

Process 2A-22 Days Process, 2-3 Days Harvest/Ship

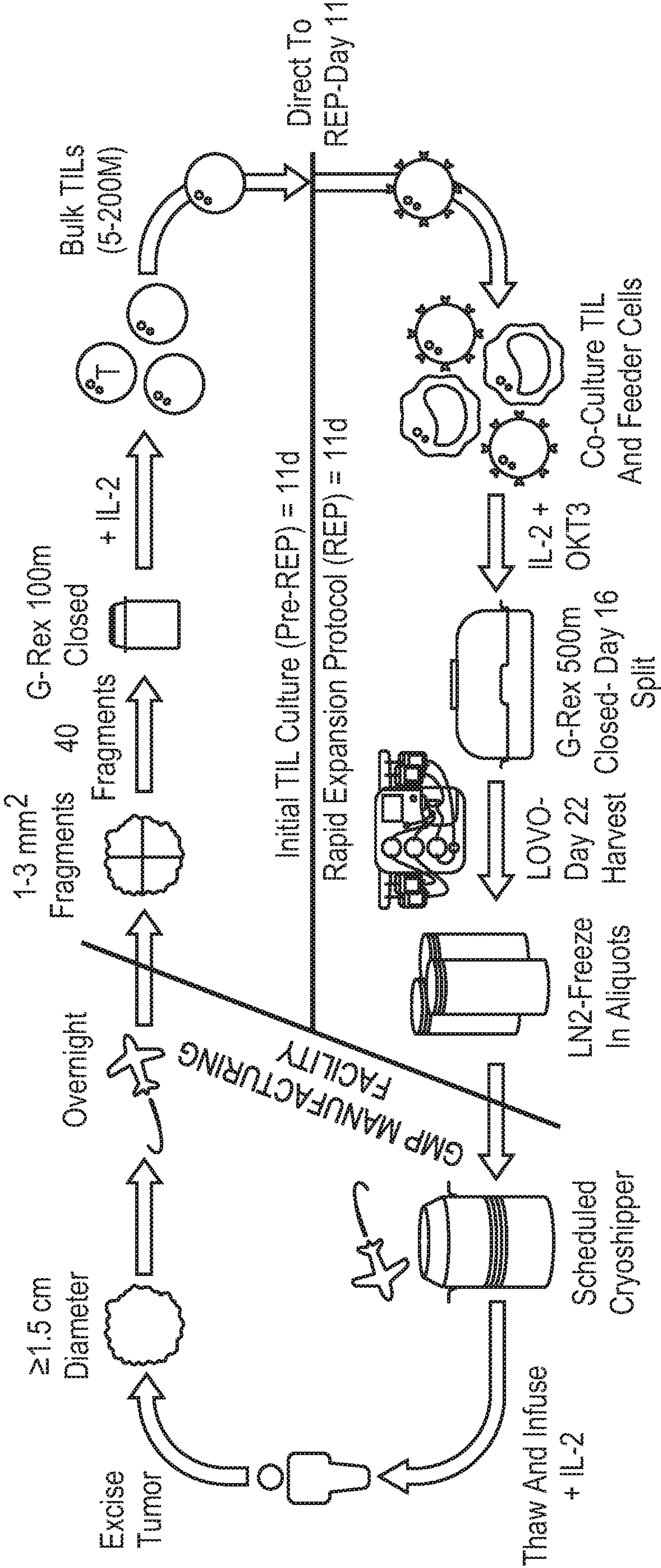


Figure 1

Process Development

Step	Current Process-1C	New Process-2A	Impact
1	4 Fragments/10 G-Rex 10-21 Days	40 Fragments/1-G-Rex 100 CS- (x2?) 11 Days	Increases Tumor Sample/Container, Shortens Culture, Reduces Steps, Amenable To Closed System
2	PreREP Freeze-> Testing -> Thaw- ~Day 27- >40e6TIL	Direct To REP- Day 11- <200e6	Shorten Process, Reduces Steps, Eliminates Testing
3	36 G-Rex 100-~Day 30 >5e6TIL - Split ~Day 36	4-5 G-Rex 500CS- TIL- Split Day 16	Reduces Steps, Closed System, Shorter REP
4	Harvest Day ~43+ Harvesting By Centrifugation	Harvest Day 22 LOVO-Automated Cell Washer	Reduces Steps, Automated, Closed System
5	Fresh Product- Hypothermosol-Single Infusion Bag	Cryopreserved Product-CS10 In LN ₂ , Multiple Aliquots	Shipping Flexibility, Patient Scheduling, Easier Release Testing, Global Trials
6	43+ Day Process Time	22 Day Process Time	Turnaround To Patient, Clean Room Throughput, COGs

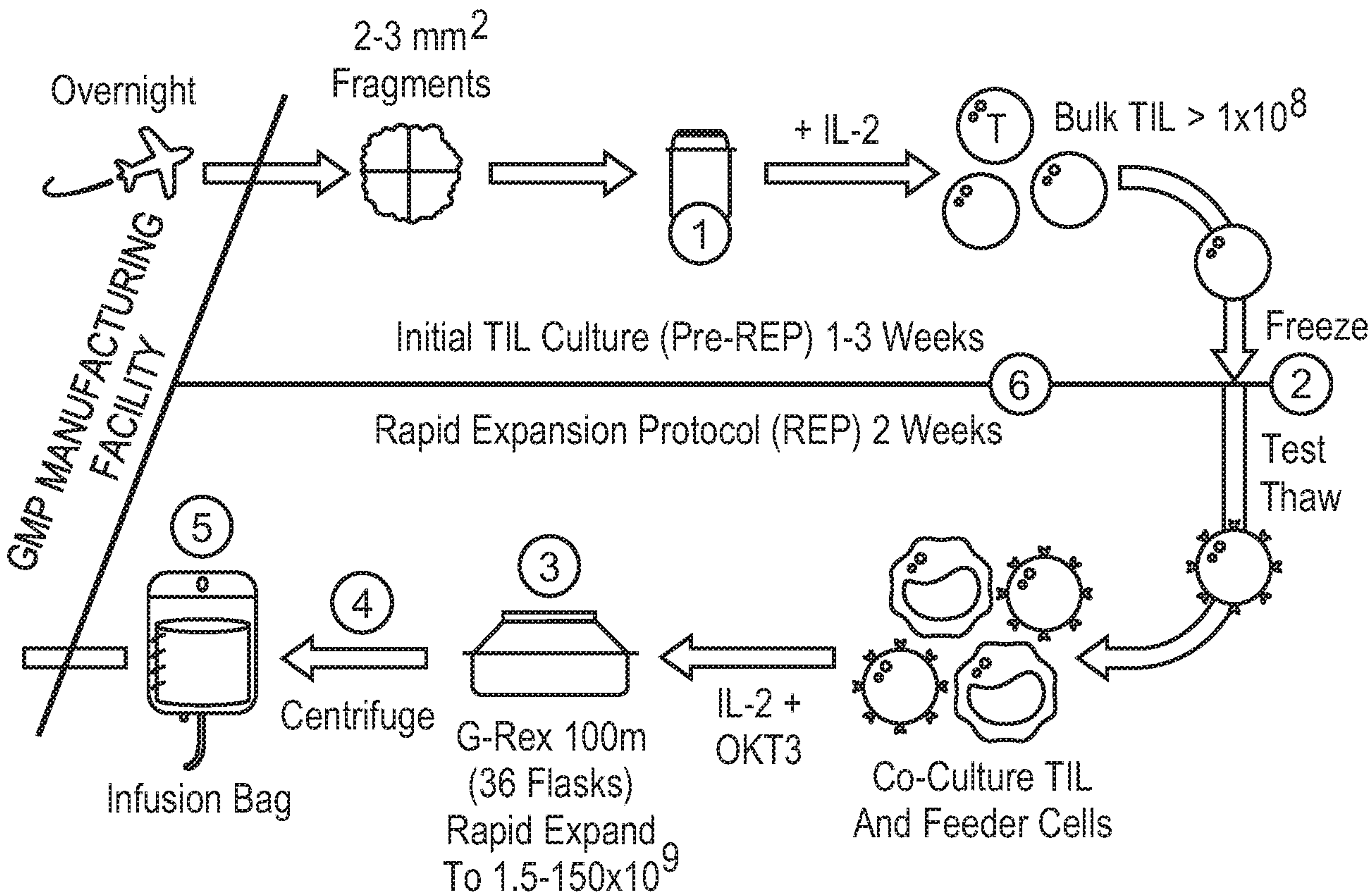


Figure 2

Timeline- Process 1C- Current process

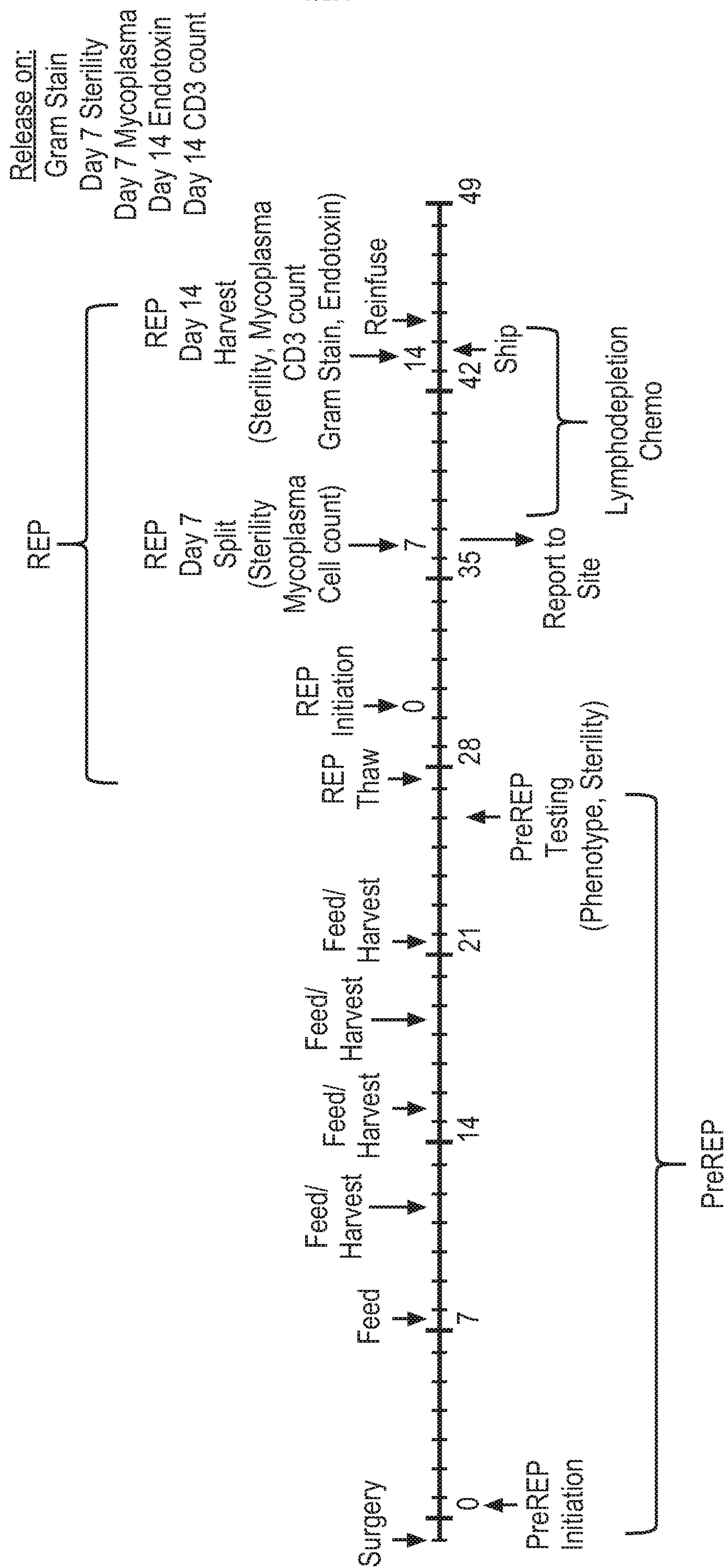


Figure 3

TIL Therapy Timeline- v2A- Day 16 REP >250e6

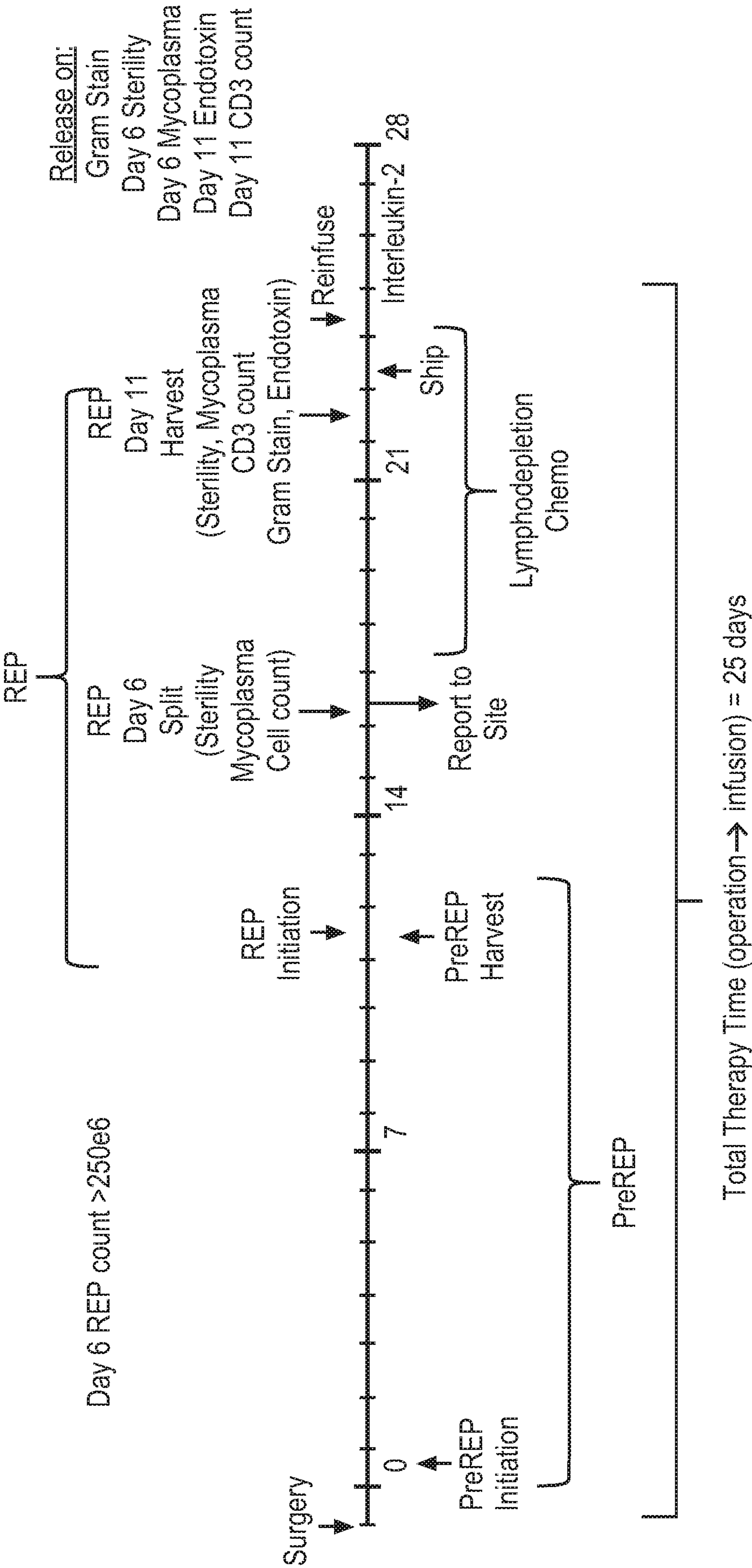


Figure 4

TIL Therapy Timeline- v2A- Day 16 REP >250e6

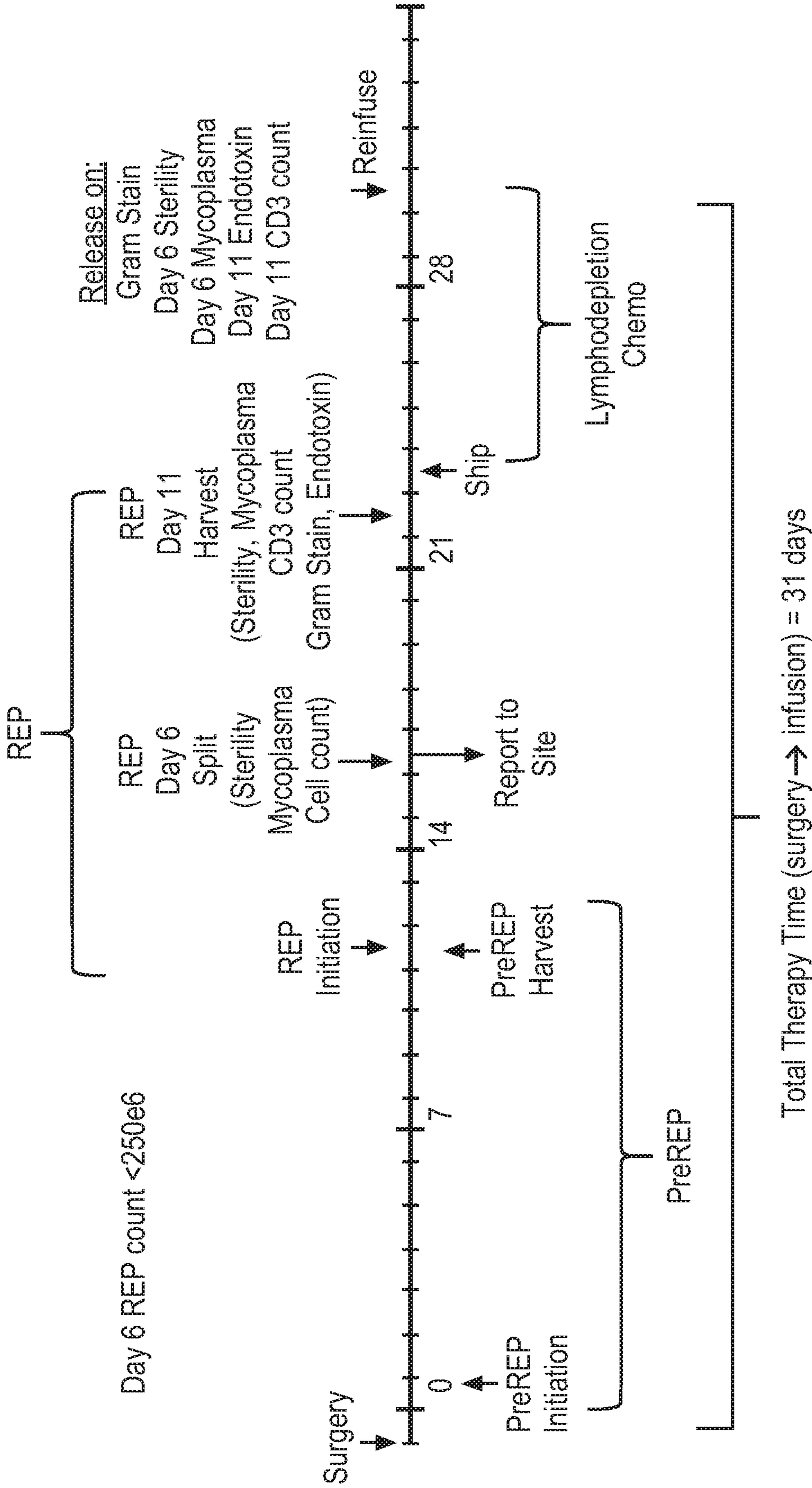


Figure 5

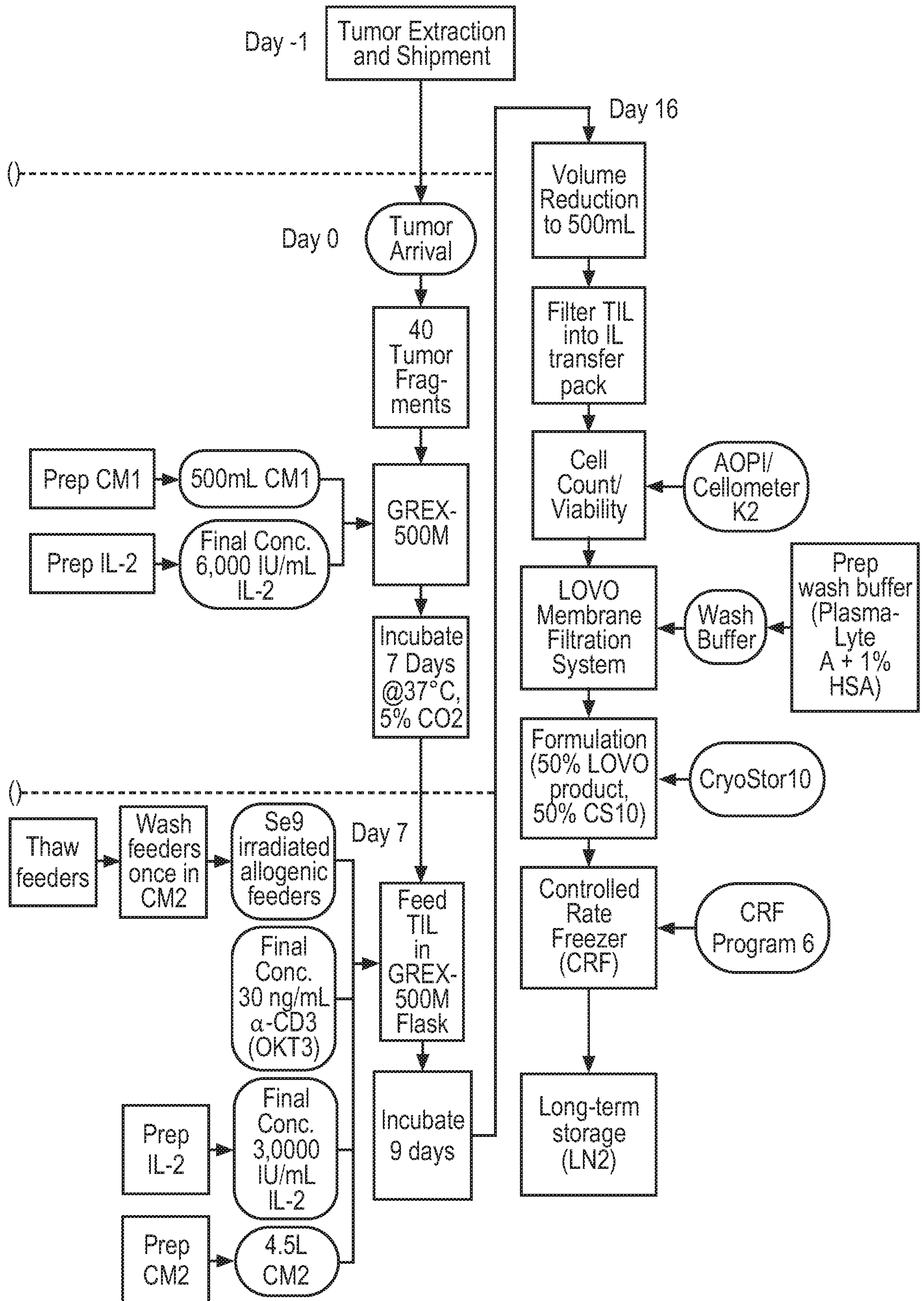
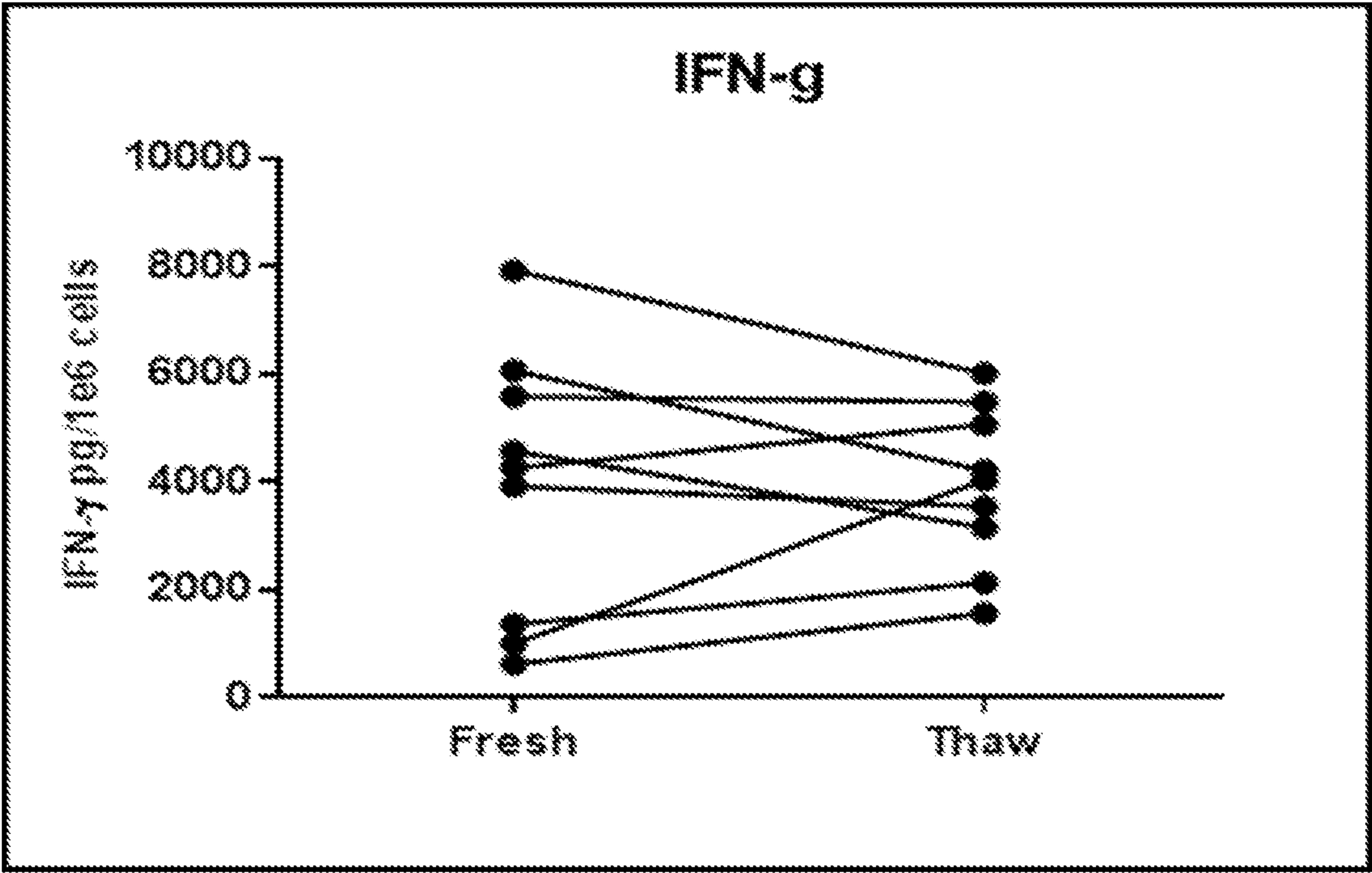


