Diln)	0.02	3		N 36.5%	N 10.2%	N -0.1%	N -17.8%	N
Virus 19	N16	Diln(1/Diln)	0.02	3		N 41.1%	N 23.5%	N 10.5%	N 2.7%	N
Virus 20	N16	Diln(1/Diln)	0.02	3		P 59.9%	N 37.4%	N 21.0%	N 7.5%	P
Virus 21	N16	Diln(1/Diln)	0.02	3		P 57.8%	N 31.3%	N 18.0%	N 15.5%	P
Virus 22	N16	Diln(1/Diln)	0.02	3		N 43.3%	N 22.7%	N 4.1%	N 8.7%	N
Virus 23	N16	Diln(1/Diln)	0.02	3		P 64.2%	N 37.9%	N 25.0%	N 16.7%	P
Virus 24	N16	Diln(1/Diln)	0.02	3		N 39.7%	N 27.9%	N 12.4%	N 5.7%	N
Virus 25	N16	Diln(1/Diln)	0.02	3		N 48.5%	N 28.1%	N 16.1%	N 10.7%	N
Virus 26	N16	Diln(1/Diln)	0.02	3		N 45.8%	N 23.0%	N 15.9%	N 9.3%	N
Virus 27	N16	Diln(1/Diln)	0.02	3		N 46.8%	N 16.8%	N -11.1%	N -4.4%	N
Virus 28	N16	Diln(1/Diln)	0.02	3		N 41.6%	N 19.3%	N 9.1%	N -0.6%	N
Virus 29	N16	Diln(1/Diln)	0.02	3		N 17.9%	N 16.7%	N 13.3%	N 10.2%	N
Virus 30	N16	Diln(1/Diln)	0.02	3		N 43.9%	N 34.9%	N 24.1%	N 9.4%	N
Virus 31	N16	Diln(1/Diln)	0.02	3		P 59.4%	N 29.5%	N 18.2%	N 7.5%	P
Virus 32	N16	Diln(1/Diln)	0.02	3		N 40.8%	N 18.4%	N 11.7%	N 10.6%	N
Virus 33	N16	Diln(1/Diln)	0.02	3		N 43.6%	N 38.0%	N 17.9%	N 4.9%	N
Virus 34	N16	Diln(1/Diln)	0.02	3		N 47.2%	N 23.0%	N 16.4%	N 2.1%	N
Virus 35	N16	Diln(1/Diln)	0.02	3		N 31.5%	N 17.9%	N 10.2%	N 9.5%	N
Virus 36	N16	Diln(1/Diln)	0.02	3		P 61.7%	N 33.6%	N 19.9%	N 18.6%	P
Virus 37	N16	Diln(1/Diln)	0.02	3		N 41.5%	N 27.1%	N 13.2%	N 2.6%	N
Virus 38	N16	Diln(1/Diln)	0.02	3		N 35.9%	N 31.2%	N 2.4%	N -12.3%	N
JRCSF	N16	Diln(1/Diln)	0.02	3		P 79.5%	N 45.3%	N 29.8%	N 10.7%	P
JRCSF	N16	Diln(1/Diln)	0.02	3		P 76.3%	N 45.2%	N 17.8%	N 6.3%	P
NL43	N16	Diln(1/Diln)	0.02	3		P 93.5%	P 84.8%	P 77.3%	P 56.6%	P
NL43	N16	Diln(1/Diln)	0.02	3		P 94.2%	P 86.8%	P 74.3%	P 54.8%	P
aMLV	N16	Diln(1/Diln)	0.02	3		N -0.7%	N -8.5%	N -0.9%	N -6.5%	N
aMLV	N16	Diln(1/Diln)	0.02	3		N -0.4%	N -0.9%	N -1.6%	N -5.1%	N

Note: P = Positive for neutralization activity; N = Negative for neutralization activity

For additional information, please contact the individuals listed below or visit the Monogram Biosciences website: <http://www.monogrambio.com/400PharmaPartnerships.aspx>

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