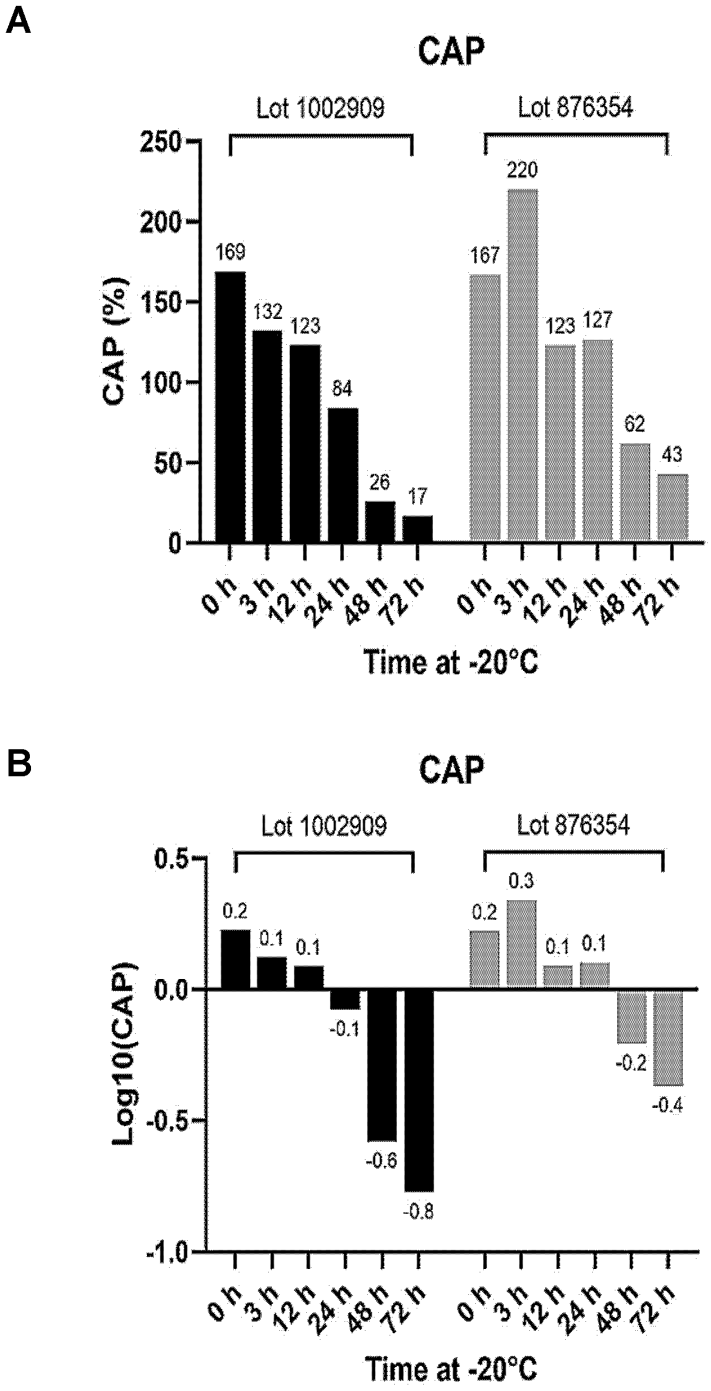
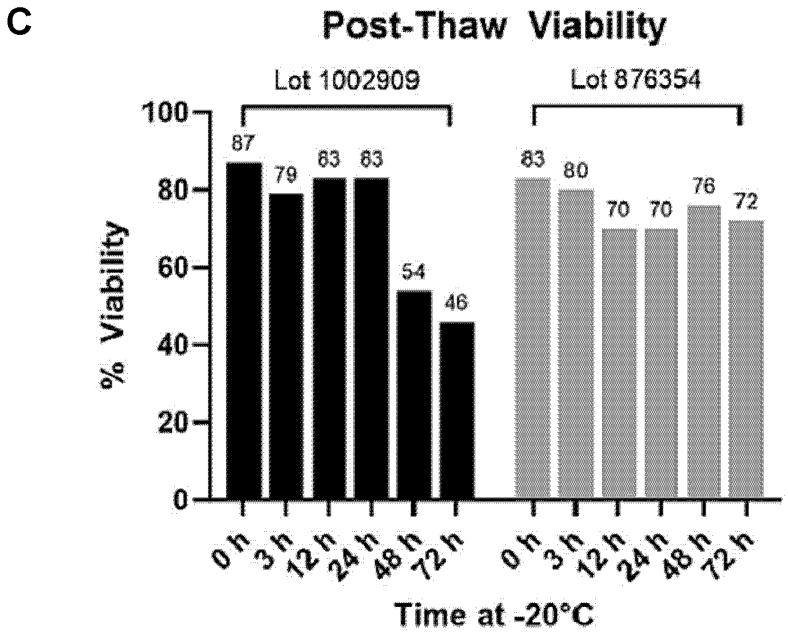

A
CAP
Lot 1002909
Lot 876354
CAP (%)
250
200
150
100
50
0
169
132
123
84
26
17
167
220
123
127
62
43
0 h
3 h
12 h
24 h
48 h
72 h
Time at -20°C
B
CAP
Lot 1002909
Lot 876354
Log10(CAP)
0.5
0.0
-0.5
-1.0
0.2
0.1
0.1
-0.1
-0.6
-0.8
0.2
0.3
0.1
0.1
-0.2
-0.4
0 h
3 h
12 h
24 h
48 h
72 h
Time at -20°C

Figure 1-1


C
Post-Thaw Viability
Lot 1002909
Lot 876354
% Viability
100
80
60
40
20
0
87
79
83
83
54
46
83
80
70
70
76
72
0 h
3 h
12 h
24 h
48 h
72 h
Time at -20°C