Figure 6

Figure 7

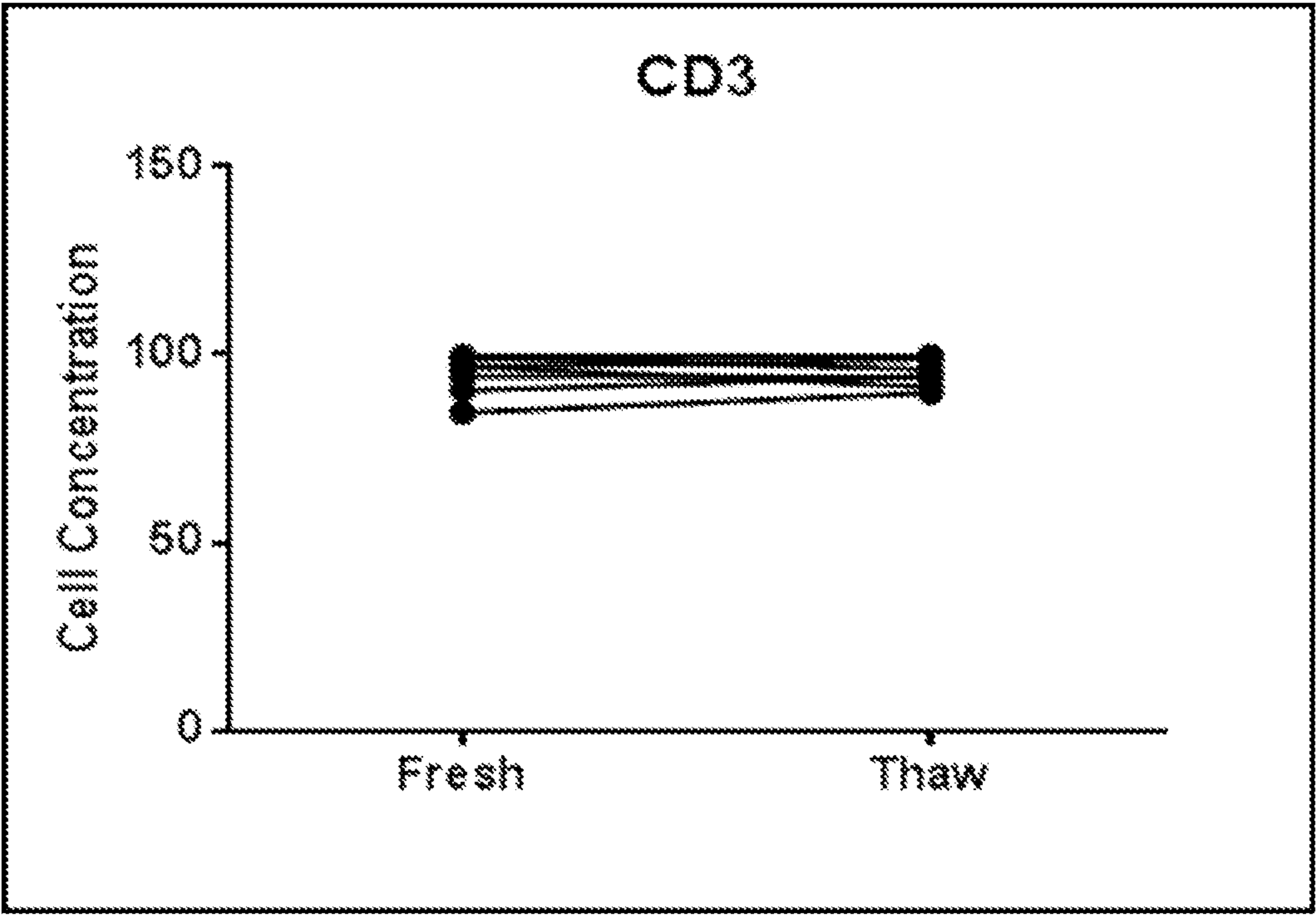
P value	0.9797
P value summary	ns
Significantly different? (P < 0.05)	No
One- or two-tailed P value?	Two-tailed
t, df	t=0.02626 df=8
Number of pairs	9



How effective was the pairing?
Correlation coefficient (r)
P value (one tailed)
P value summary
Was the pairing significantly effective?

Figure 8

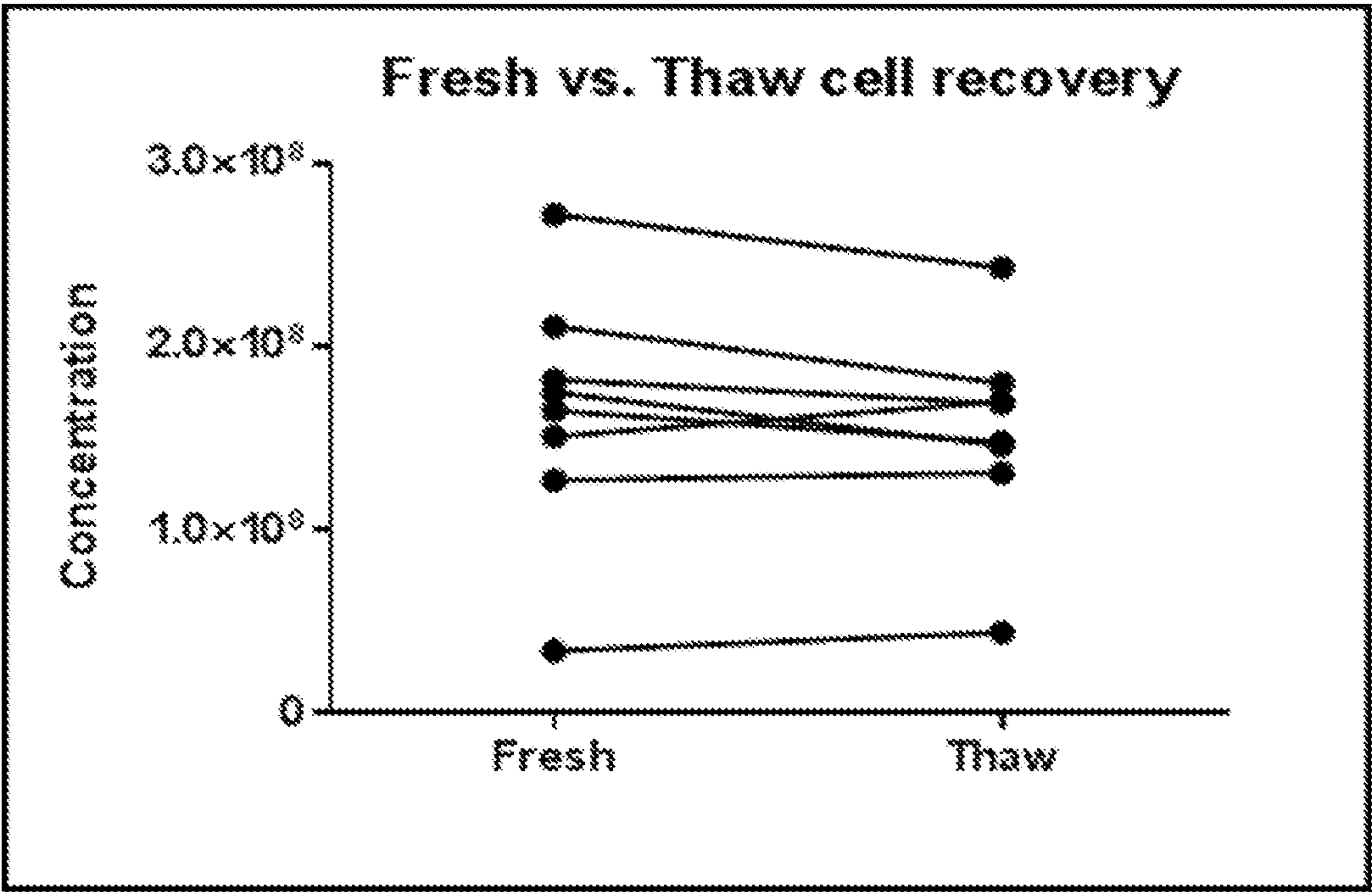
P value summary	ns
Significantly different? (P < 0.05)	No
One- or two-tailed P value?	Two-tailed
t, df	t=0.8479 df=7
Number of pairs	8



How effective was the pairing?	0.9711
Correlation coefficient (r)	< 0.0001
P value (one tailed)	****
P value summary	Yes
Was the pairing significantly effective?	

Figure 9

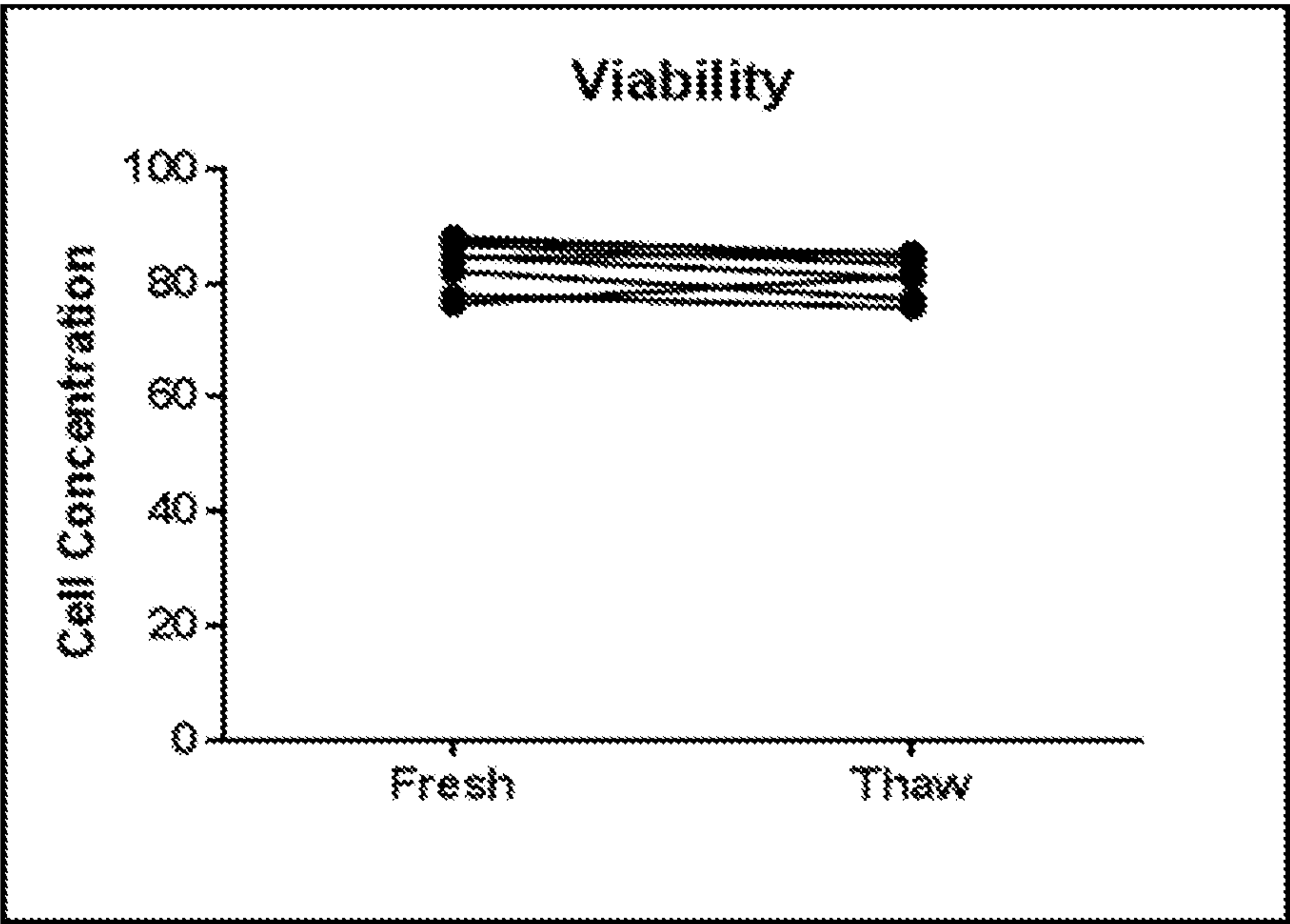
P value summary	ns
Significantly different? (P < 0.05)	No
One- or two-tailed P value?	Two-tailed
t, df	t=1.568 df=7
Number of pairs	8



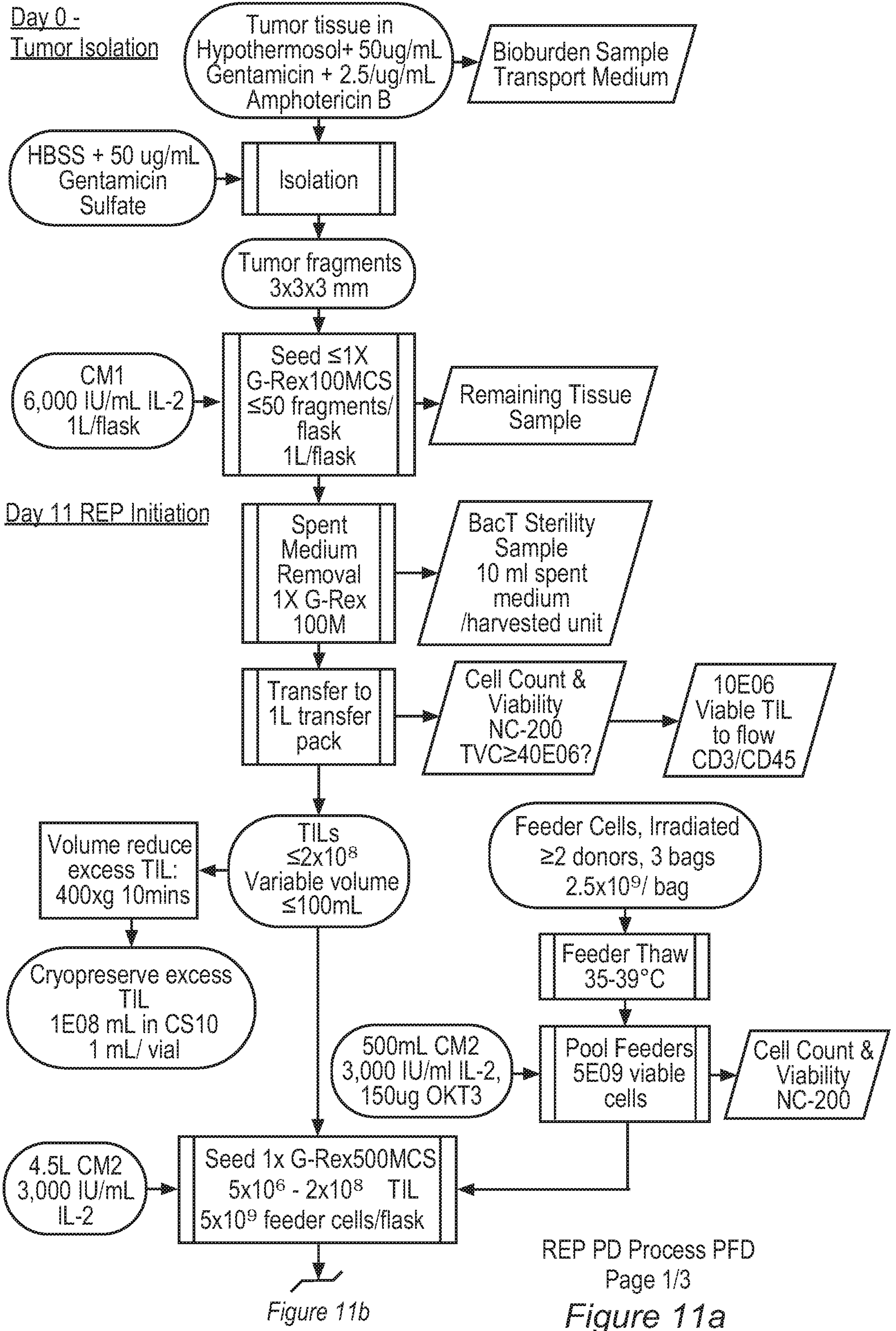
How effective was the pairing?	
Correlation coefficient (r)	0.7448
P value (one tailed)	0.017
P value summary	*
Was the pairing significantly effective?	Yes

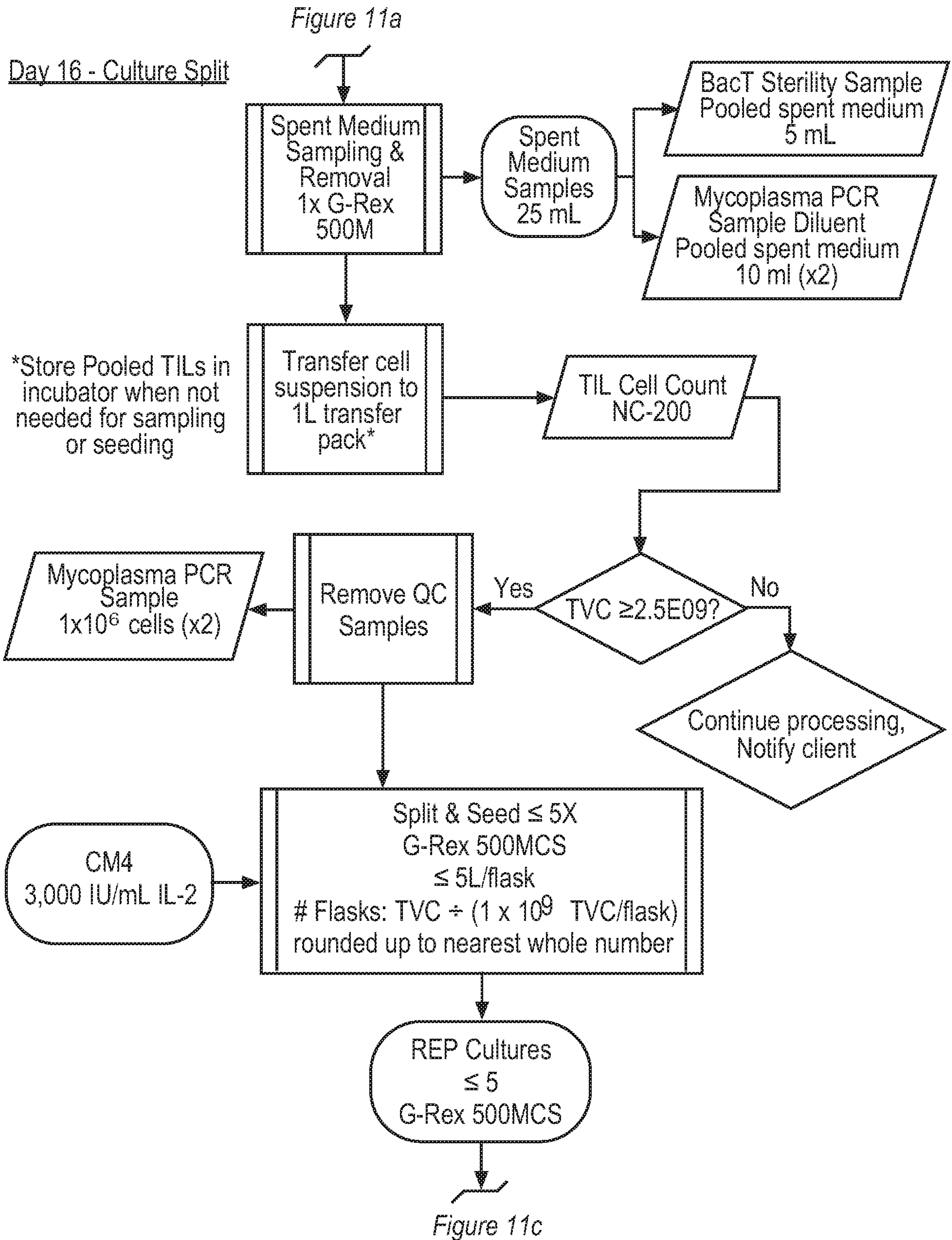
Figure 10

P value summary	ns
Significantly different? (P < 0.05)	No
One- or two-tailed P value?	Two-tailed
t, df	t=1.596 df=7
Number of pairs	8



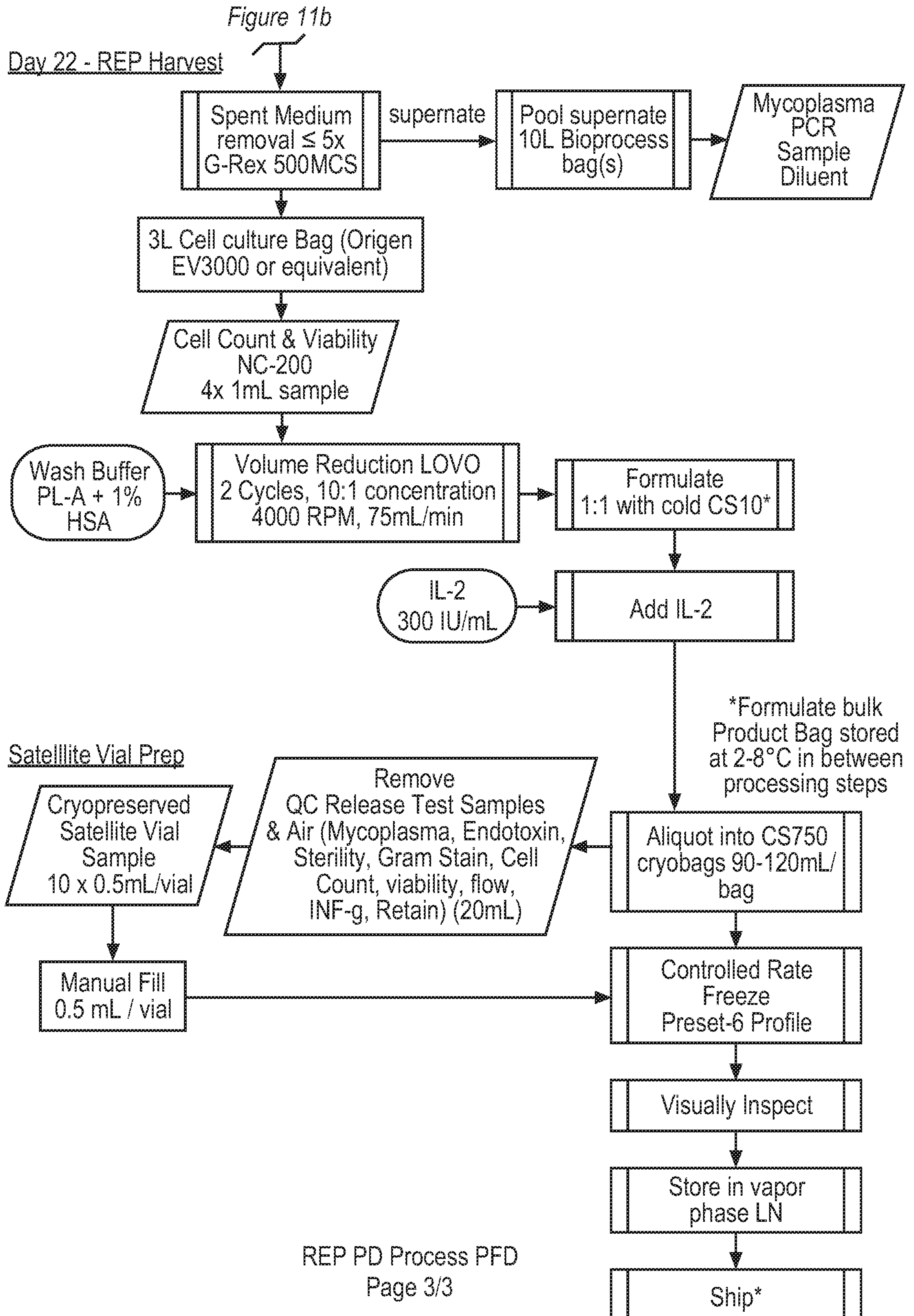
How effective was the pairing?	
Correlation coefficient (r)	0.6932
P value (one tailed)	0.0283
P value summary	*
Was the pairing significantly effective?	Yes