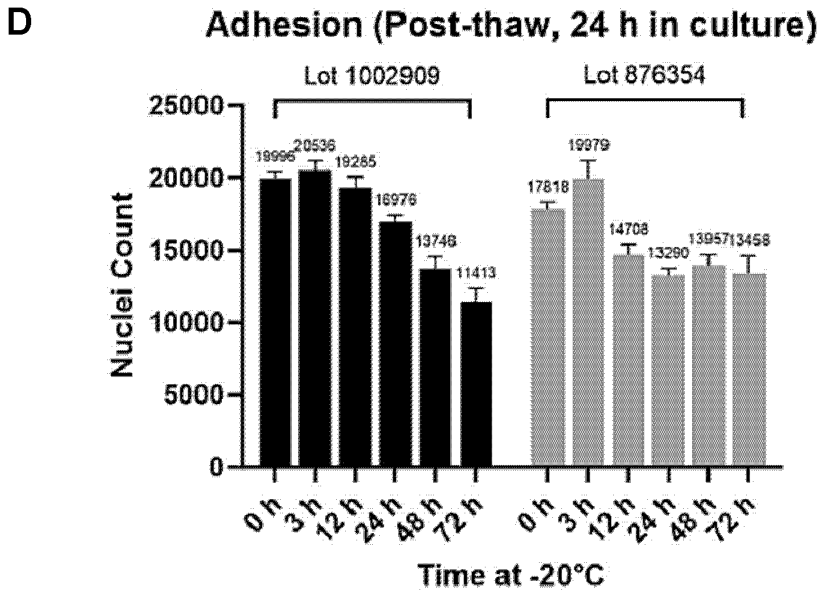
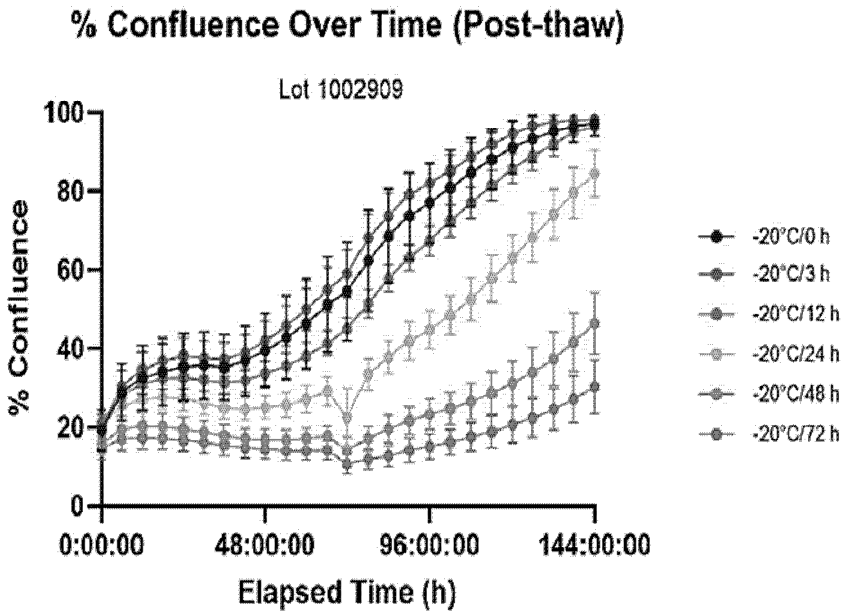

D
Adhesion (Post-thaw, 24 h in culture)
Lot 1002909
Lot 876354
Nuclei Count
25000
20000
15000
10000
5000
0
19996
20536
19265
16976
13746
11413
17818
19979
14708
13290
13957
13458
0 h
3 h
12 h
24 h
48 h
72 h
Time at -20°C

Figure 1-2

E


% Confluence Over Time (Post-thaw)
Lot 1002909
% Confluence
100
80
60
40
20
0
0:00:00
48:00:00
96:00:00
144:00:00
Elapsed Time (h)
-20°C/0 h
-20°C/3 h
-20°C/12 h
-20°C/24 h
-20°C/48 h
-20°C/72 h

F

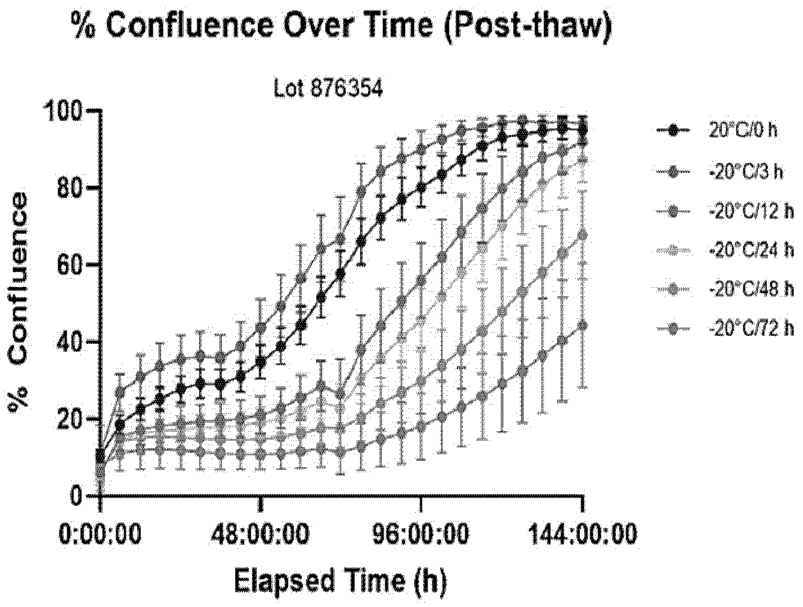
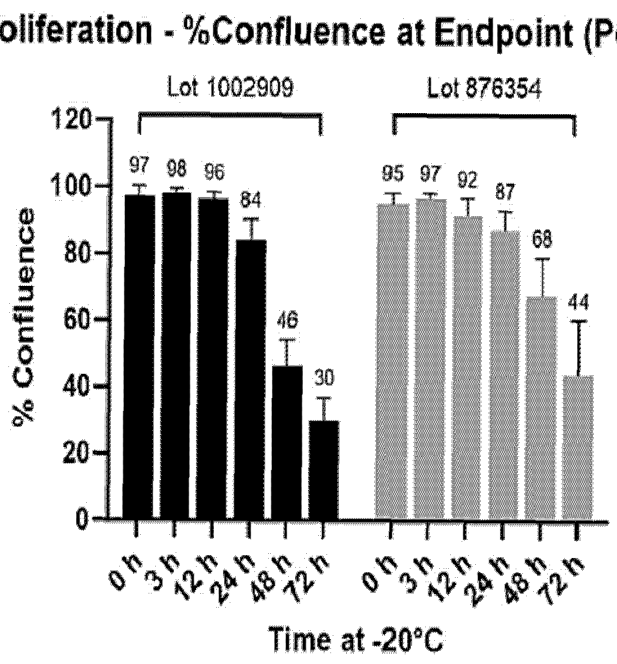

% Confluence Over Time (Post-thaw)
Lot 876354
% Confluence
100
80
60
40
20
0
0:00:00
48:00:00
96:00:00
144:00:00
Elapsed Time (h)
20°C/0 h
-20°C/3 h
-20°C/12 h
-20°C/24 h
-20°C/48 h
-20°C/72 h

Figure 1-3

G


Proliferation - %Confluence at Endpoint (Post-thaw)
Lot 1002909
Lot 876354
% Confluence
120
100
80
60
40
20
0
97
98
96
84
46
30
95
97
92
87
68
44
0 h
3 h
12 h
24 h
48 h
72 h
Time at -20°C

H

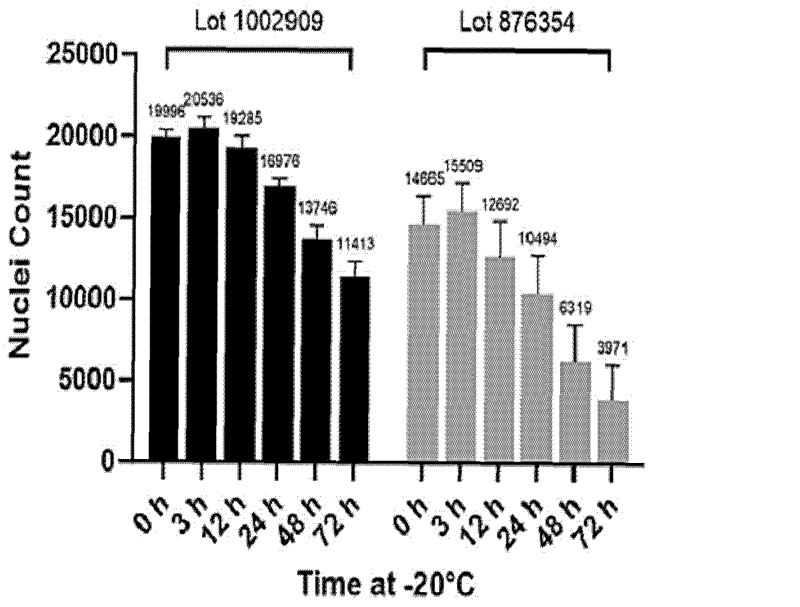

Proliferation - Nuclei Count at Endpoint (Post-thaw)
Lot 1002909
Lot 876354
Nuclei Count
25000
20000
15000
10000
5000
0
19996
20536
19285
16976
13746
11413
14665
15509
12692
10494
6319
3971
0 h
3 h
12 h
24 h
48 h
72 h
Time at -20°C