REP PD Process PFD
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Figure 11b



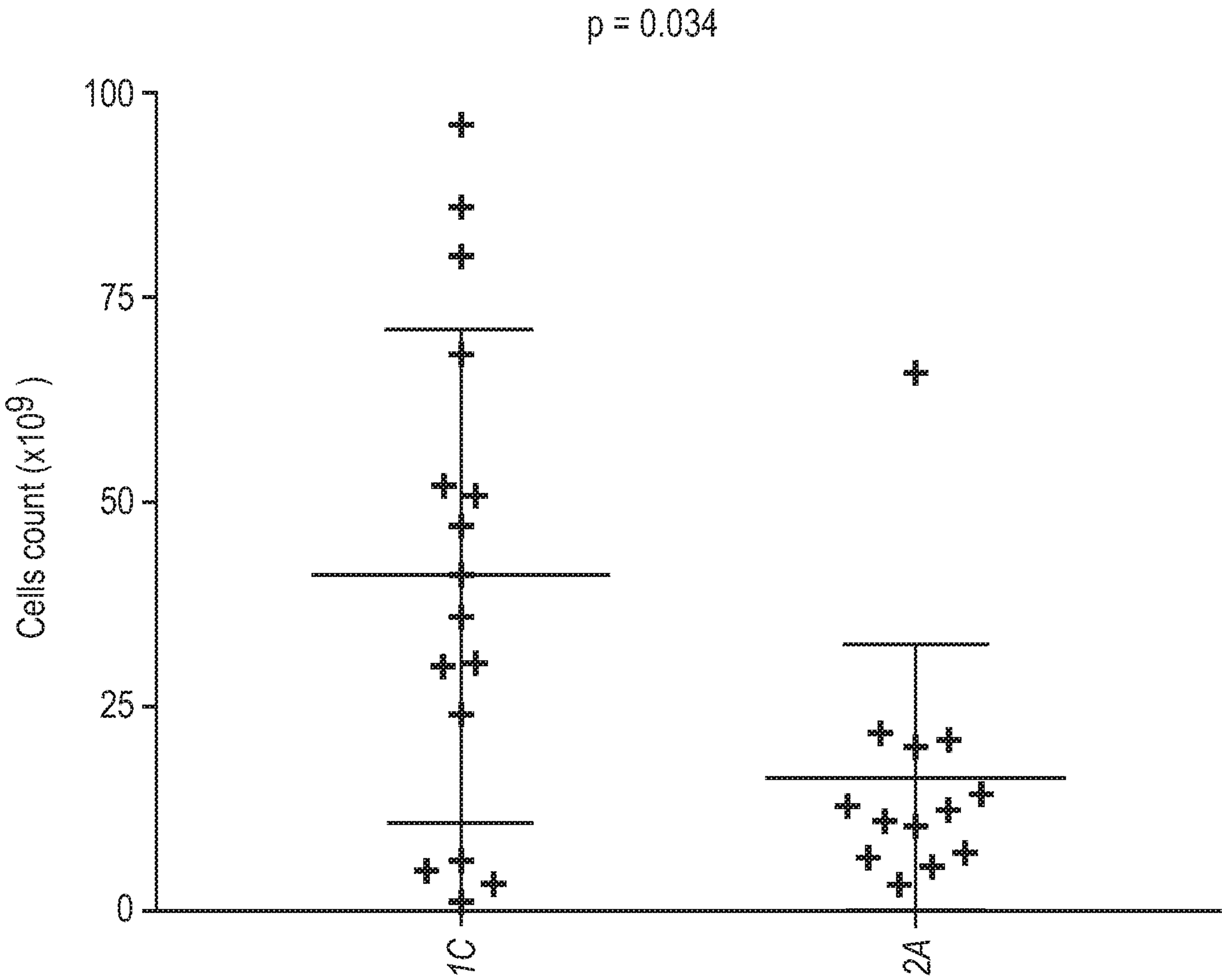


Figure 12

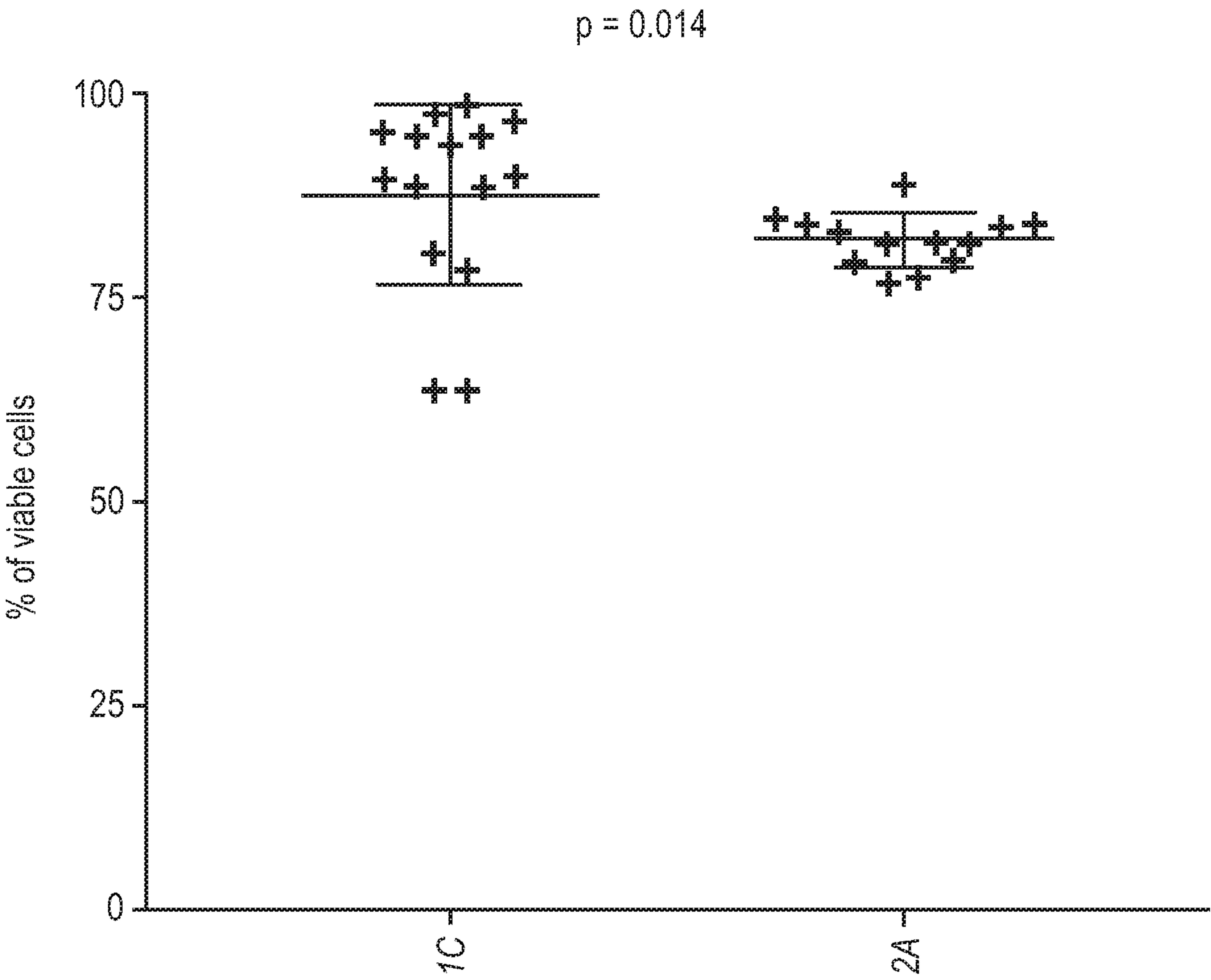


Figure 13

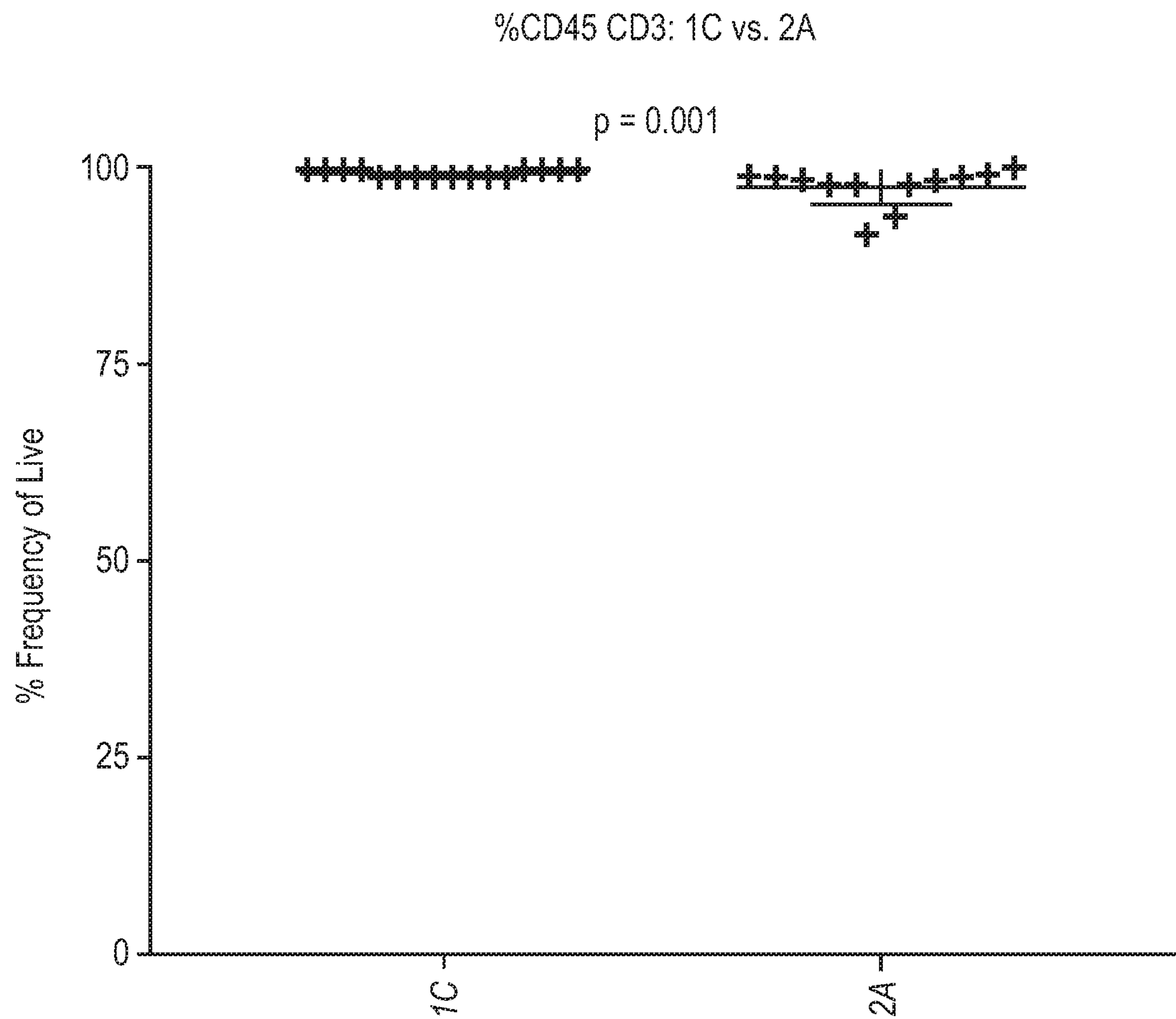


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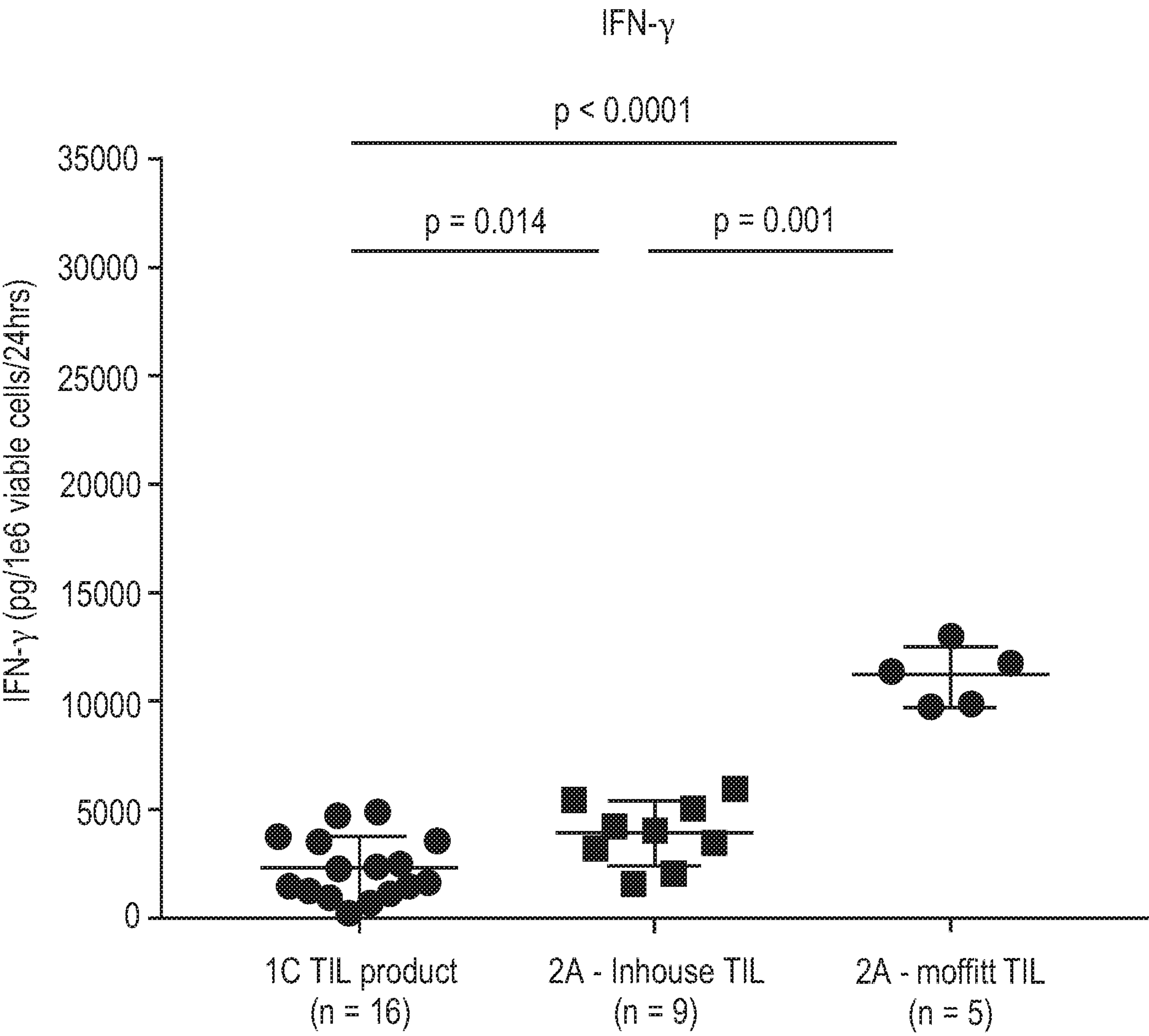


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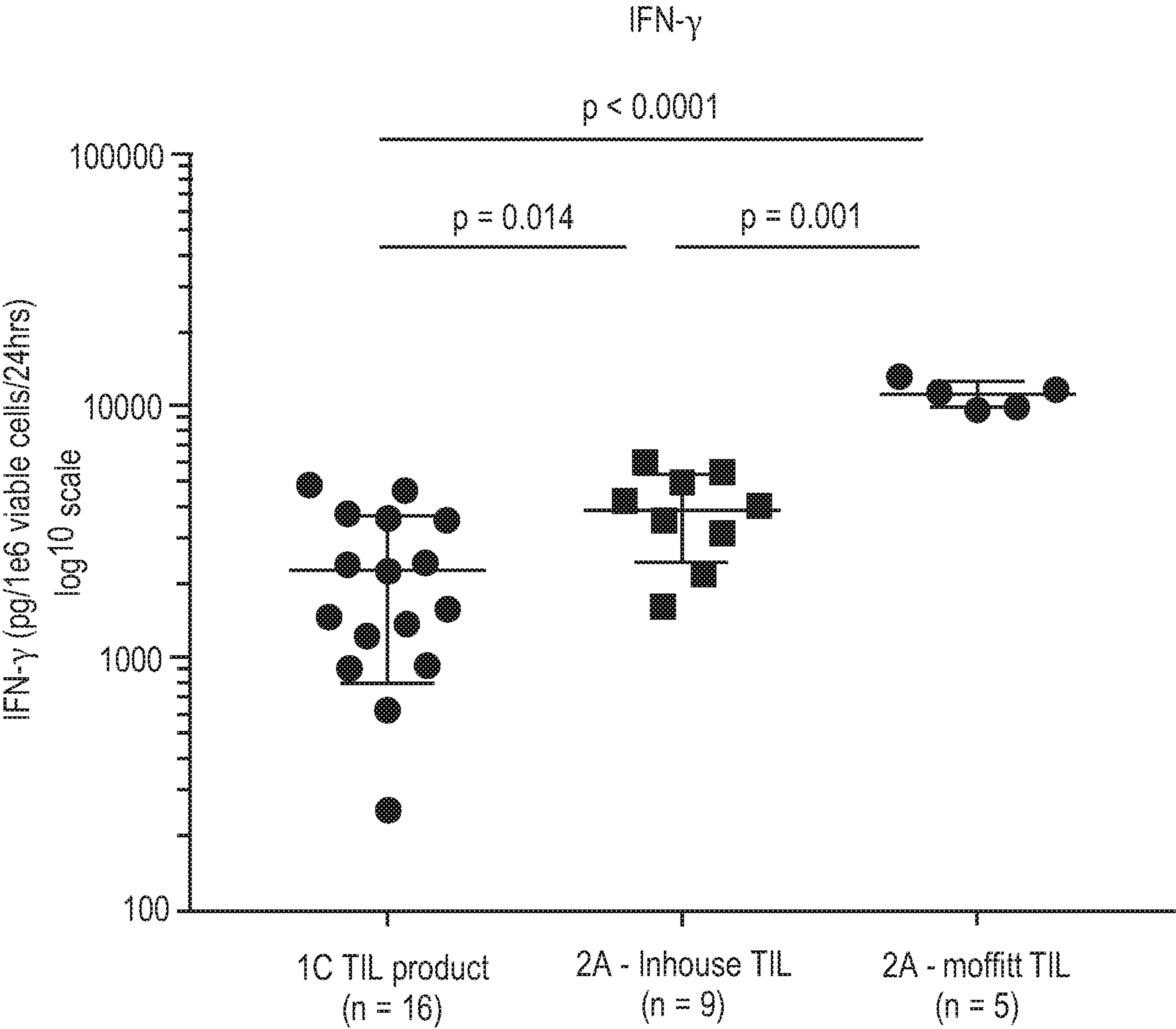


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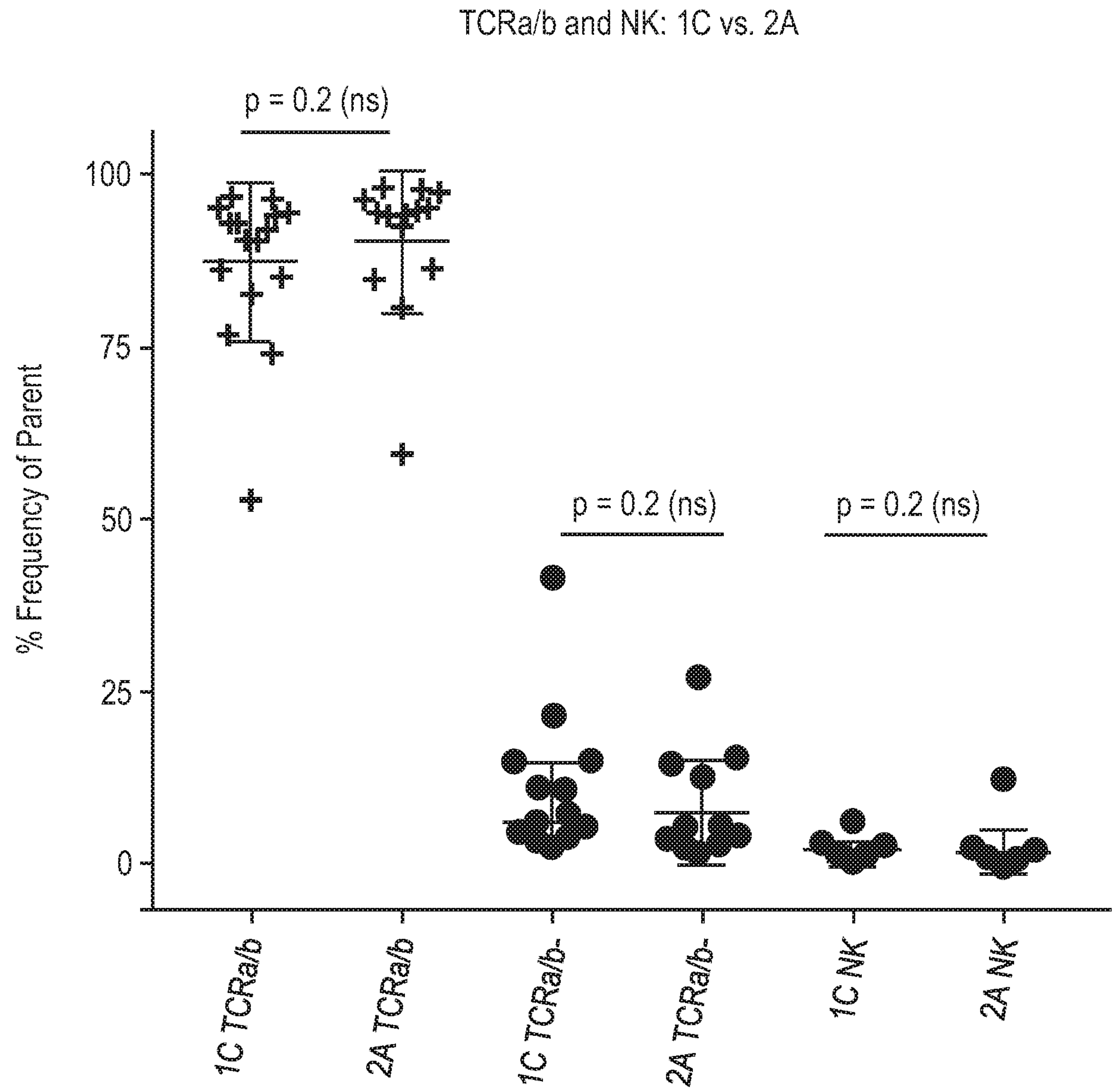


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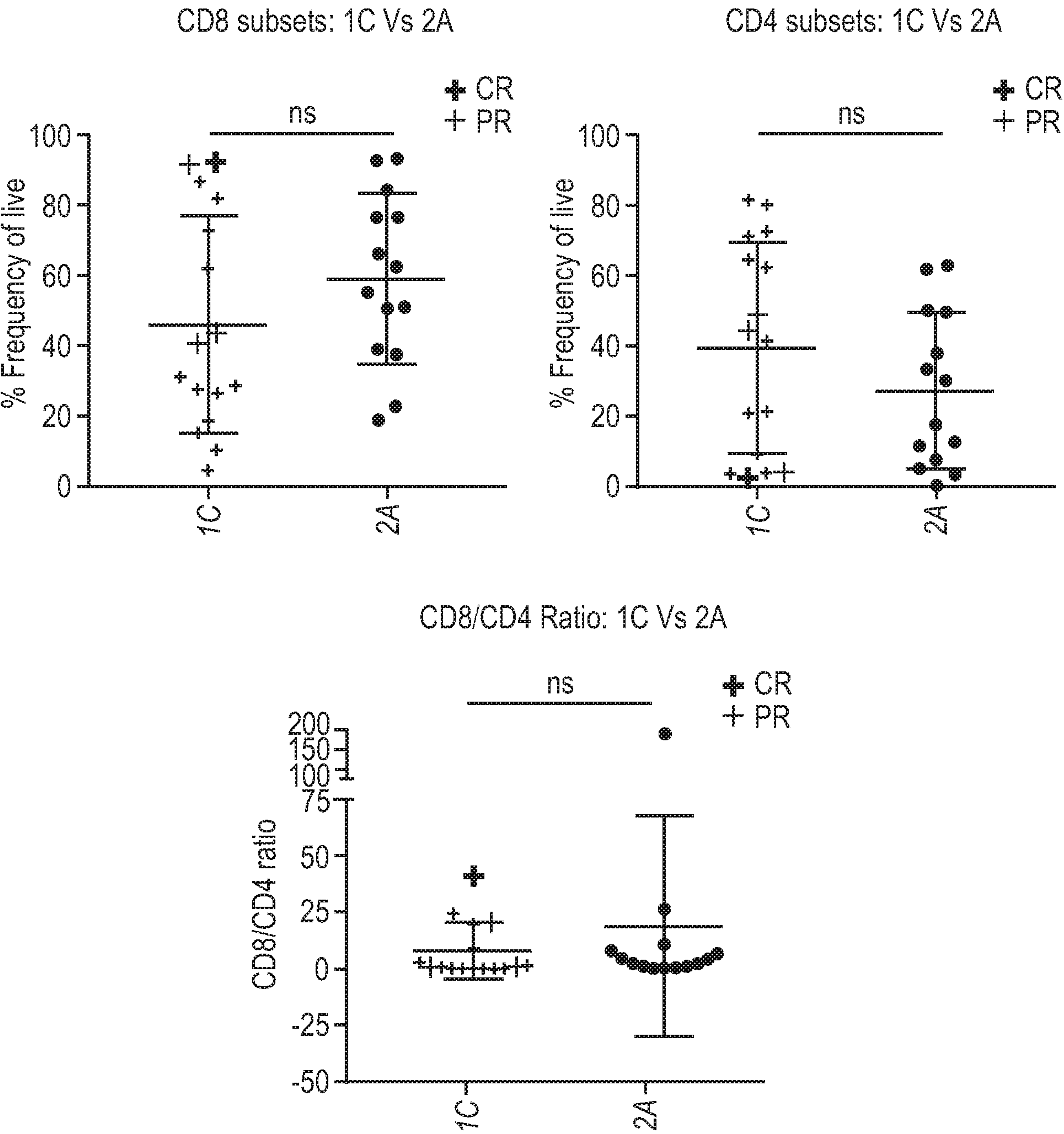