Figure 1-4

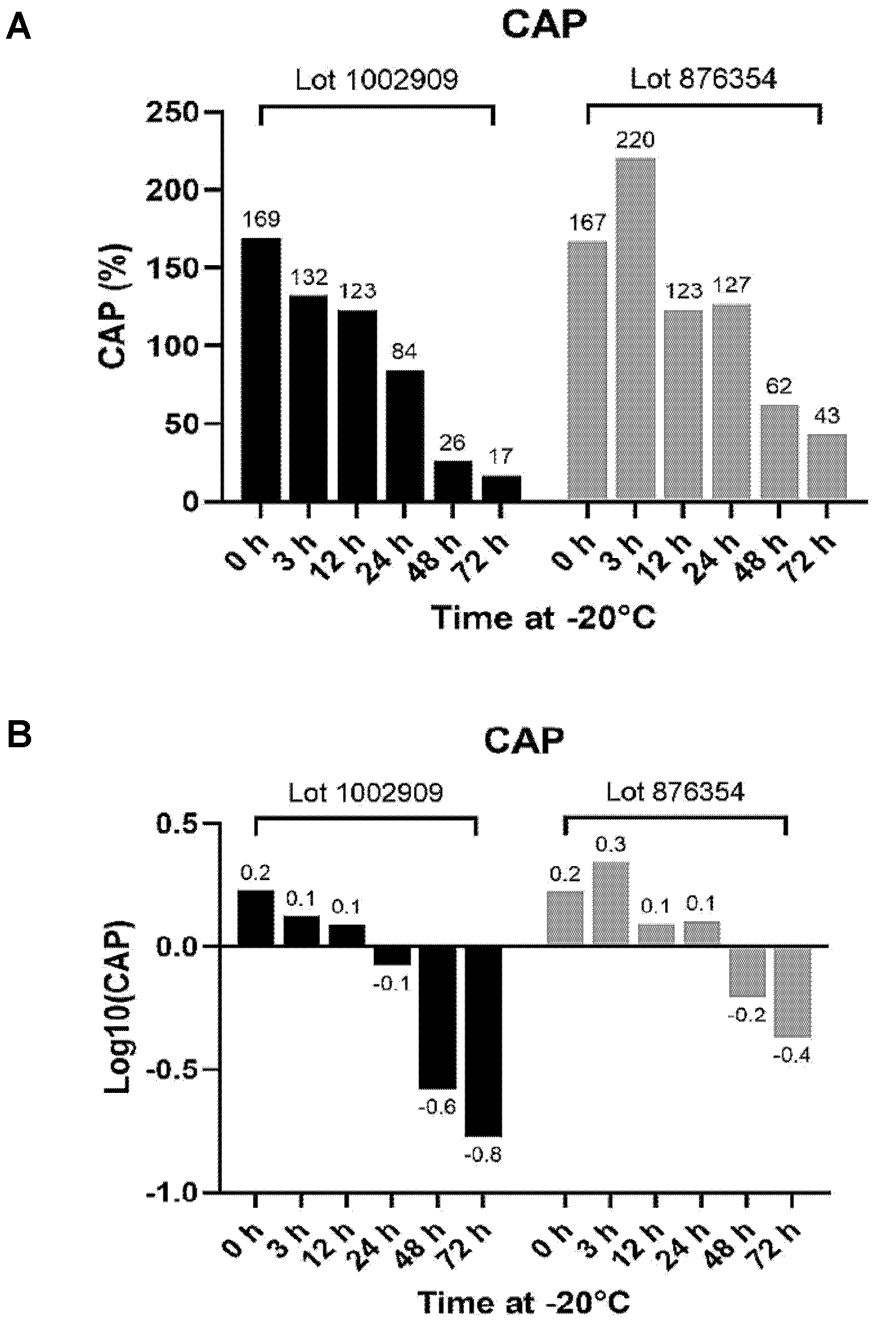
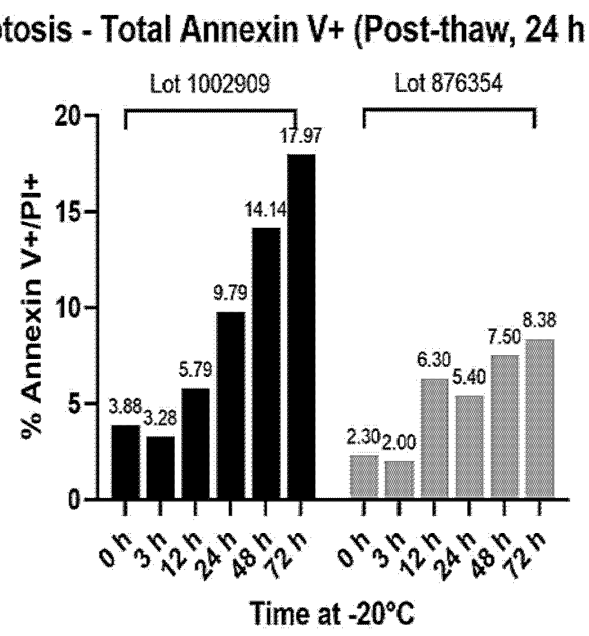

A
CAP
Lot 1002909
Lot 876354
CAP (%)
250
200
150
100
50
0
169
132
123
84
26
17
167
220
123
127
62
43
0 h
3 h
12 h
24 h
48 h
72 h
Time at -20°C
B
CAP
Lot 1002909
Lot 876354
Log10(CAP)
0.5
0.0
-0.5
-1.0
0.2
0.1
0.1
-0.1
-0.6
-0.8
0.2
0.3
0.1
0.1
-0.2
-0.4
0 h
3 h
12 h
24 h
48 h
72 h
Time at -20°C

Figure 2-1

C


Apoptosis - Total Annexin V+ (Post-thaw, 24 h in culture)
Lot 1002909
Lot 876354
% Annexin V+/PI+
20
15
10
5
0
3.88
3.28
5.79
9.79
14.14
17.97
2.30
2.00
6.30
5.40
7.50
8.38
0 h
3 h
12 h
24 h
48 h
72 h
Time at -20°C