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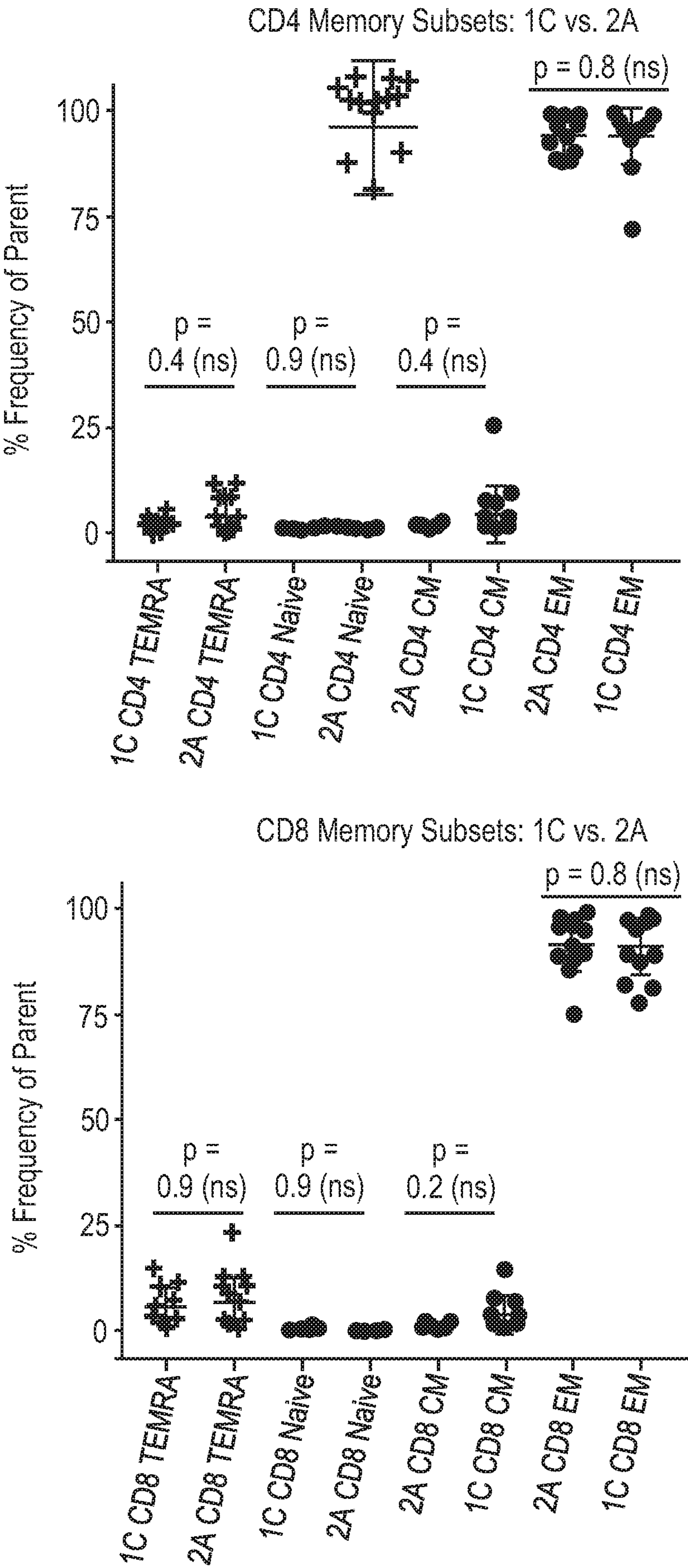


Figure 19

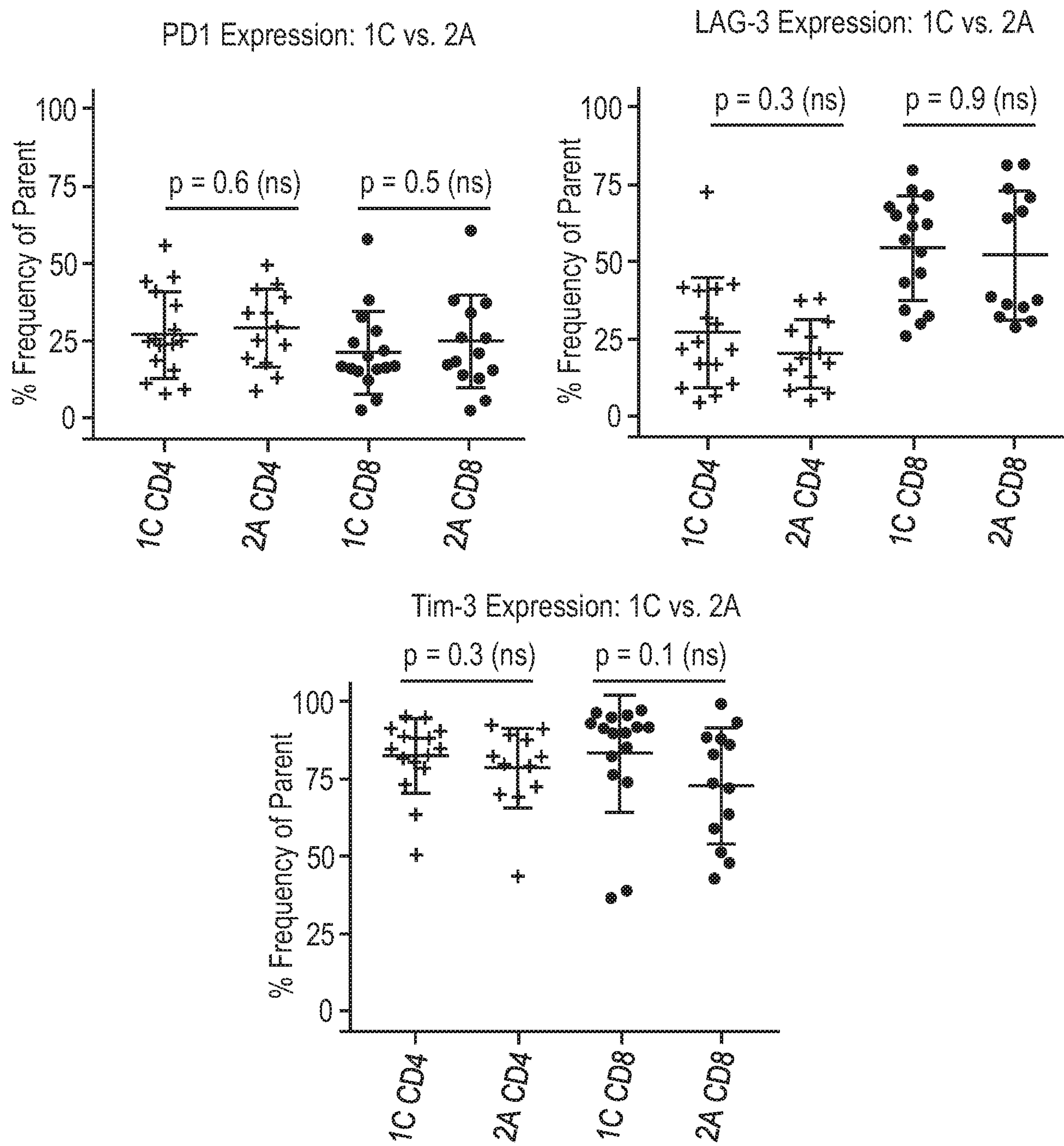


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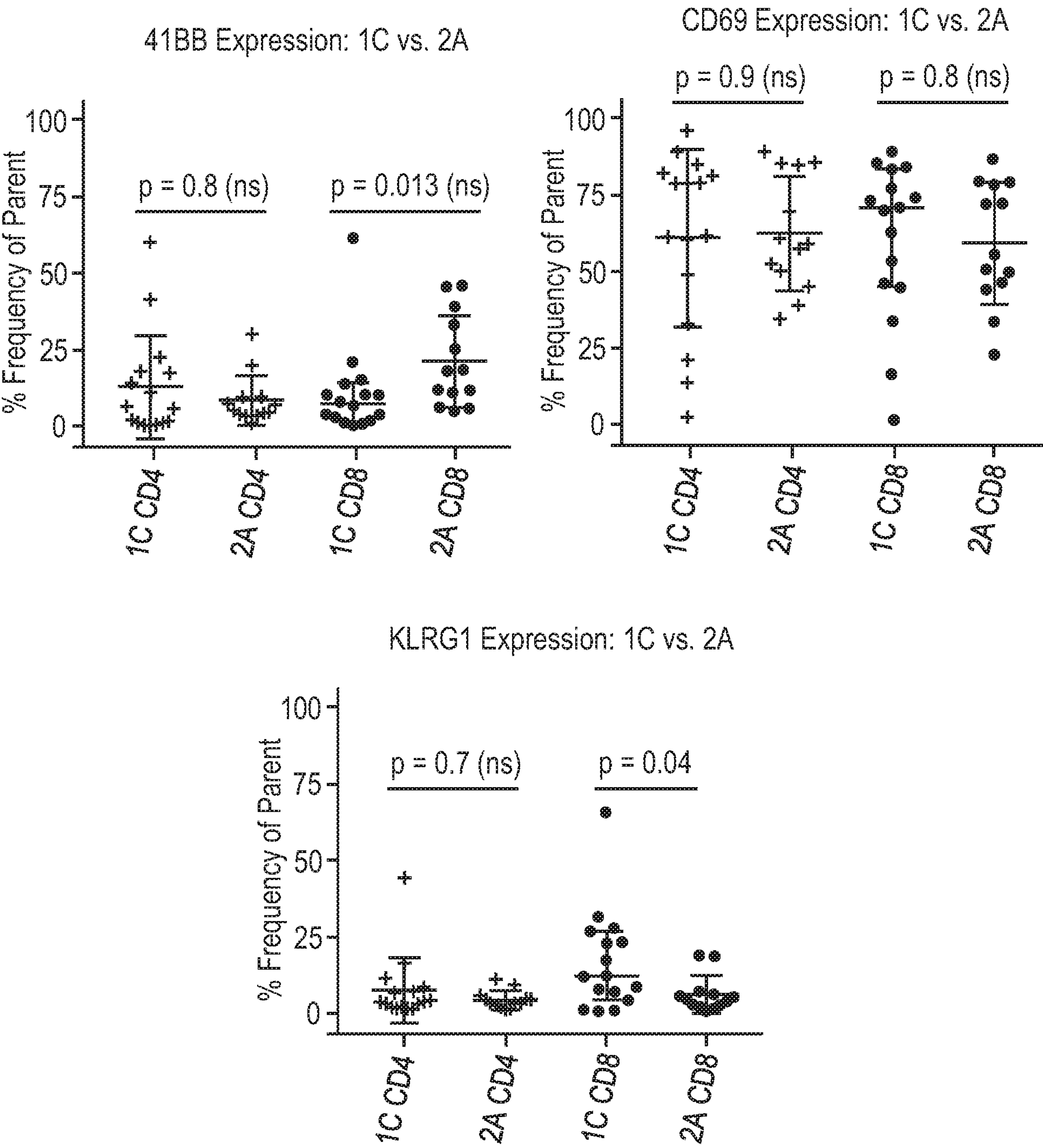


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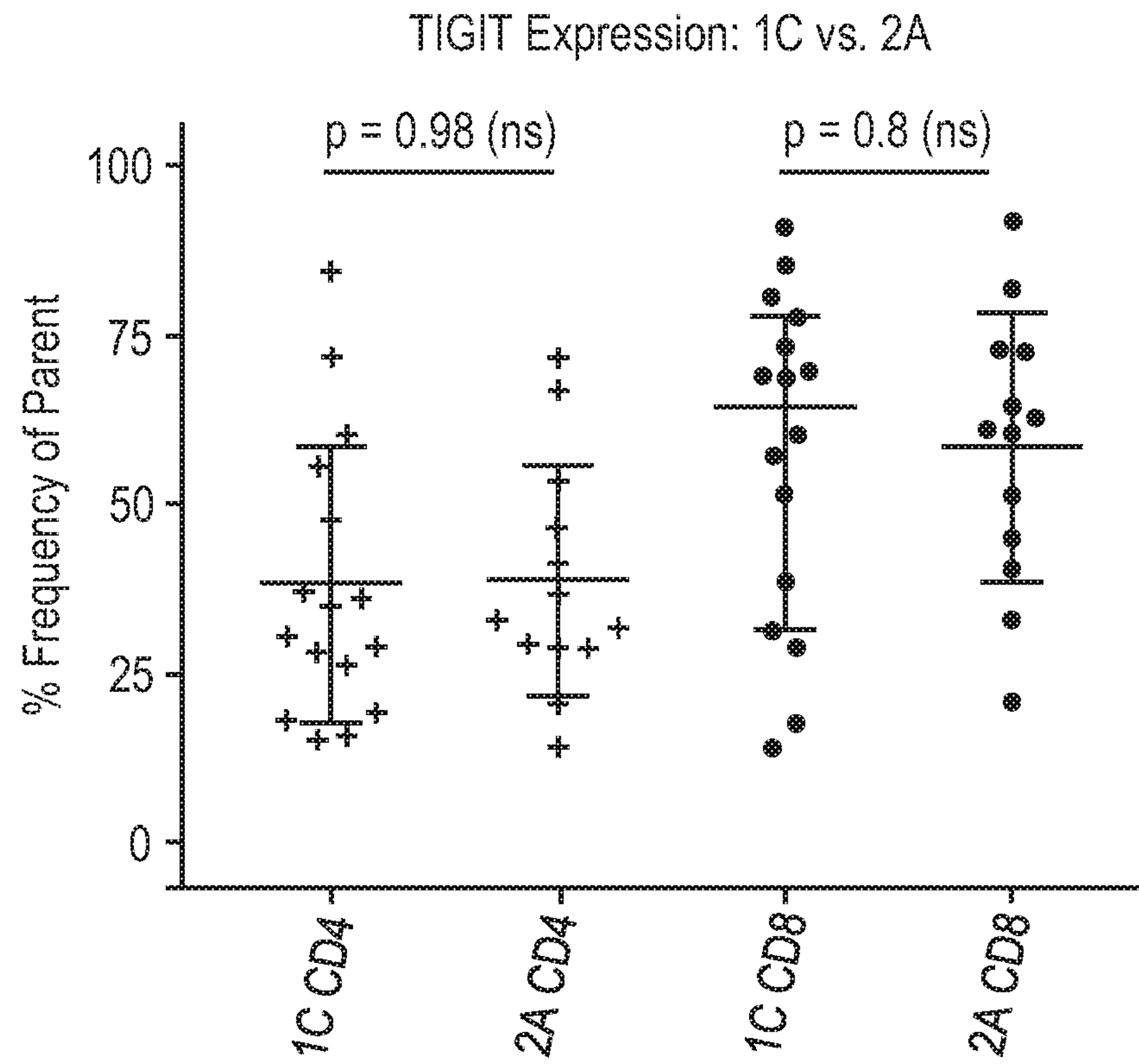


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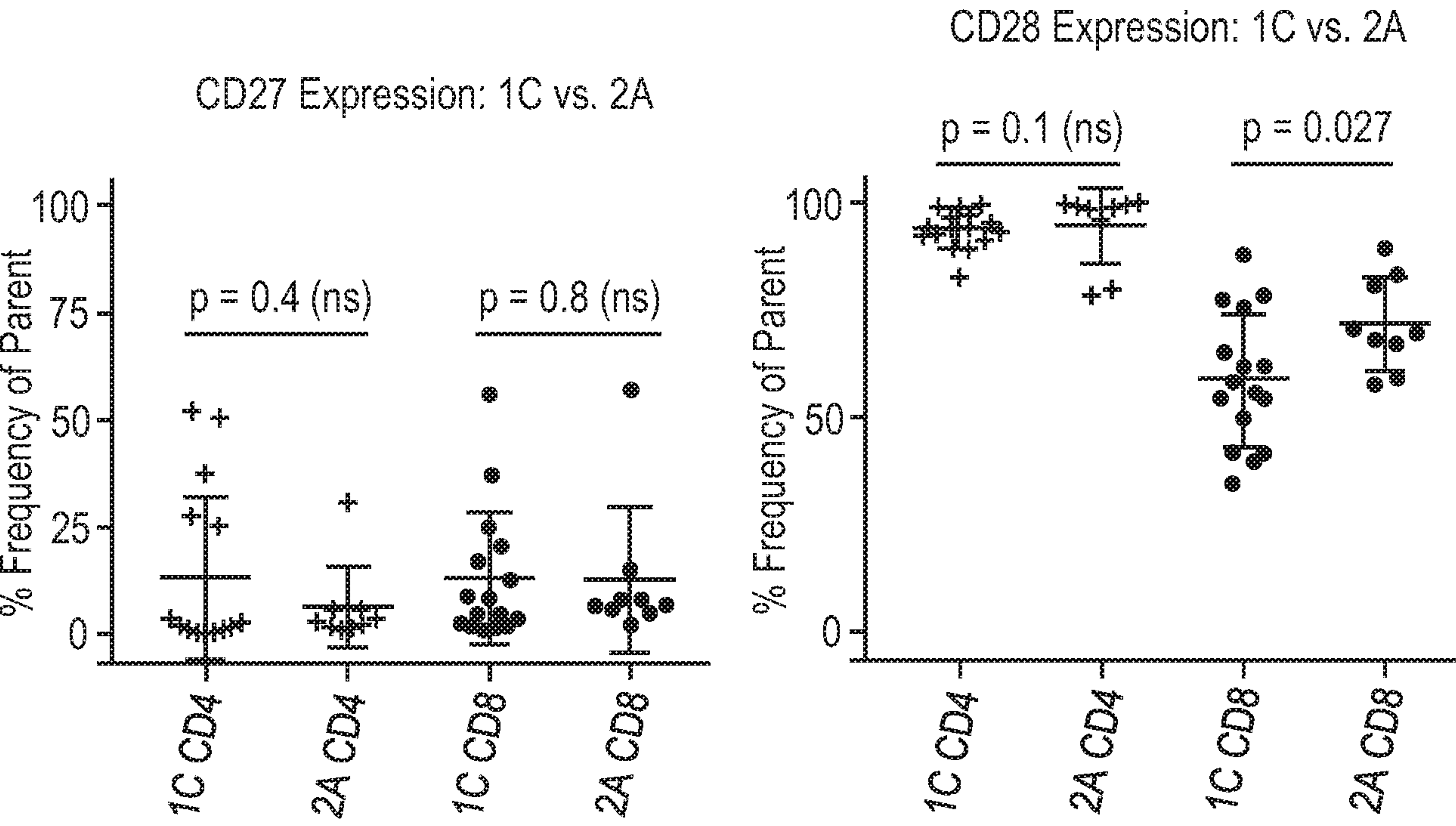


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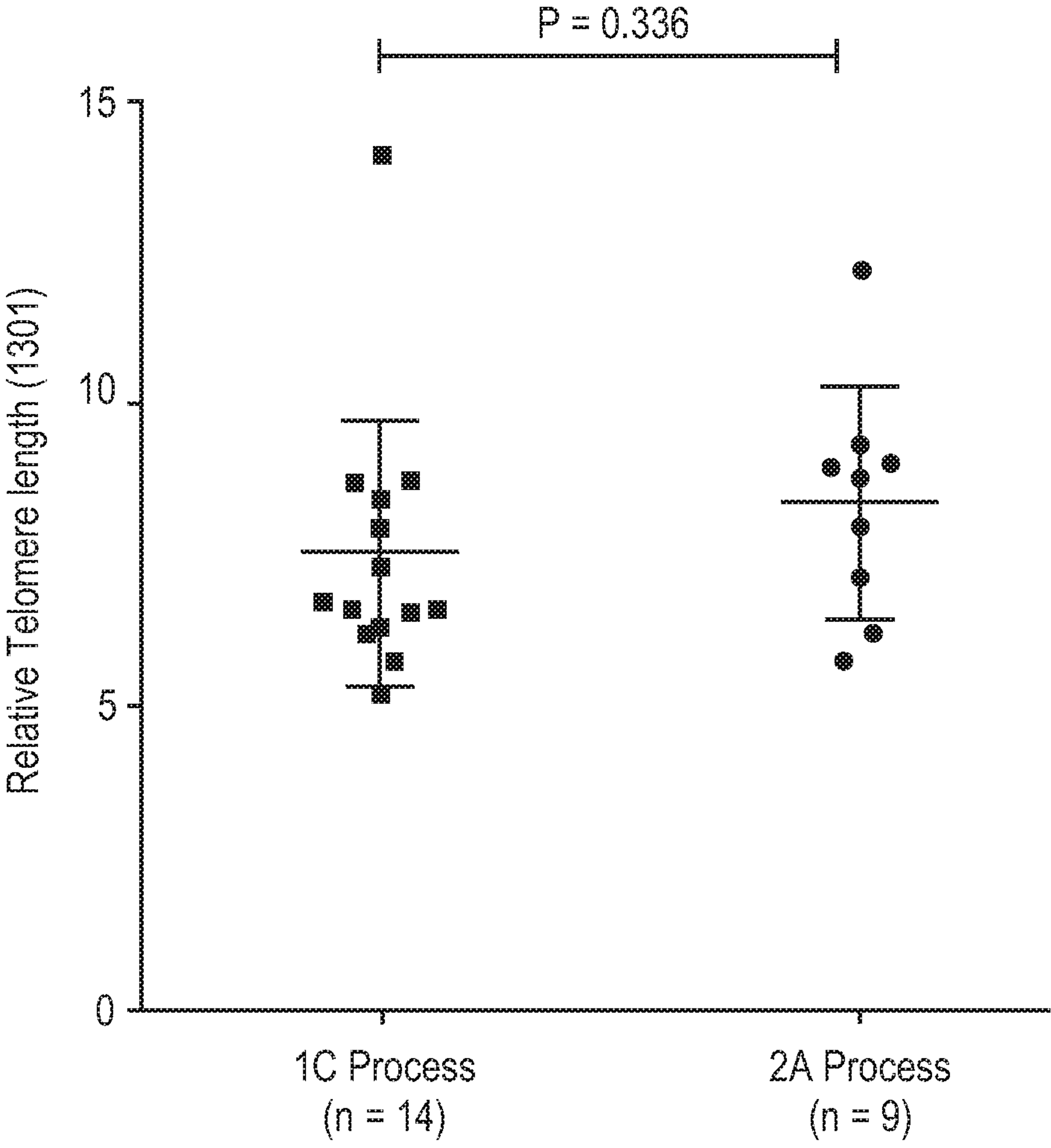


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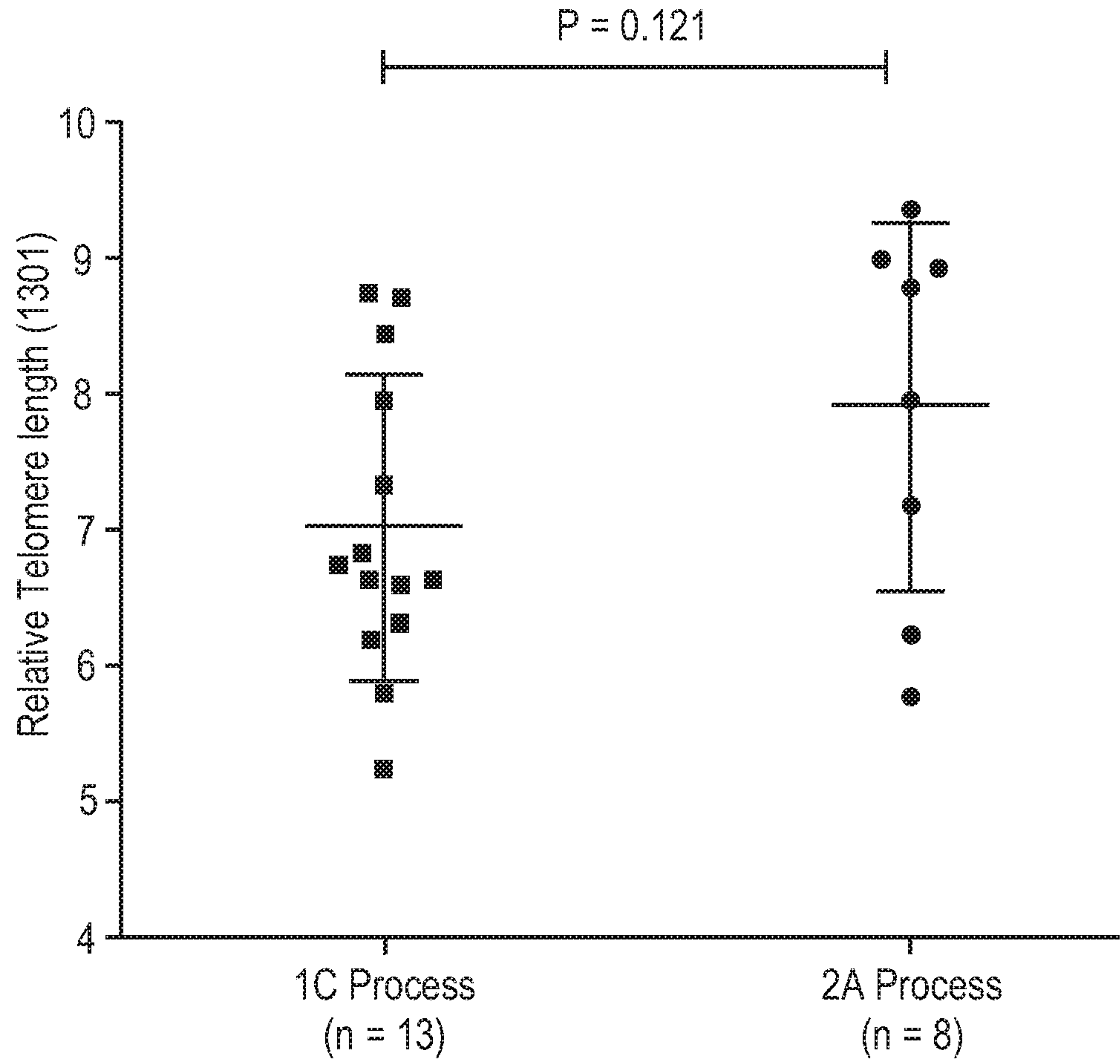


Figure 25

Figure 26

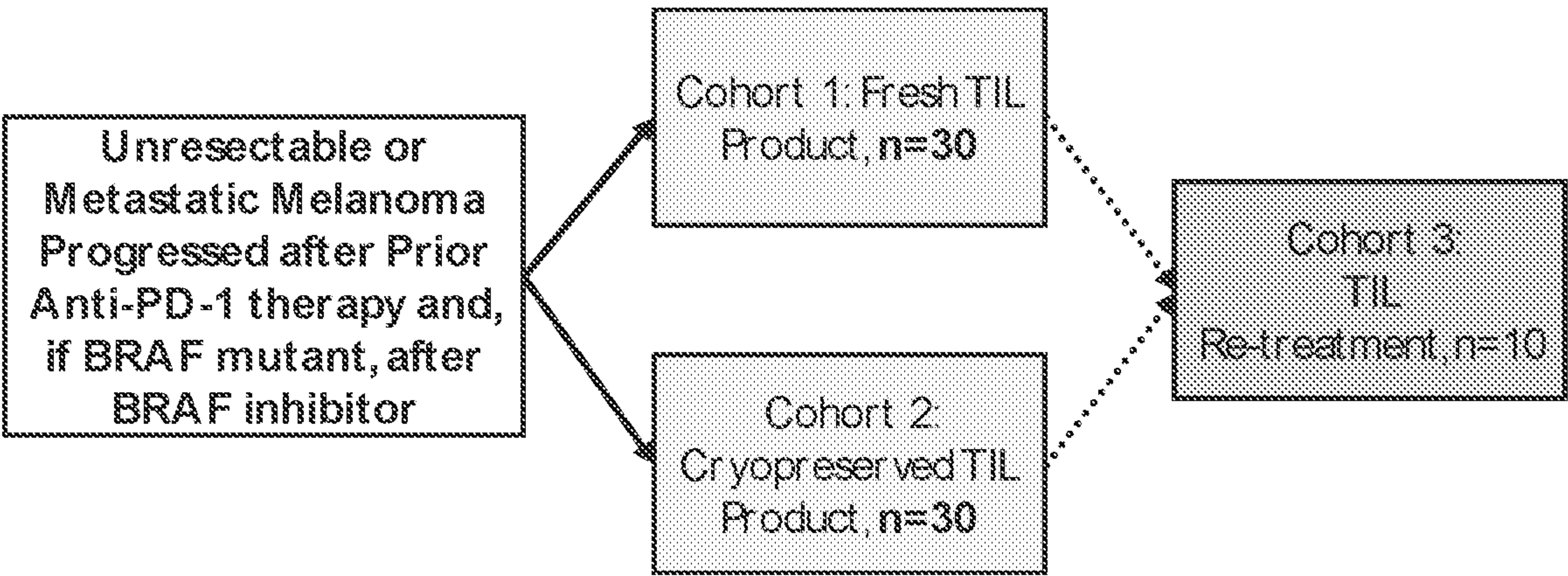


Figure 27

Process 2A: about 22 days from Steps A - E

1. STEP A

Obtain Patient Tumor Sample

2. STEP B

Fragmentation and First Expansion

3 days to 14 days

3. STEP C

First Expansion to Second Expansion Transition

No Storage and Closed System

4. STEP D

Second Expansion

IL-2, OKT-3, and antigen-presenting feeder cells

Closed System

5. STEP E

Harvest TILS from Step D

Closed System

6. STEP F

Final Formulation and/or Transfer to Infusion Bag

(optionally cryopreserve)

Day 0 -
Tumor Isolation

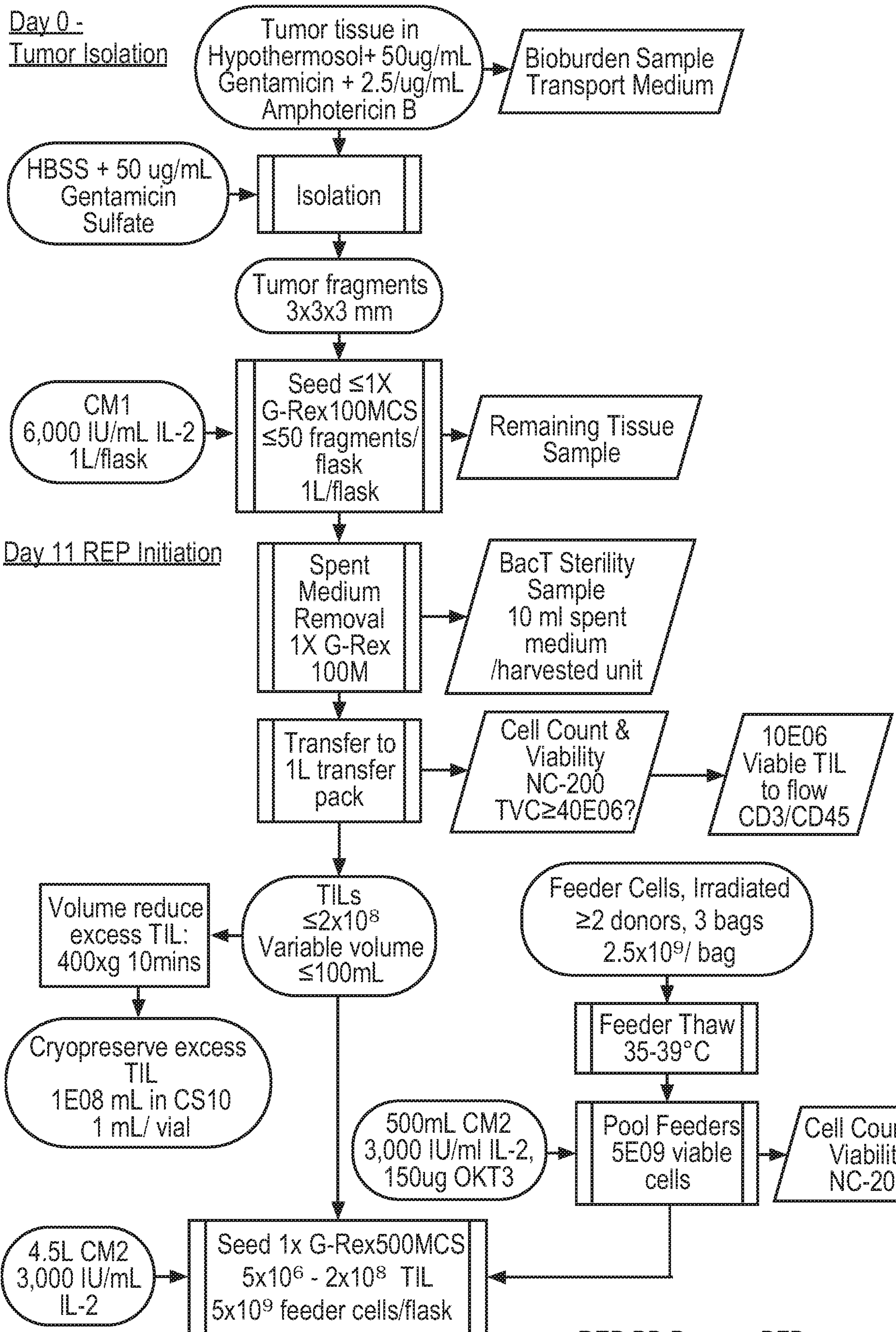
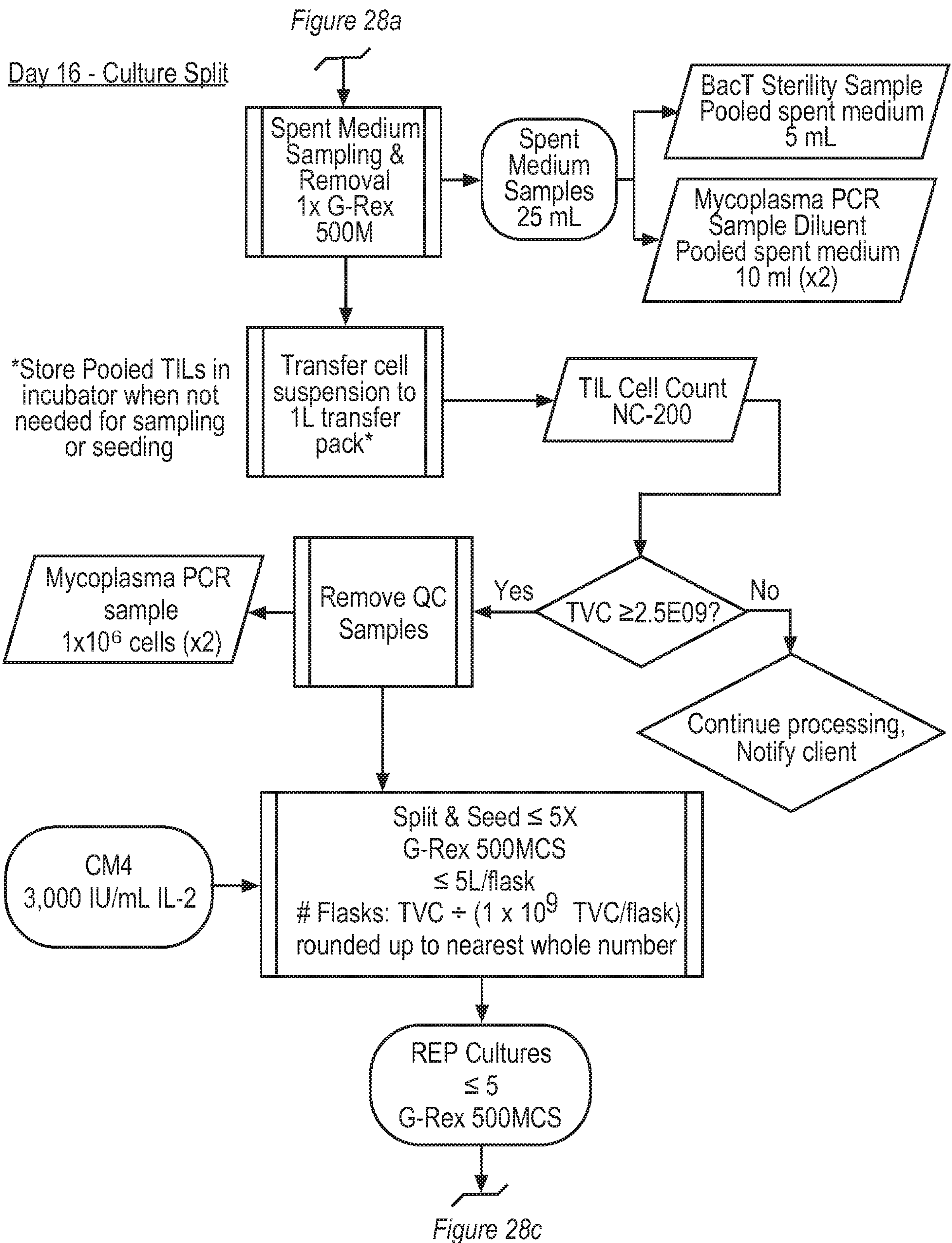
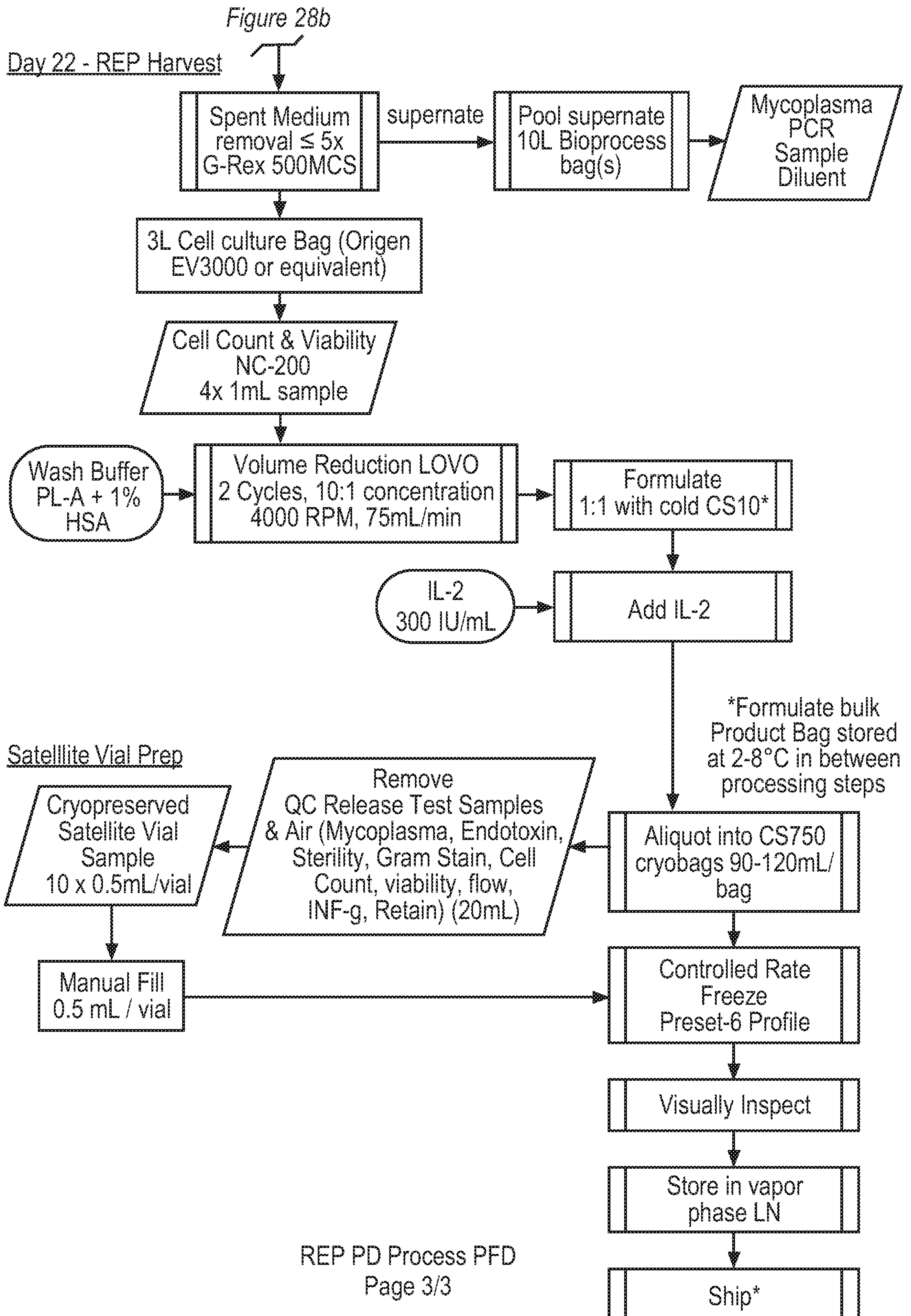


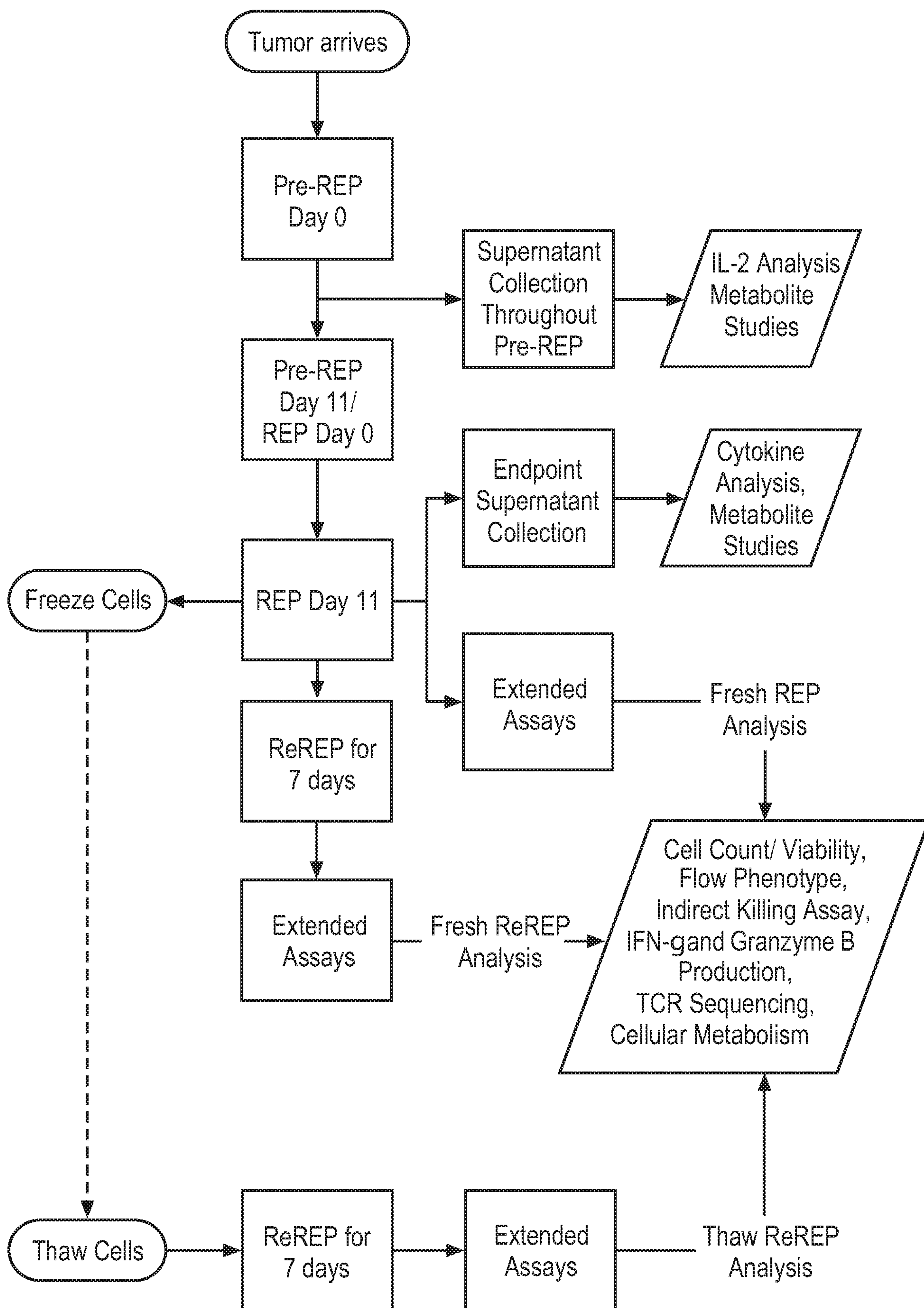
Figure 28b

REP PD Process PFD
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Figure 28a





*Figure 29*

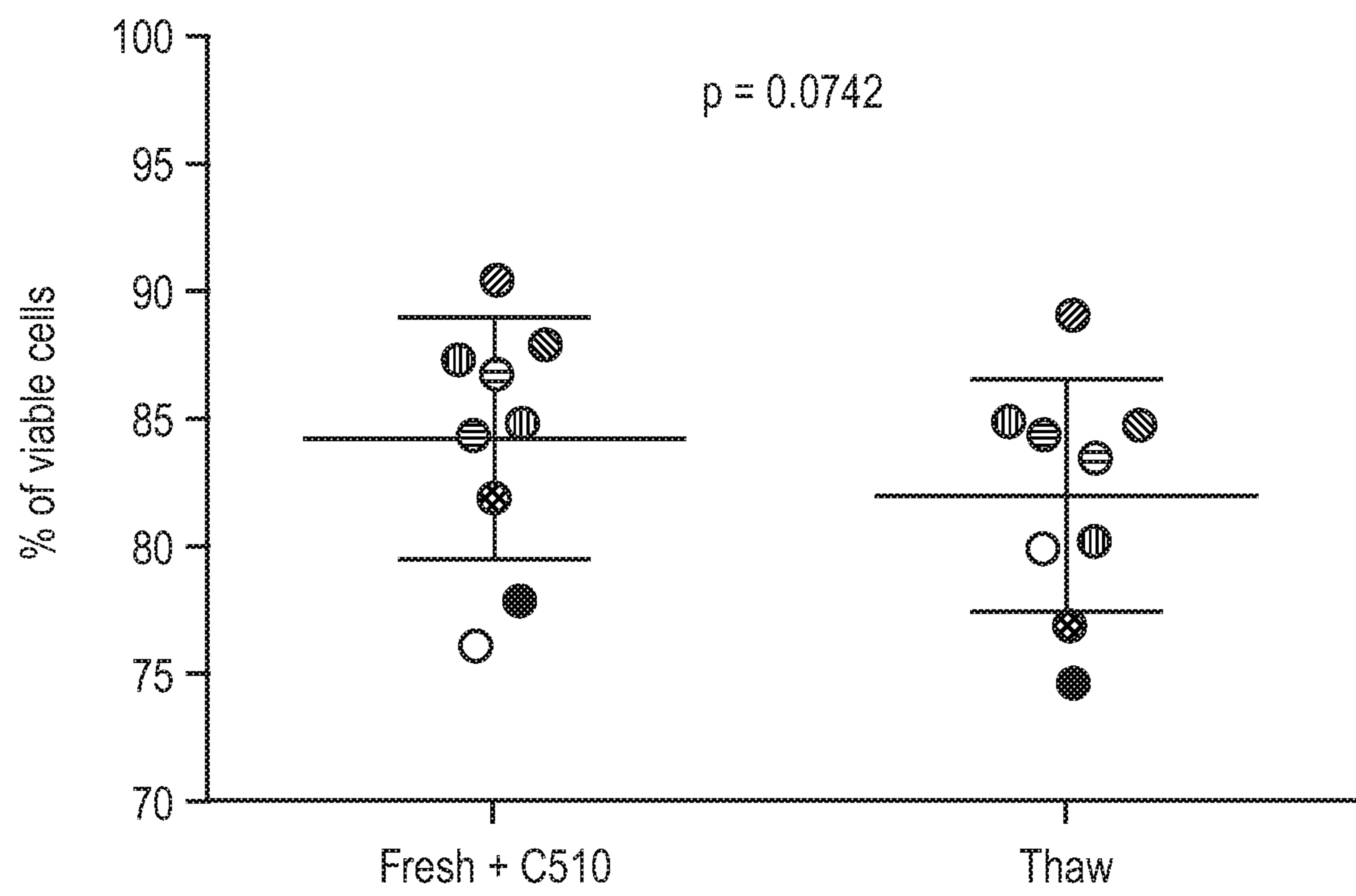


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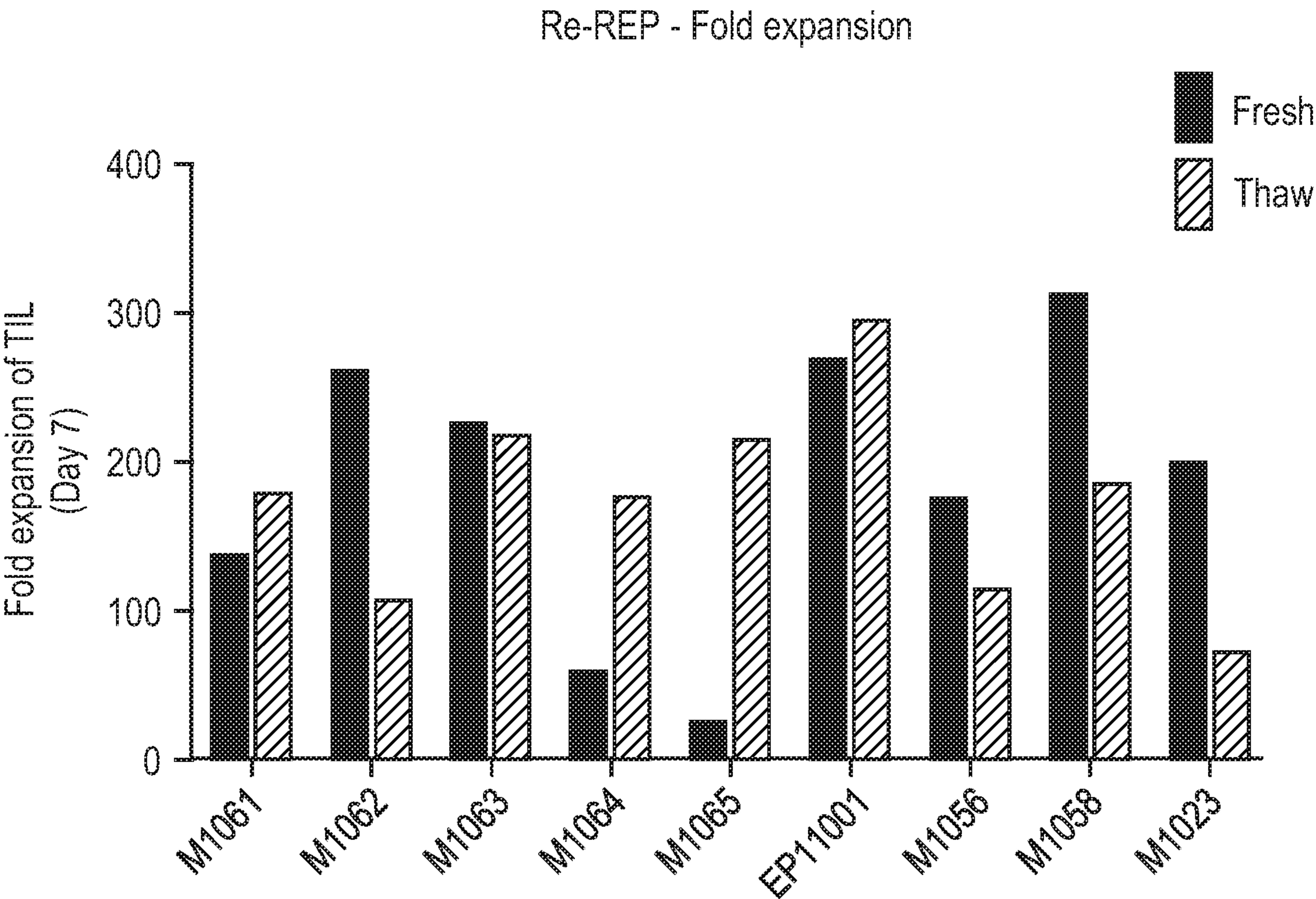