D

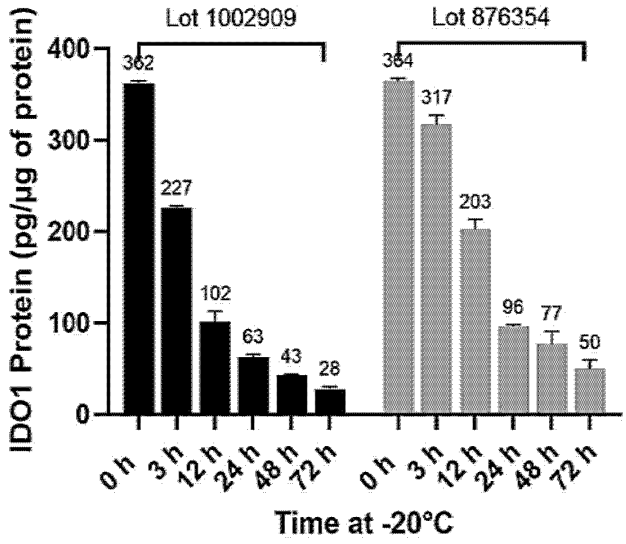
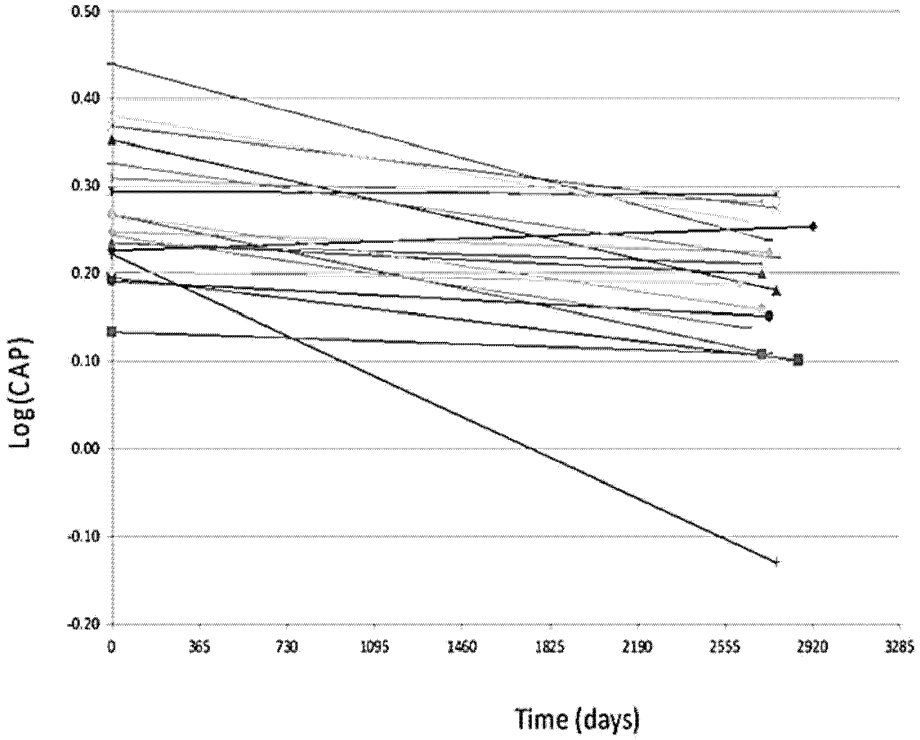
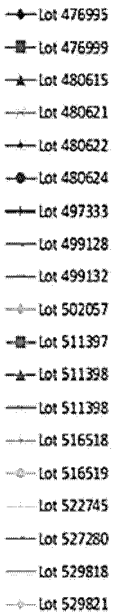

IFNγ-Stimulated IDO (Post-thaw, 24 h in culture)
Lot 1002909
Lot 876354
IDO1 Protein (pg/µg of protein)
400
300
200
100
0
362
227
102
63
43
28
364
317
203
96
77
50
0 h
3 h
12 h
24 h
48 h
72 h
Time at -20°C

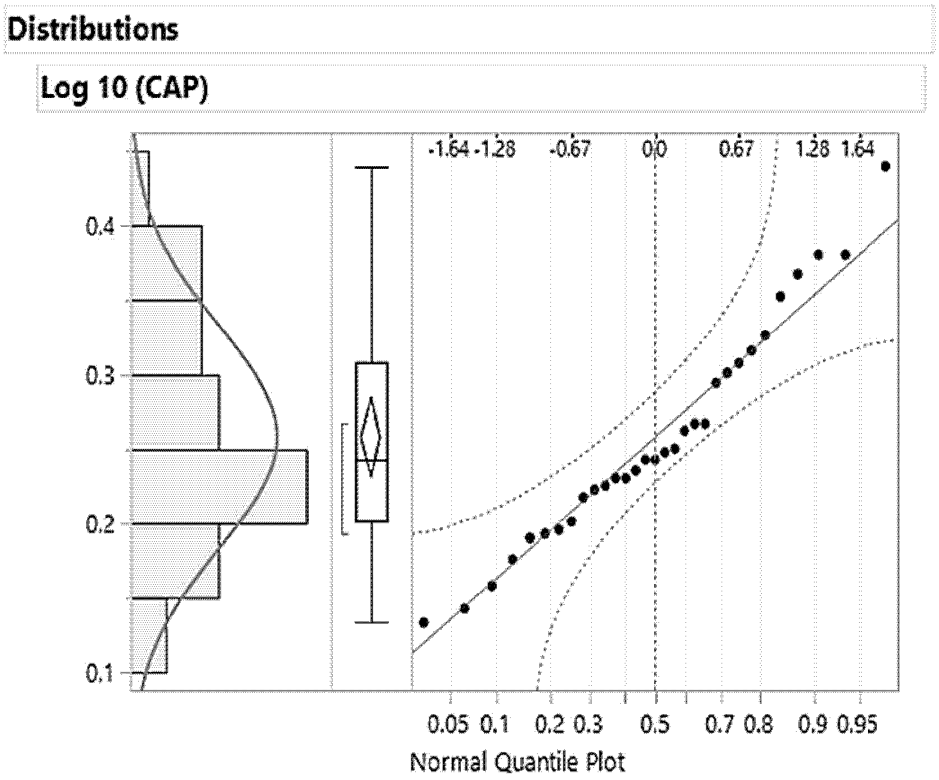
Figure 2-2





slope per day	-3.2243E-05
se slope	7.27653E-06
slope per yr	-0.01176873
se slope per yr	0.002657754
assay sd	0.061463096