Figure 31

Normal Blood Values	
Glucose	0.7-1g/l
Glutamine	0.3-0.65mmol/l
Sodium	135-145mol/l
Potassium	3.5-5.0mmol/l
Lactic Acid	0.060-.16g/l
Ammonia	.023-.047mmol/l

Figure 32

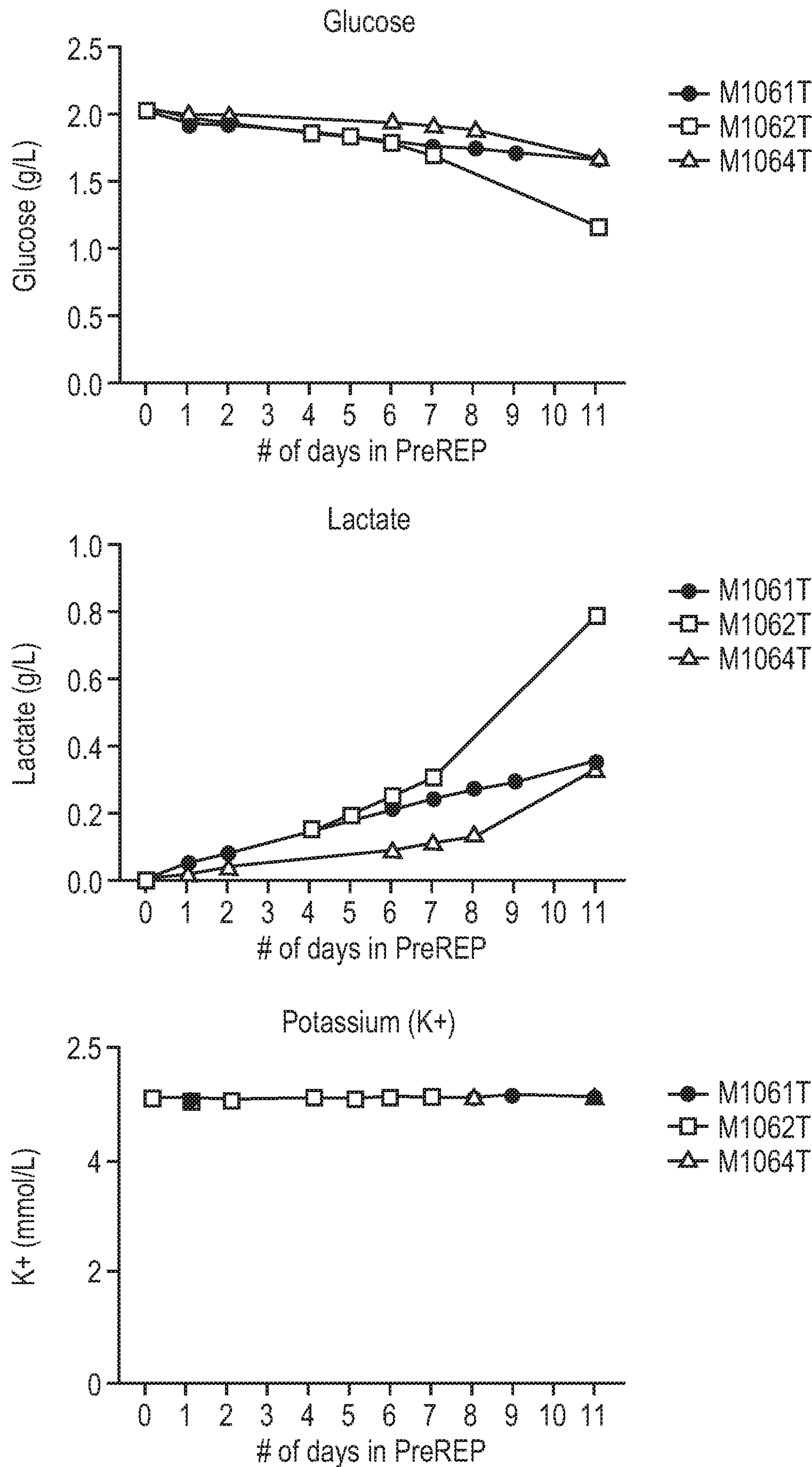


Figure 33a

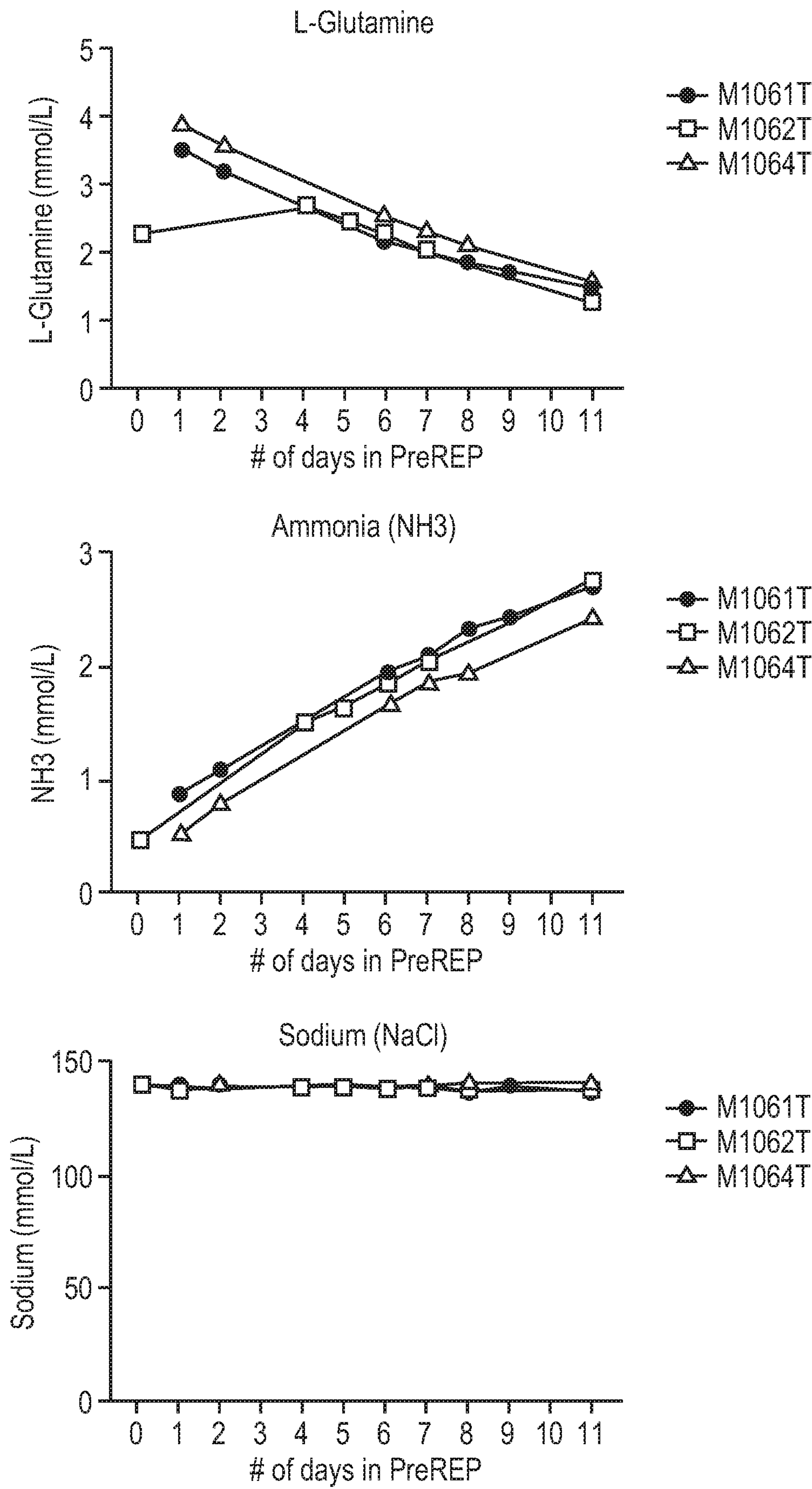


Figure 33b

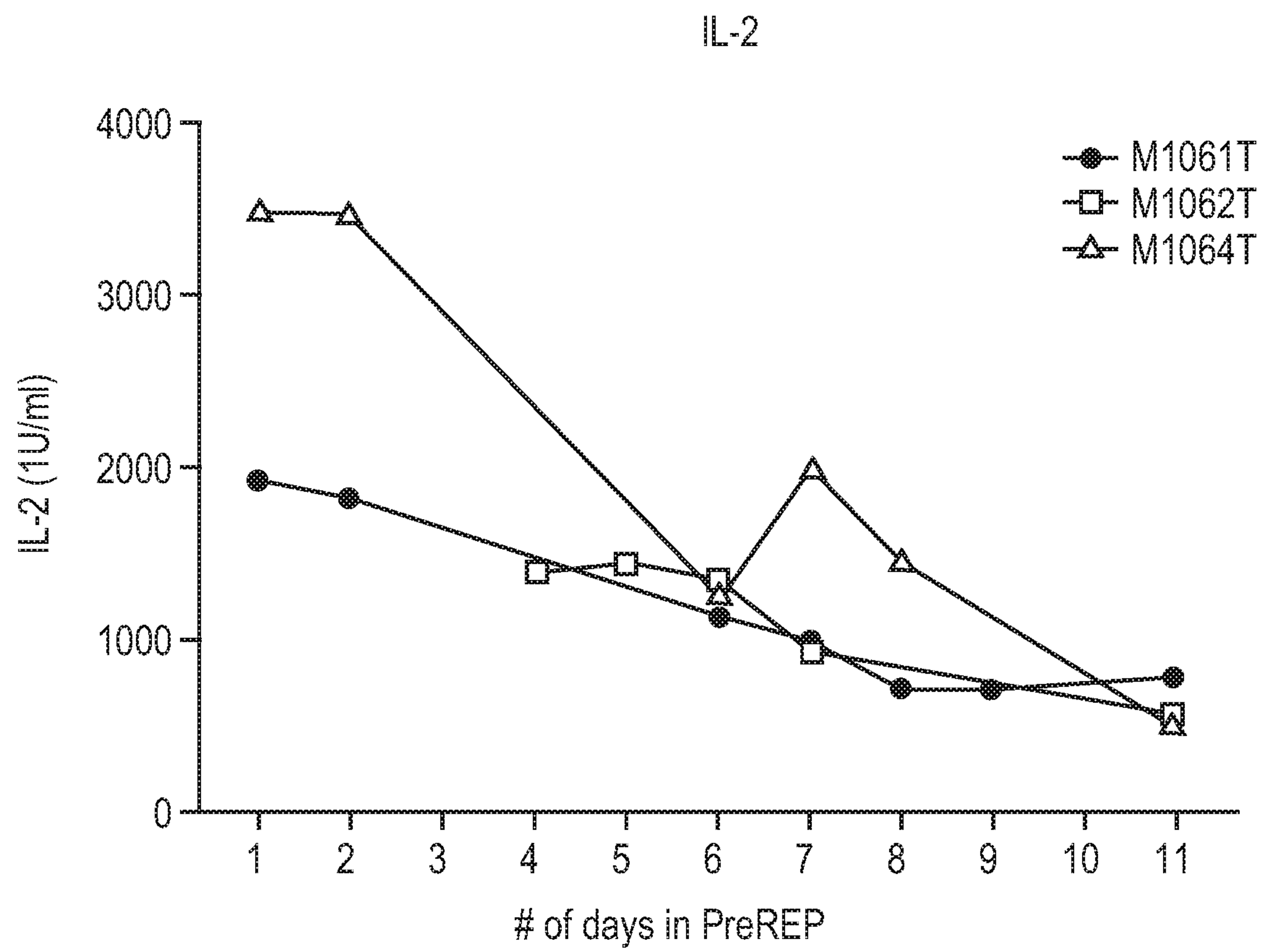


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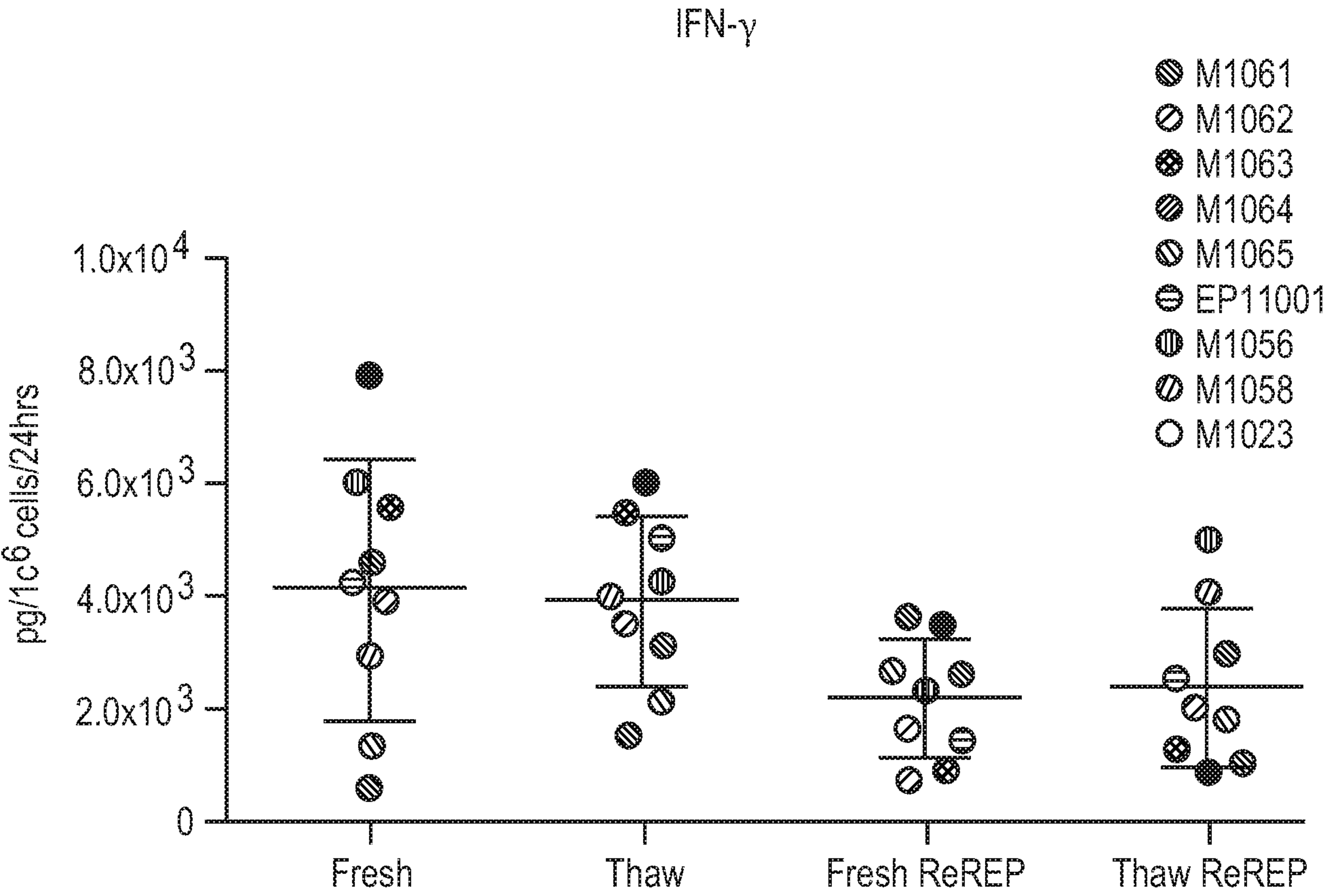


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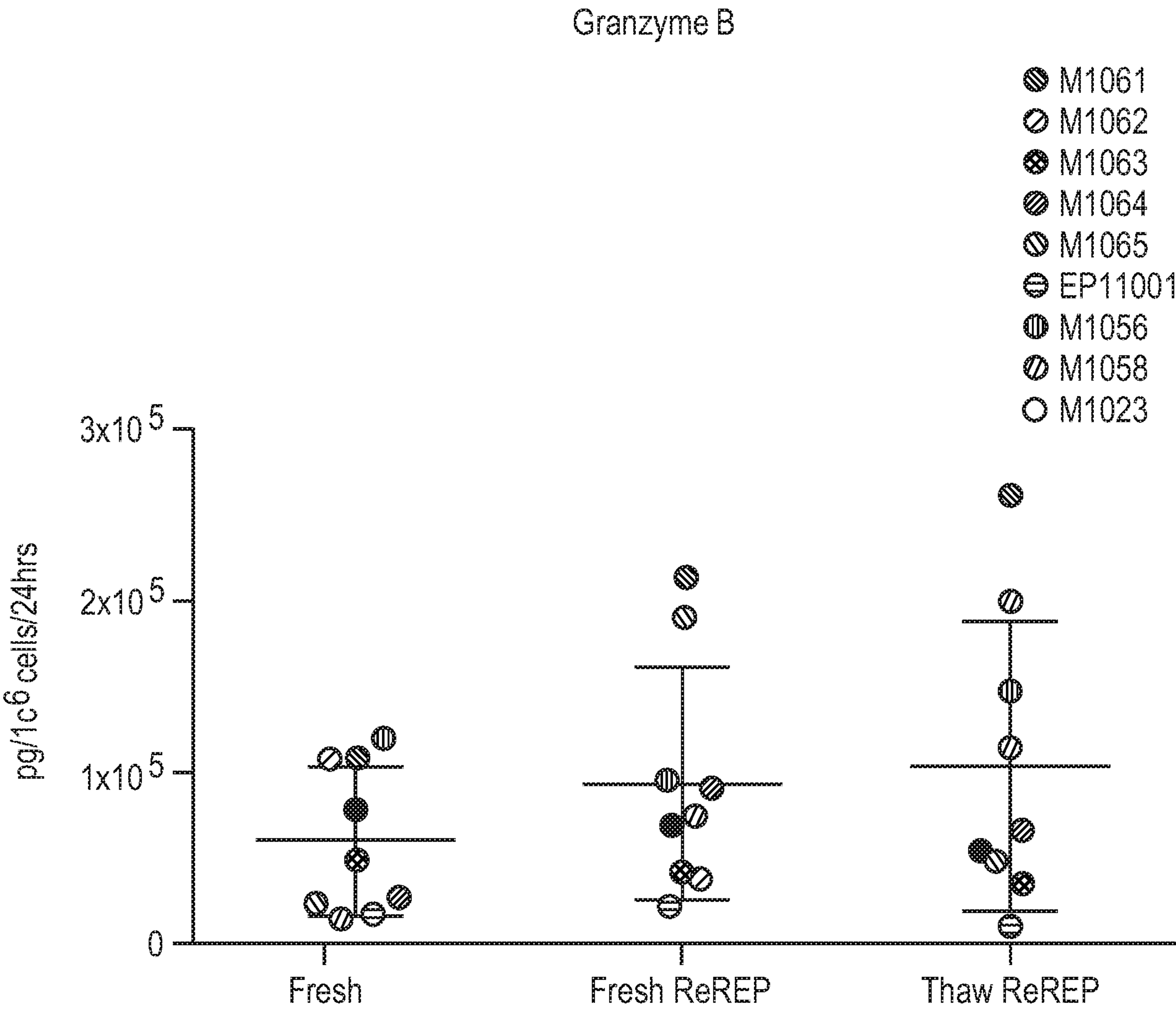


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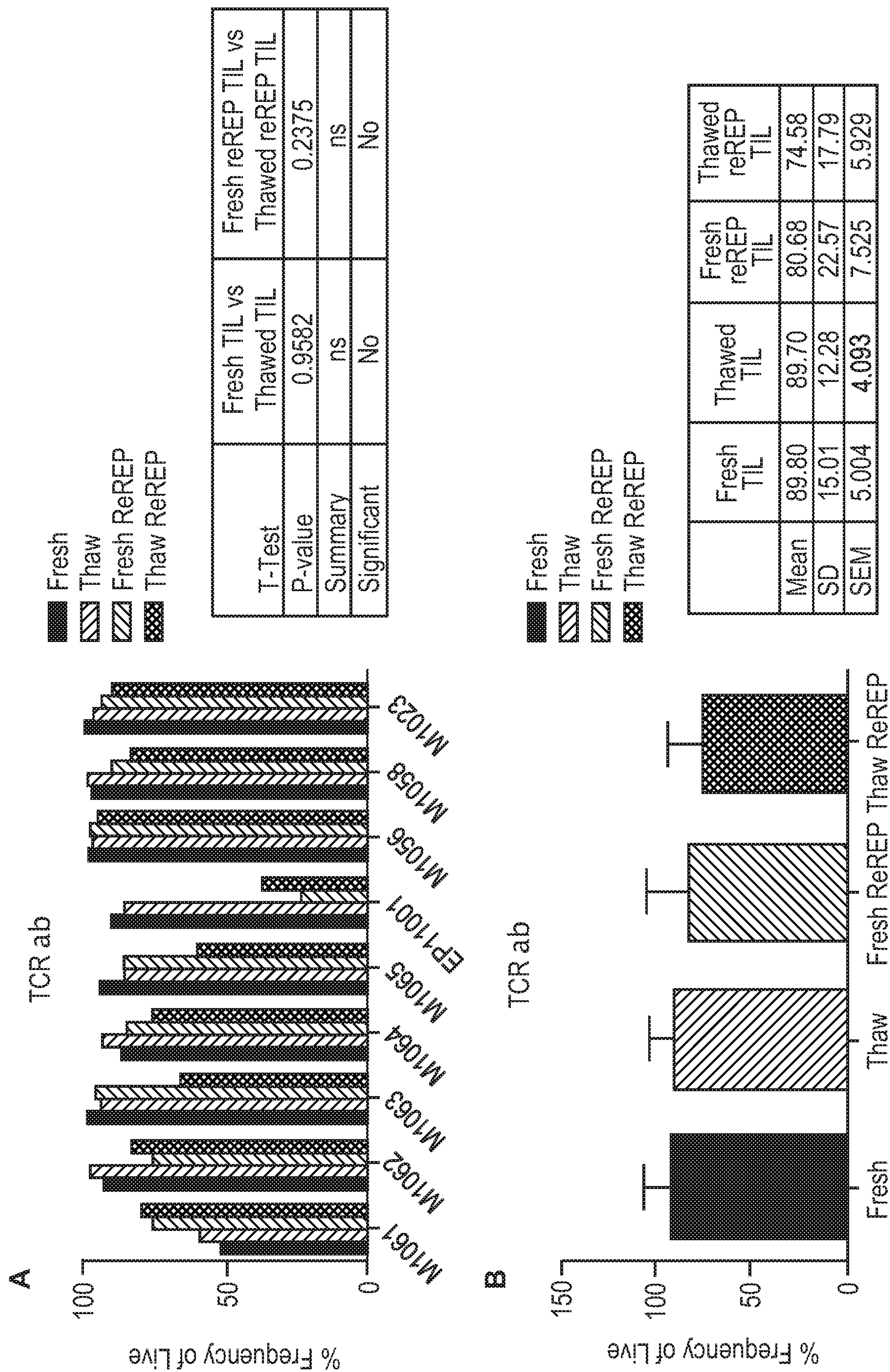