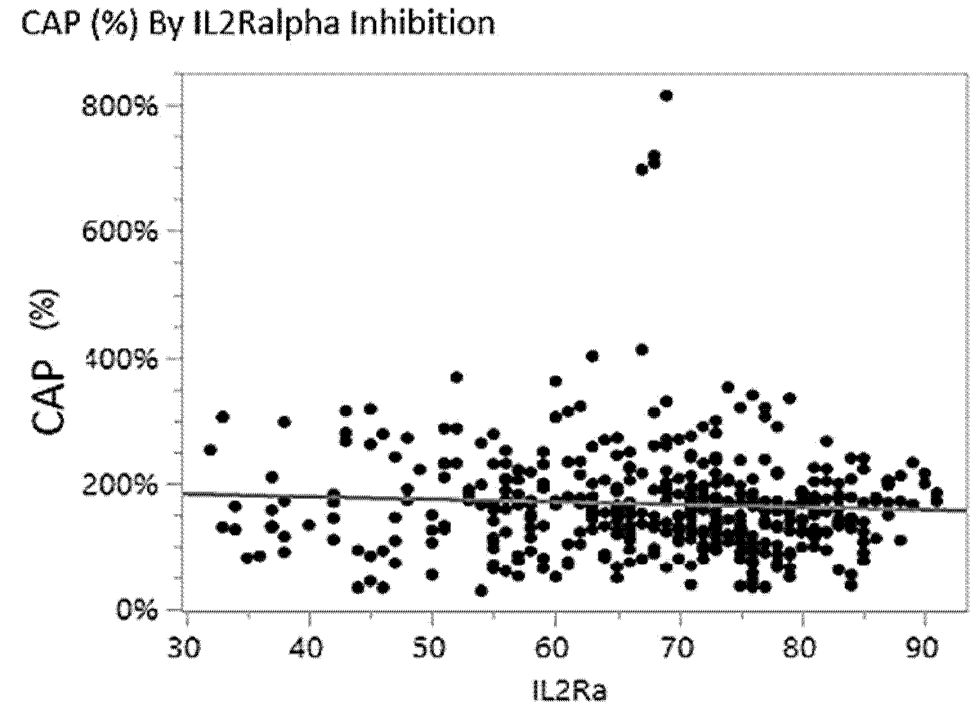
Figure 3



CAP (%)	Log_{10} (CAP)
50%	-0.30
80%	-0.10
100%	**0.00**
110%	0.04
150%	0.18
200%	0.30
300%	0.48

GVHD001 lots	Log_{10} (CAP)
Average	0.26
SD	0.07
CV	28.80
Min	0.13
Max	0.44
Mean-3SD	**0.0351 (108.4%)**
Mean+3SD	0.4808
N	31

Figure 4



Linear Fit

Linear Fit

CAG (%) = 1.9596644 - 0.0041818*IL2Ra

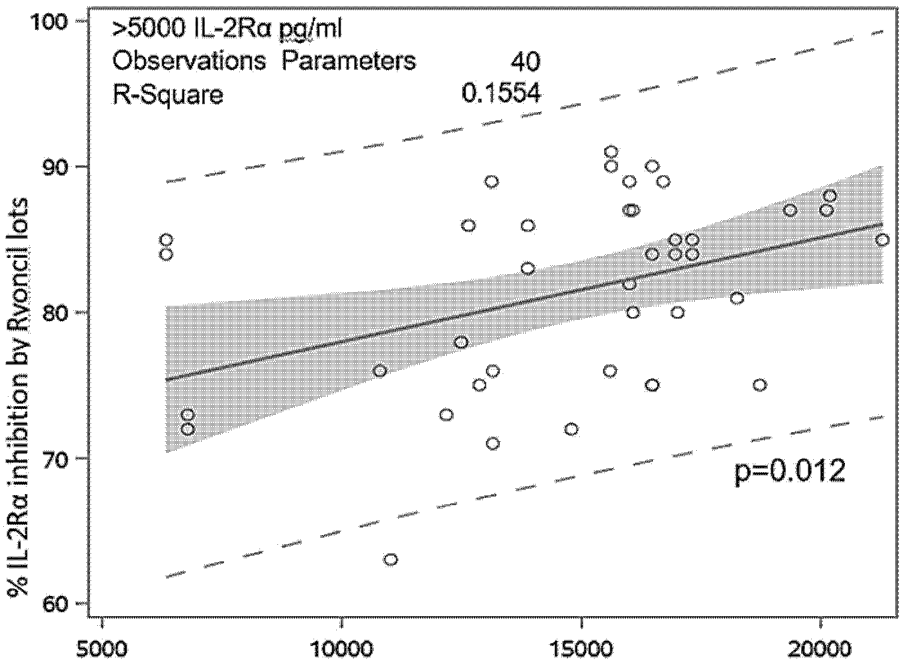
Summary of Fit

RSquare	0.003767
RSquare Adj	0.001423
Root Mean Square Error	0.867524
Mean of Response	1.675293
Observations (or Sum Wgts)	427

$R^2 = 0.003767$
P = 0.2056

Figure 5

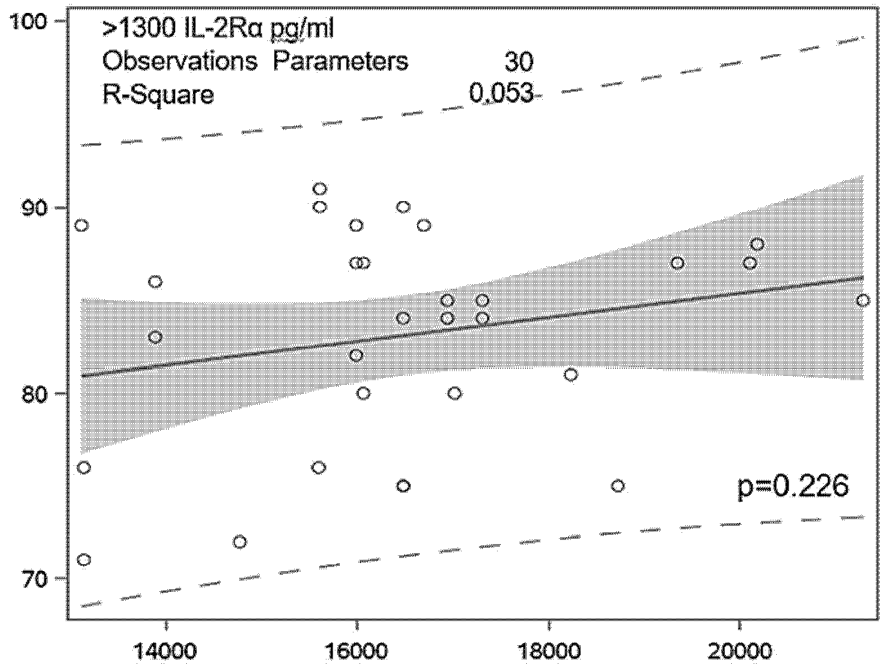
A



PBMC stim pg/ml IL2Ralpha	Number of Lots	R squared	p value
>10000	36	0.22	0.0043
>11000	35	0.20	0.0074
>12000	34	0.11	0.0525
>13000	30	0.05	0.2216

Figure 6-1

B



PBMC stimulation	N	Mean	SD	SE	Min	Max	p value
<13000 pg/ml	10	76.5	7.1	2.2	63	86	0.005
>13000 pg/ml	30	83.1	5.8	1.1	71	91	

Figure 6-2

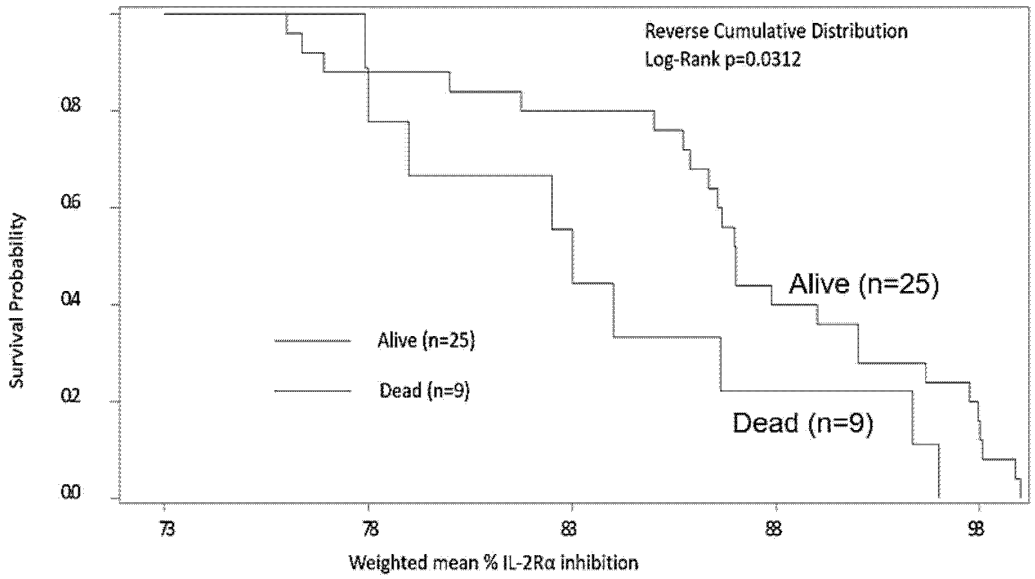

Reverse Cumulative Distribution
Log-Rank p=0.0312
Survival Probability
08
06
04
02
00
Alive (n=25)
Dead (n=9)
Alive (n=25)
Dead (n=9)
73
78
83
88
98
Weighted mean % IL-2Rα inhibition