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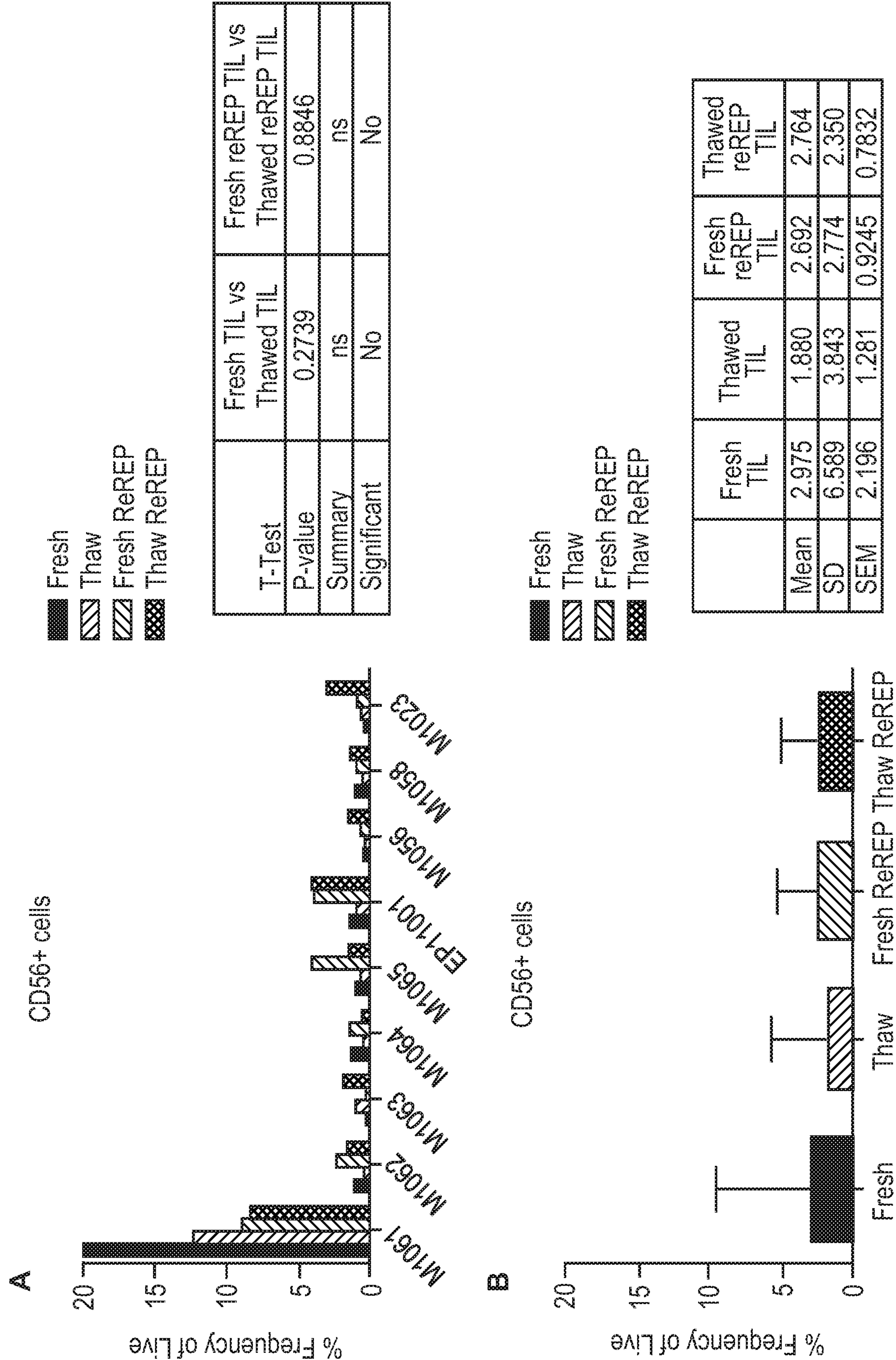


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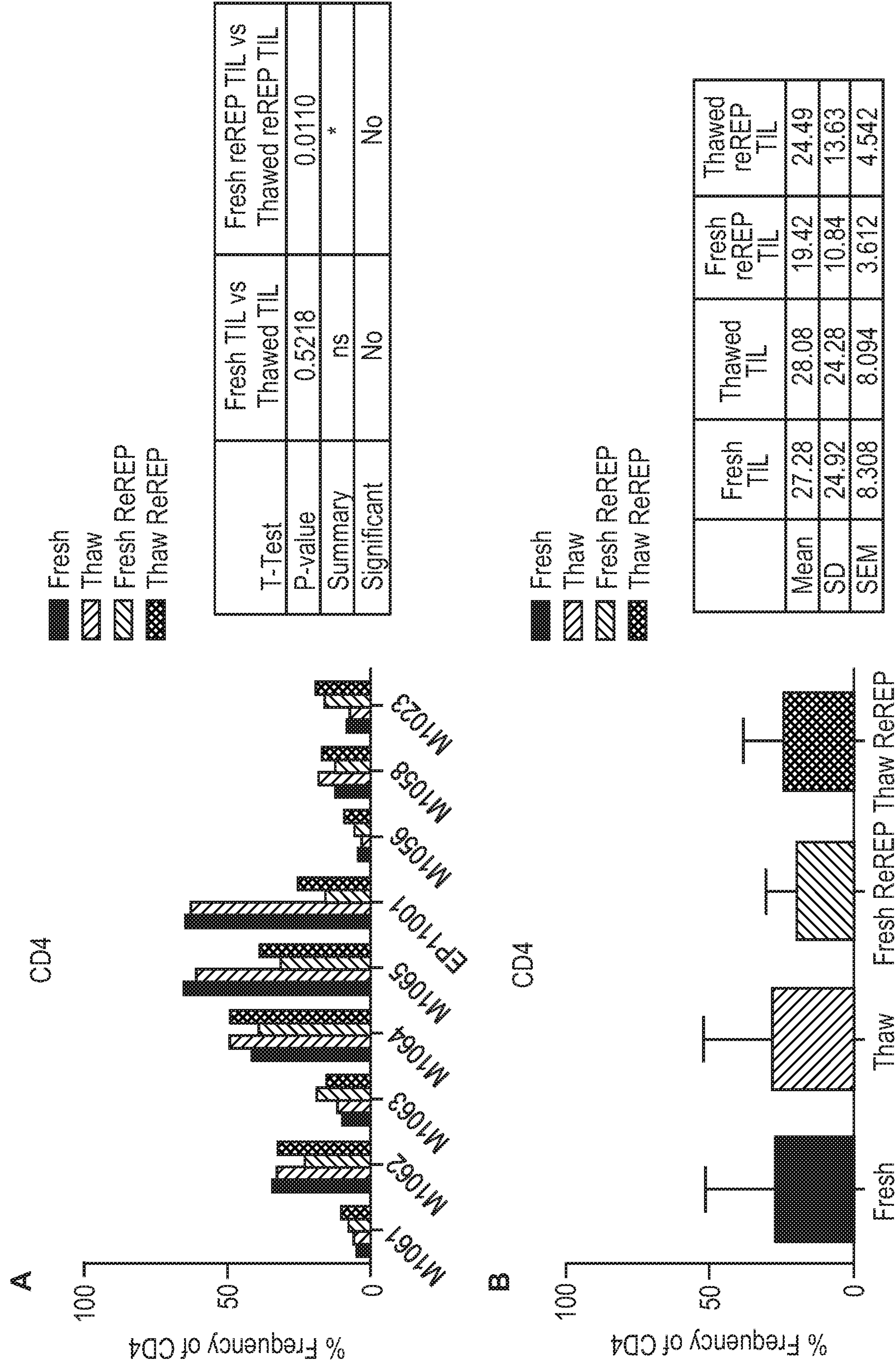


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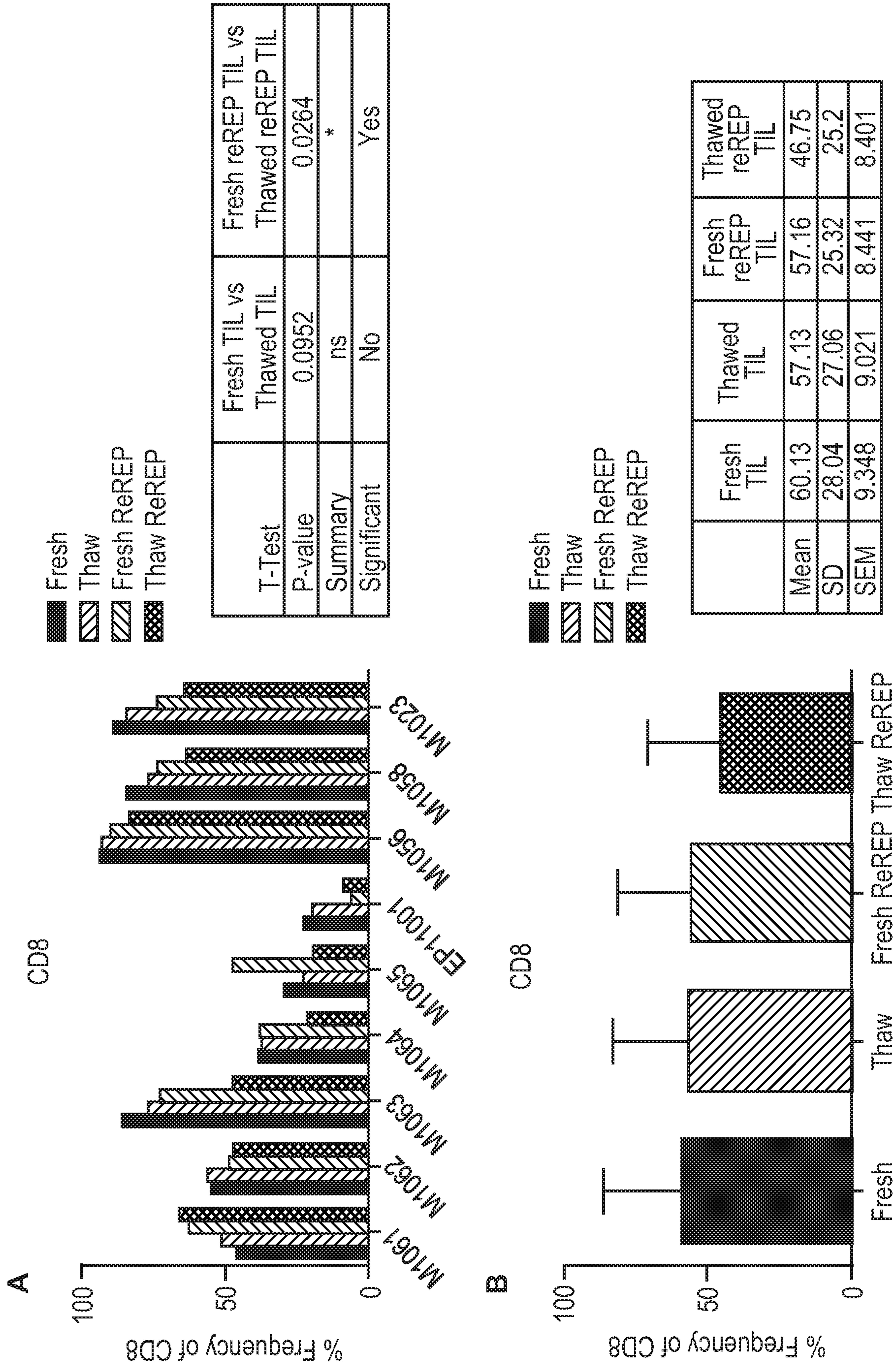


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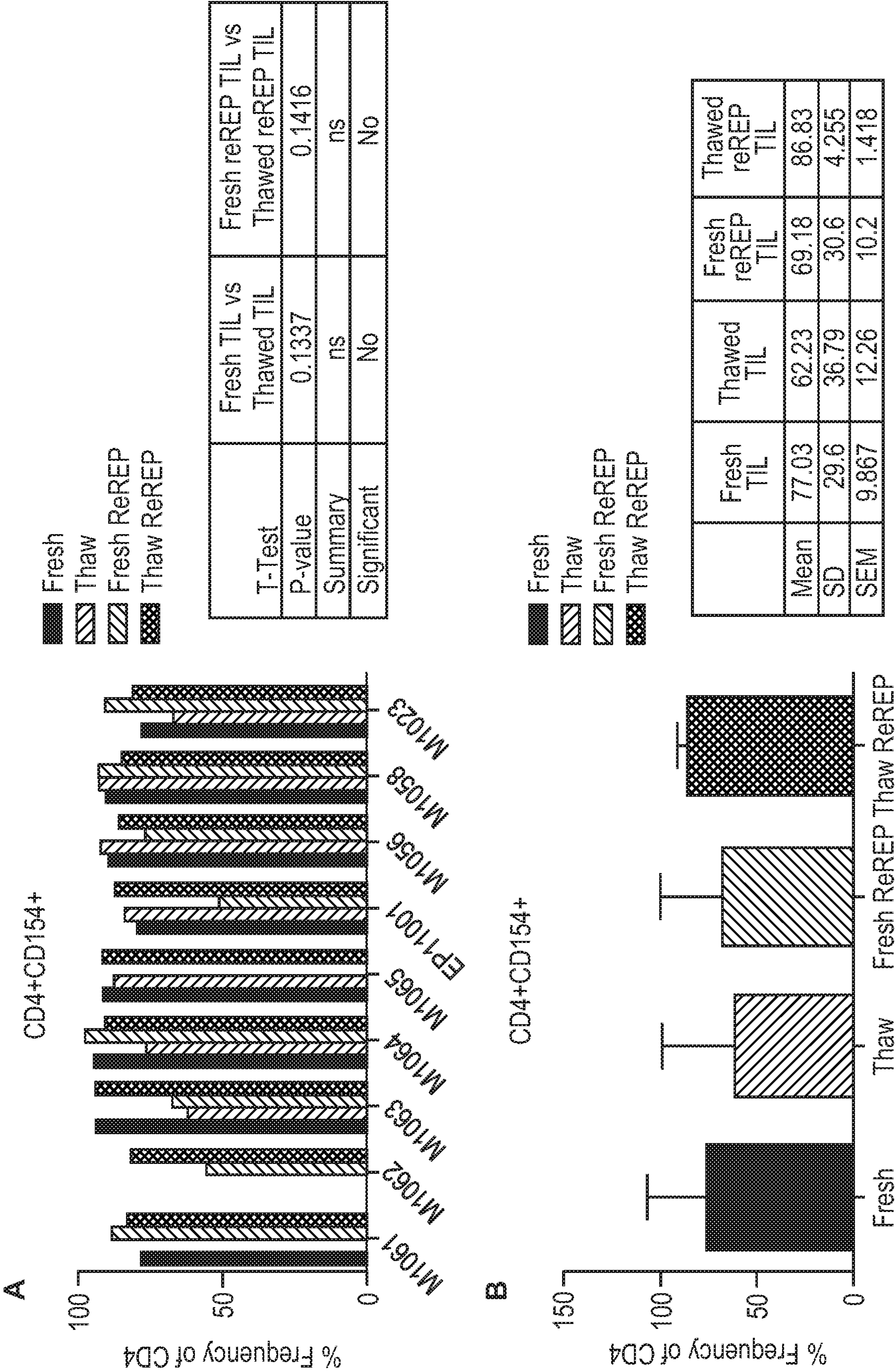


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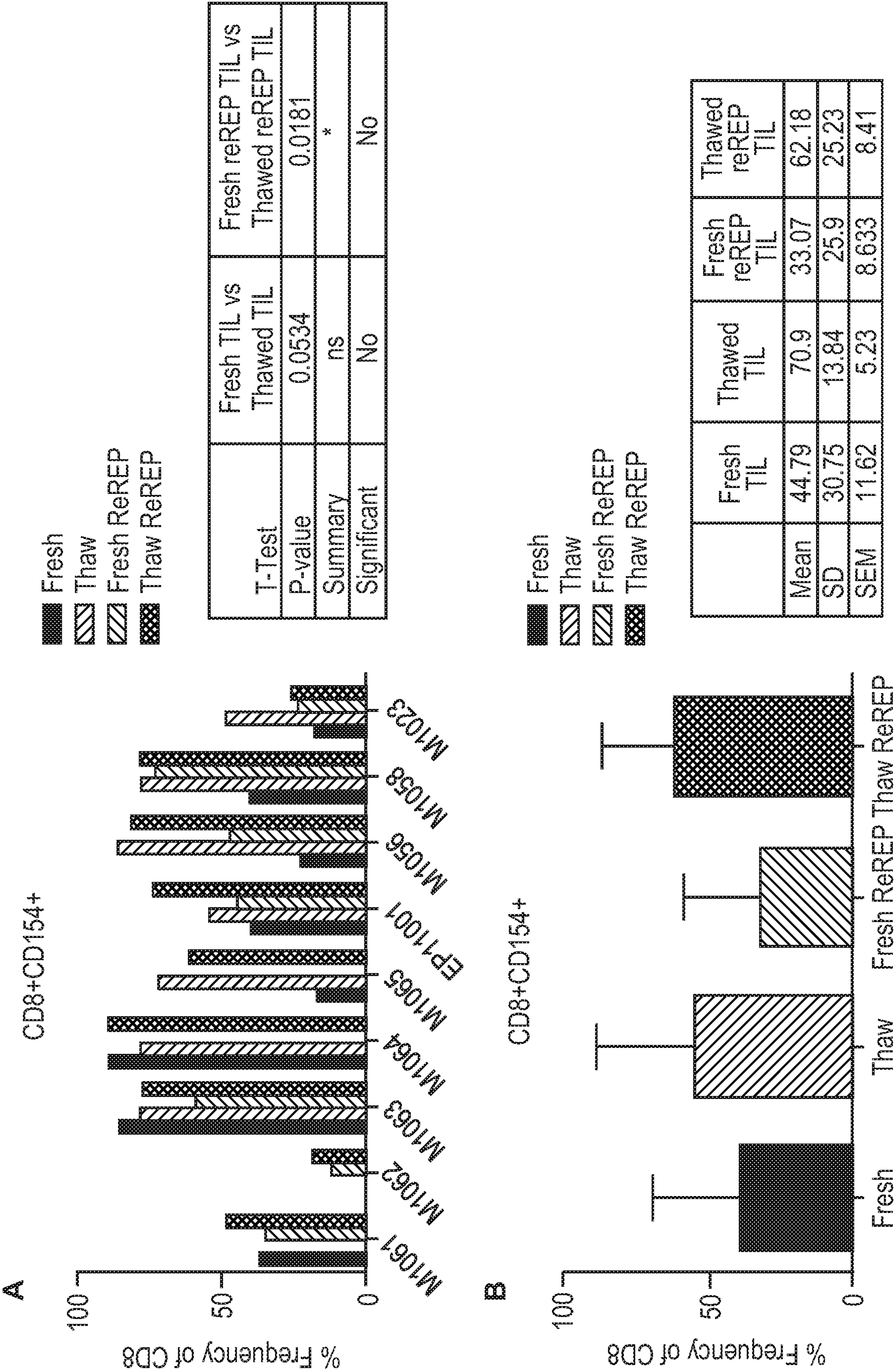


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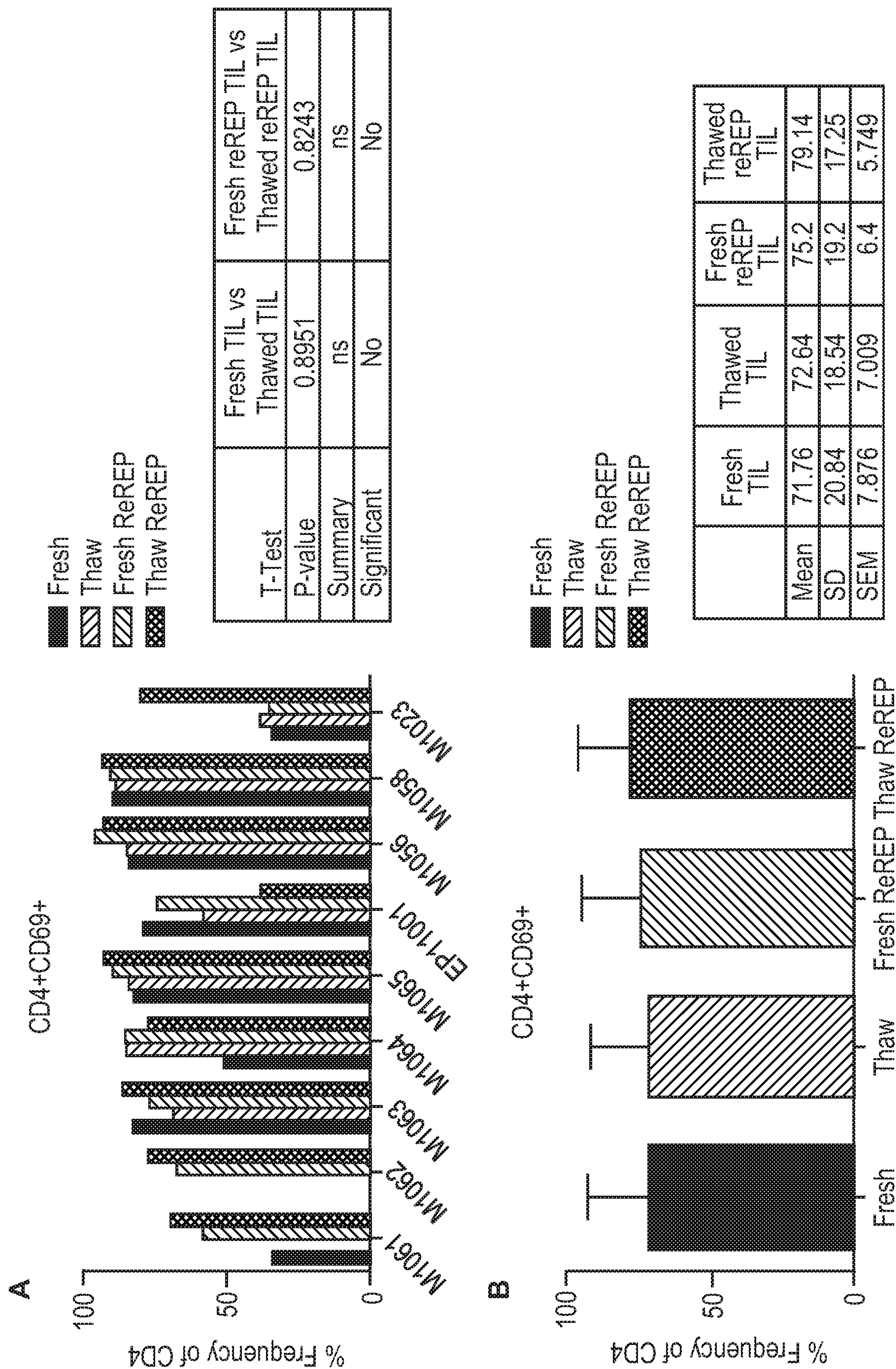