Figure 7

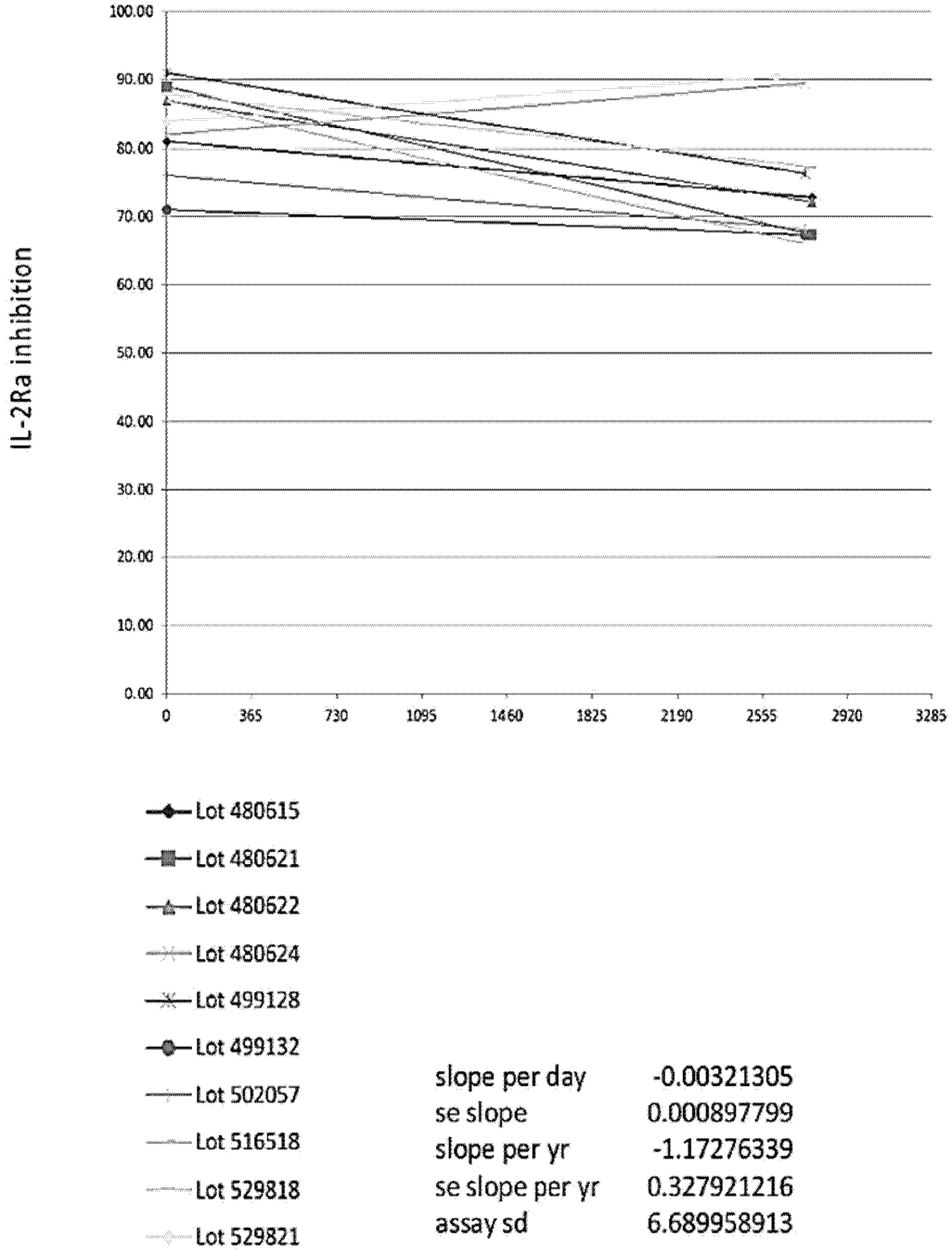

IL-2Ra inhibition
100.00
90.00
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
0
365
730
1095
1460
1825
2190
2555
2920
3285
Lot 480615
Lot 480621
Lot 480622
Lot 480624
Lot 499128
Lot 499132
Lot 502057
Lot 516518
Lot 529818
Lot 529821
slope per day -0.00321305
se slope 0.000897799
slope per yr -1.17276339
se slope per yr 0.327921216
assay sd 6.689958913

Figure 8

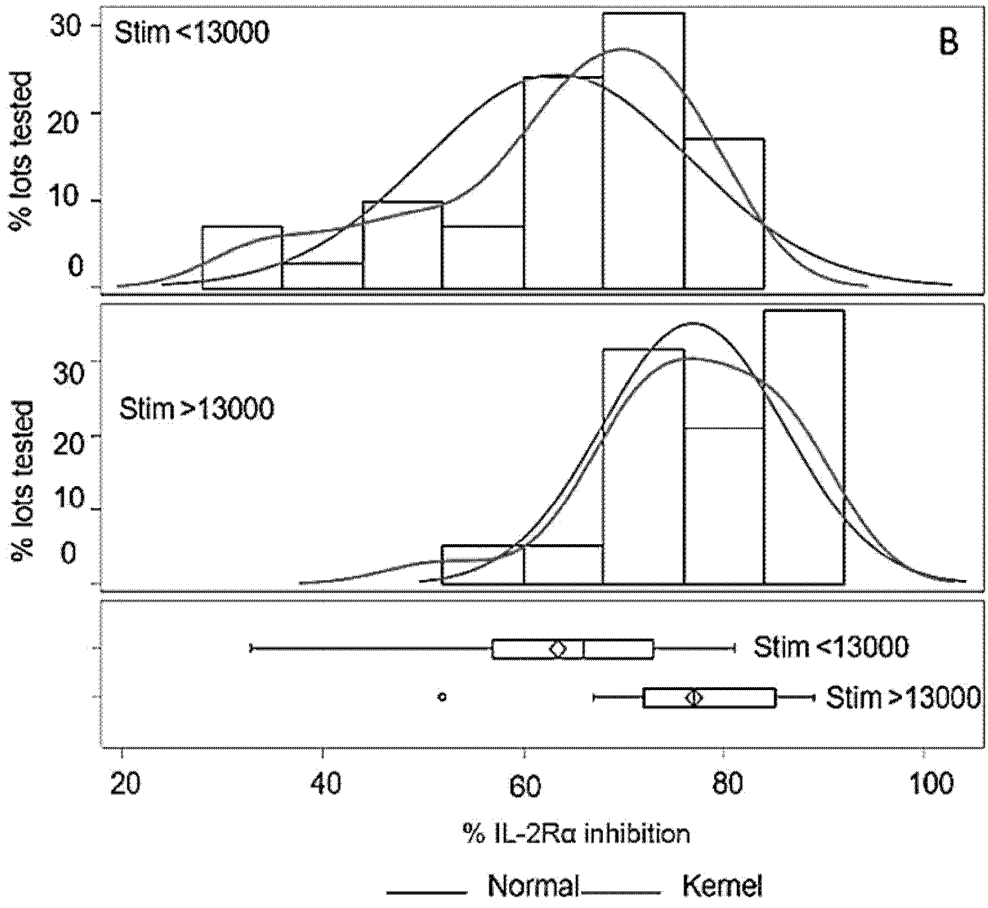

Stim <13000
B
% lots tested
30
20
10
0
Stim >13000
% lots tested
30
20
10
0
Stim <13000
Stim >13000
20
40
60
80
100
% IL-2Rα inhibition
Normal
Kernel

Figure 9