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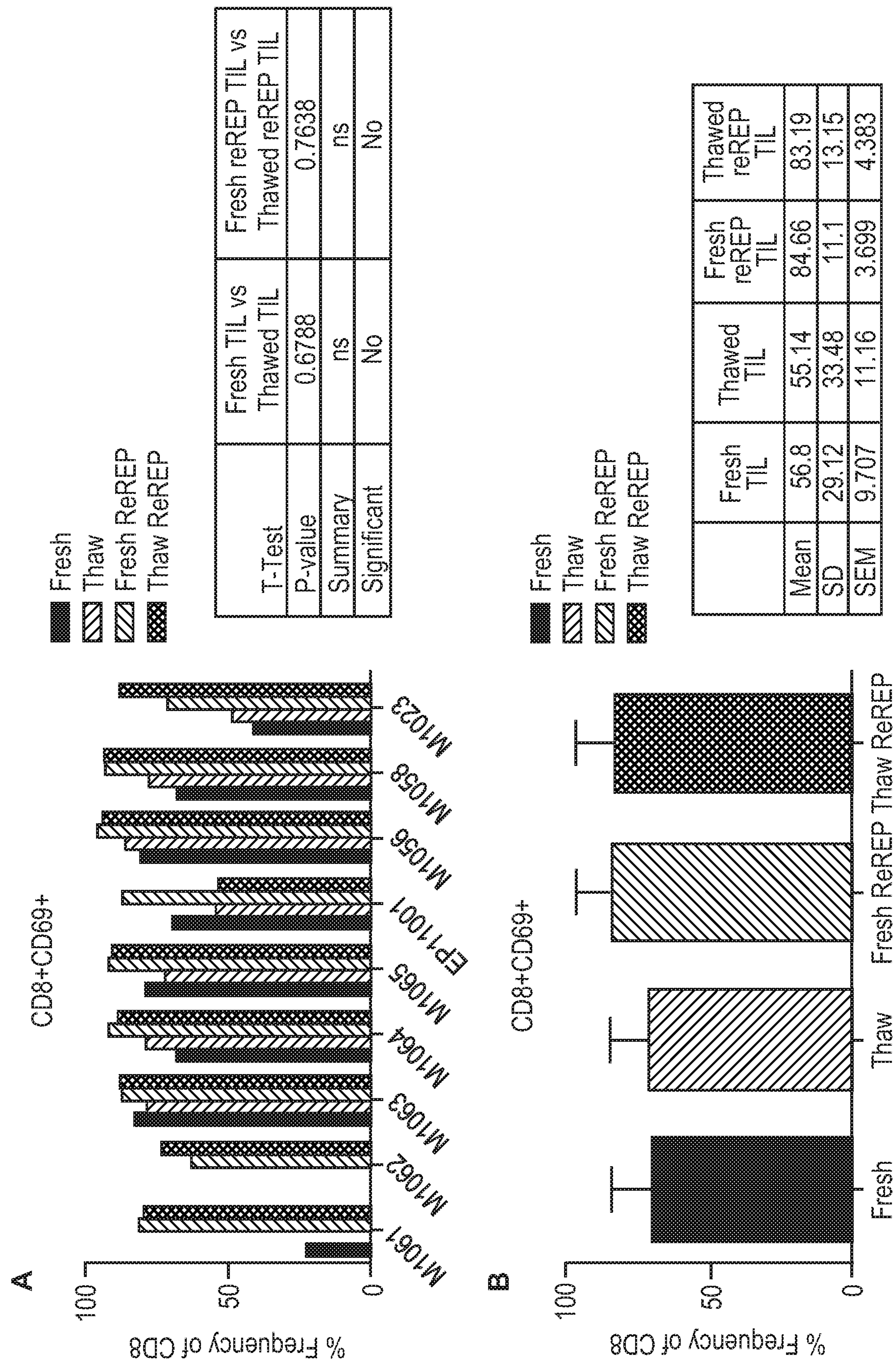


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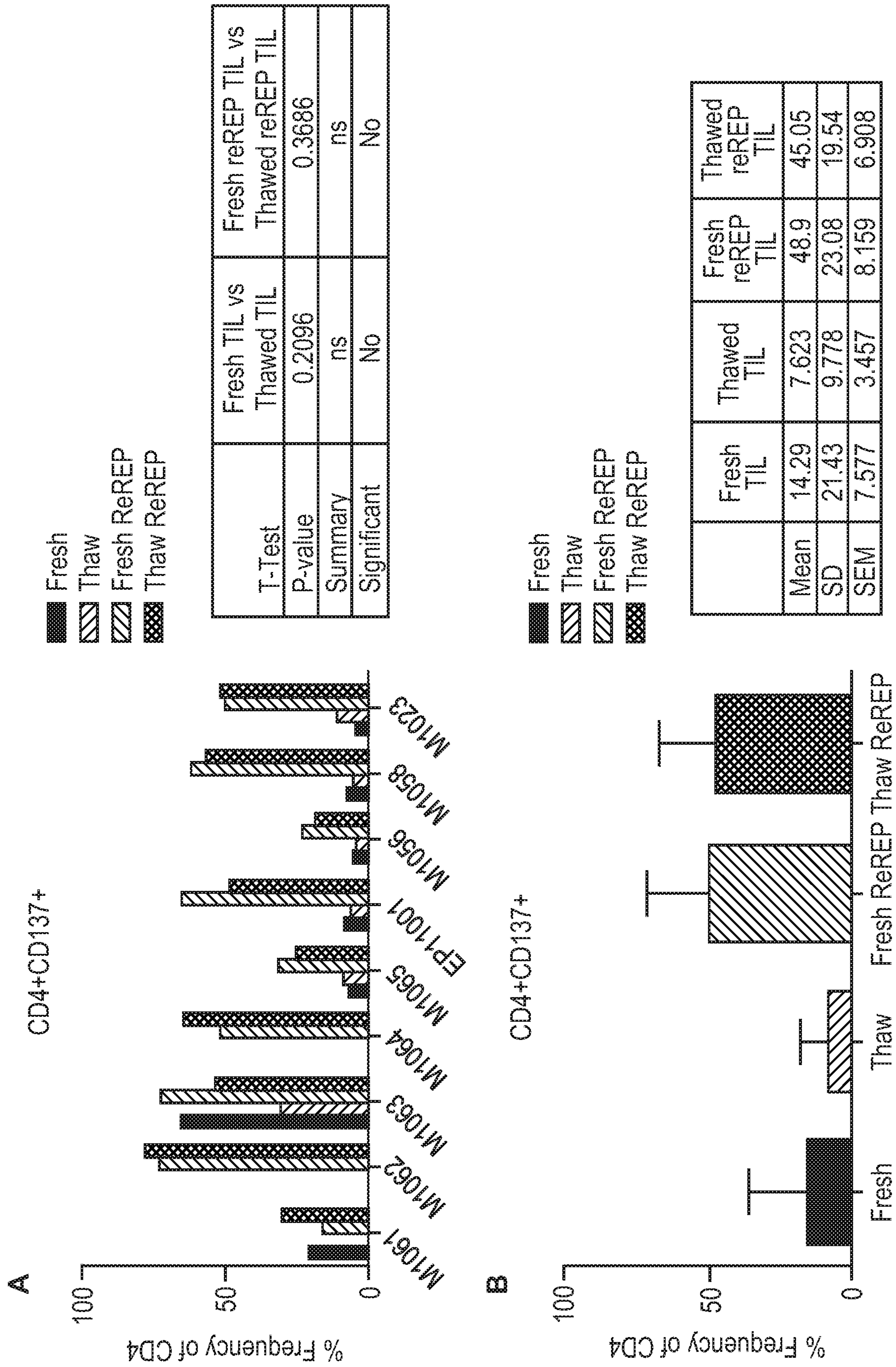


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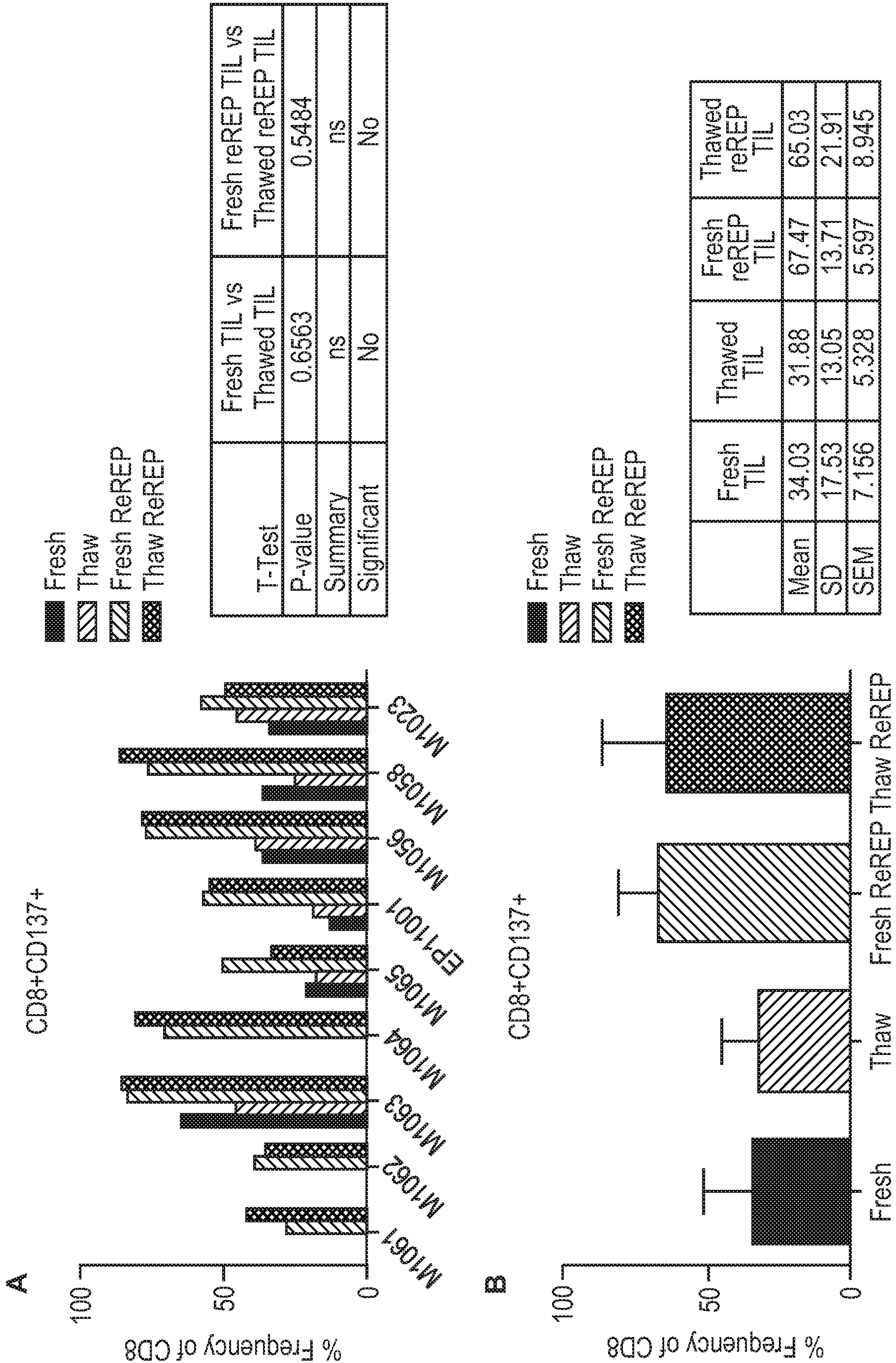


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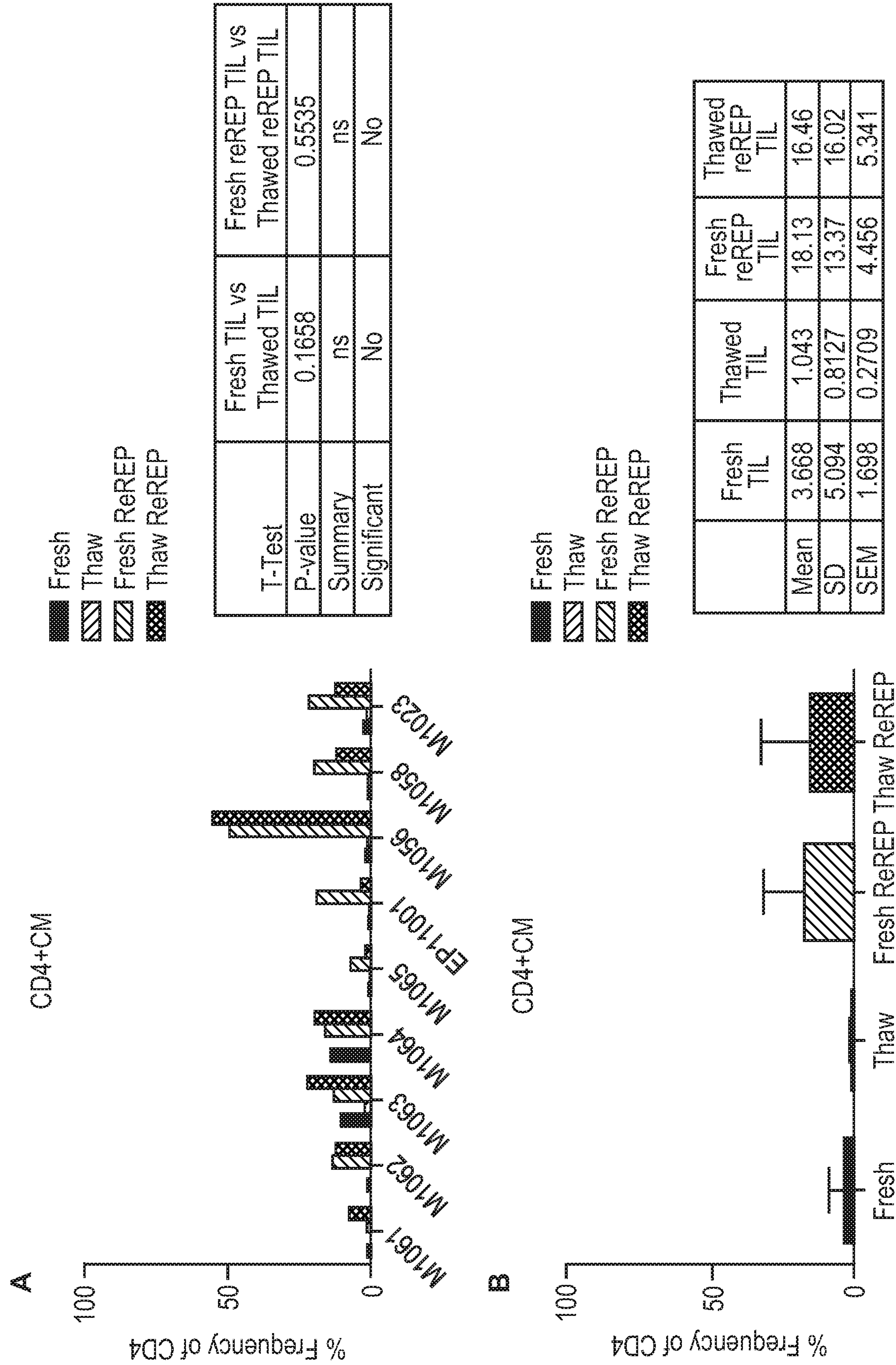


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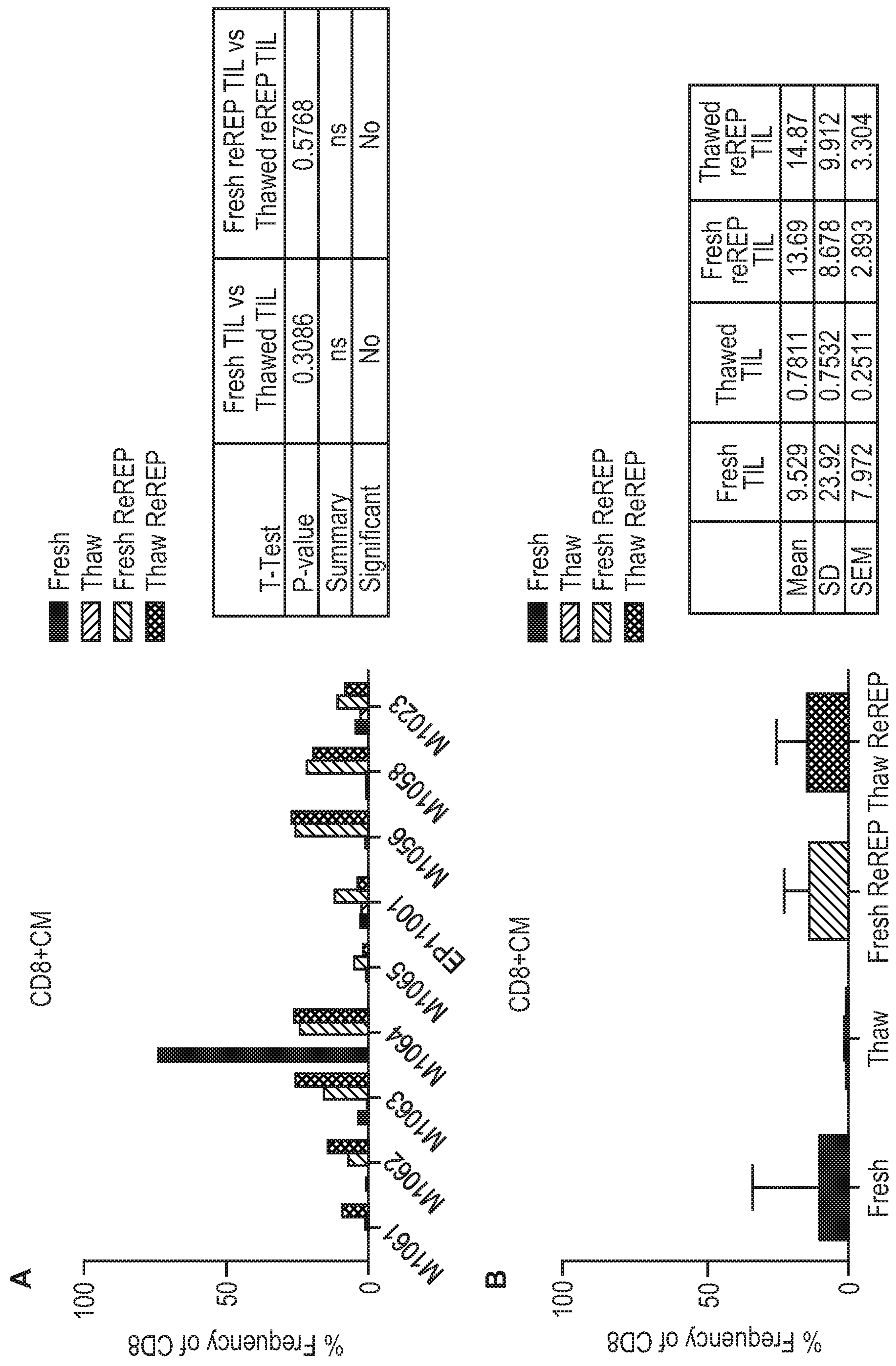


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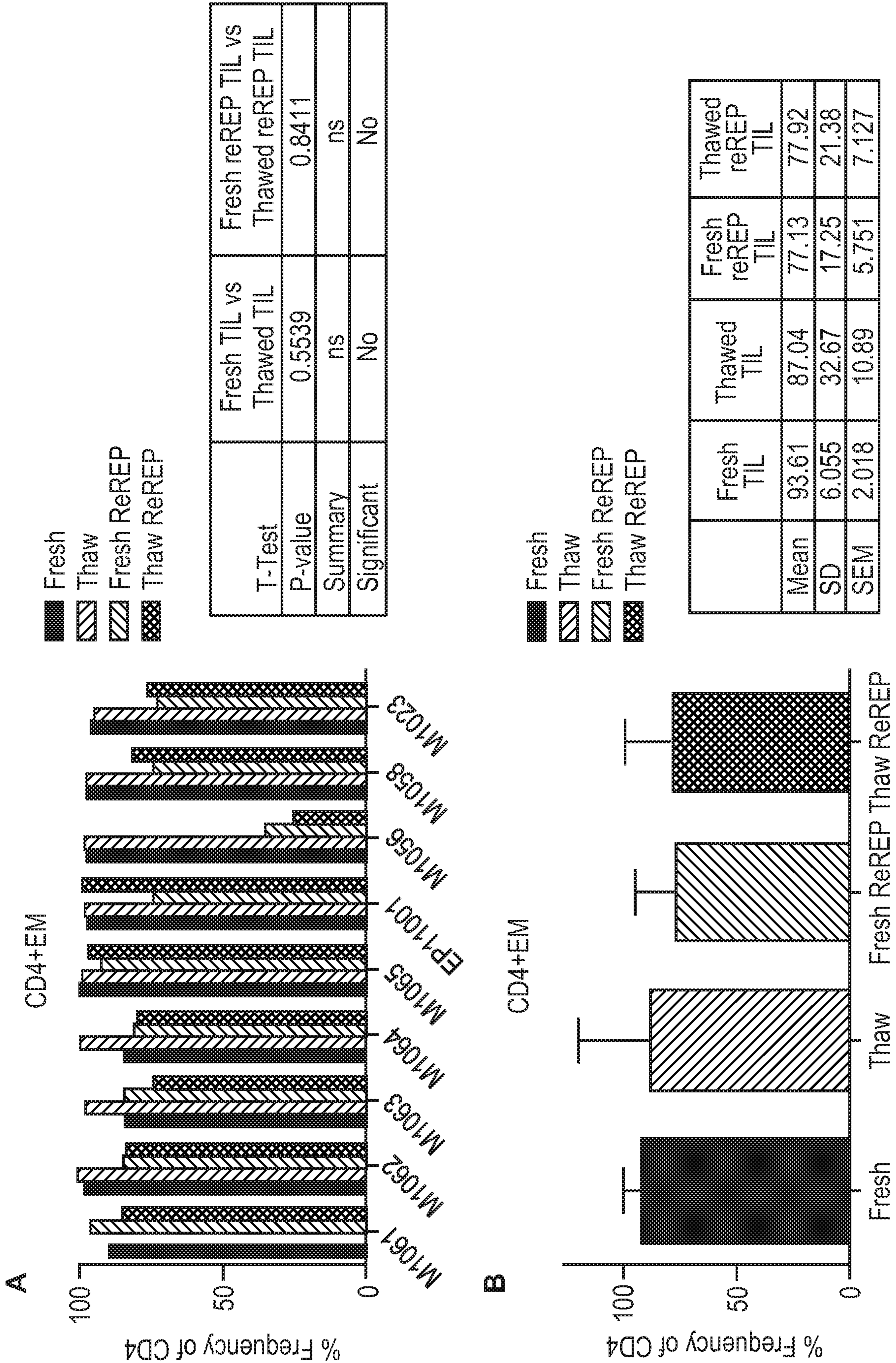


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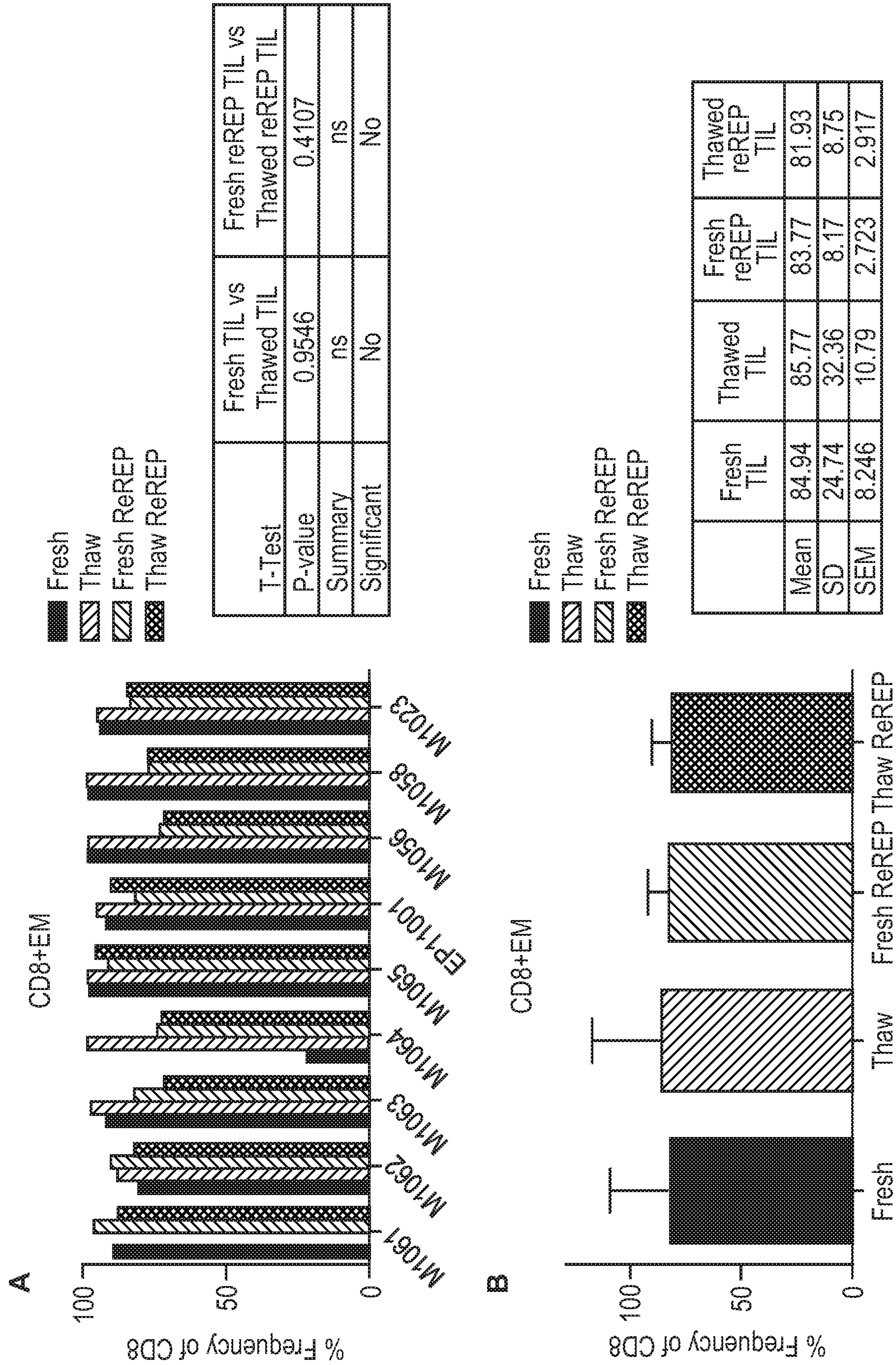


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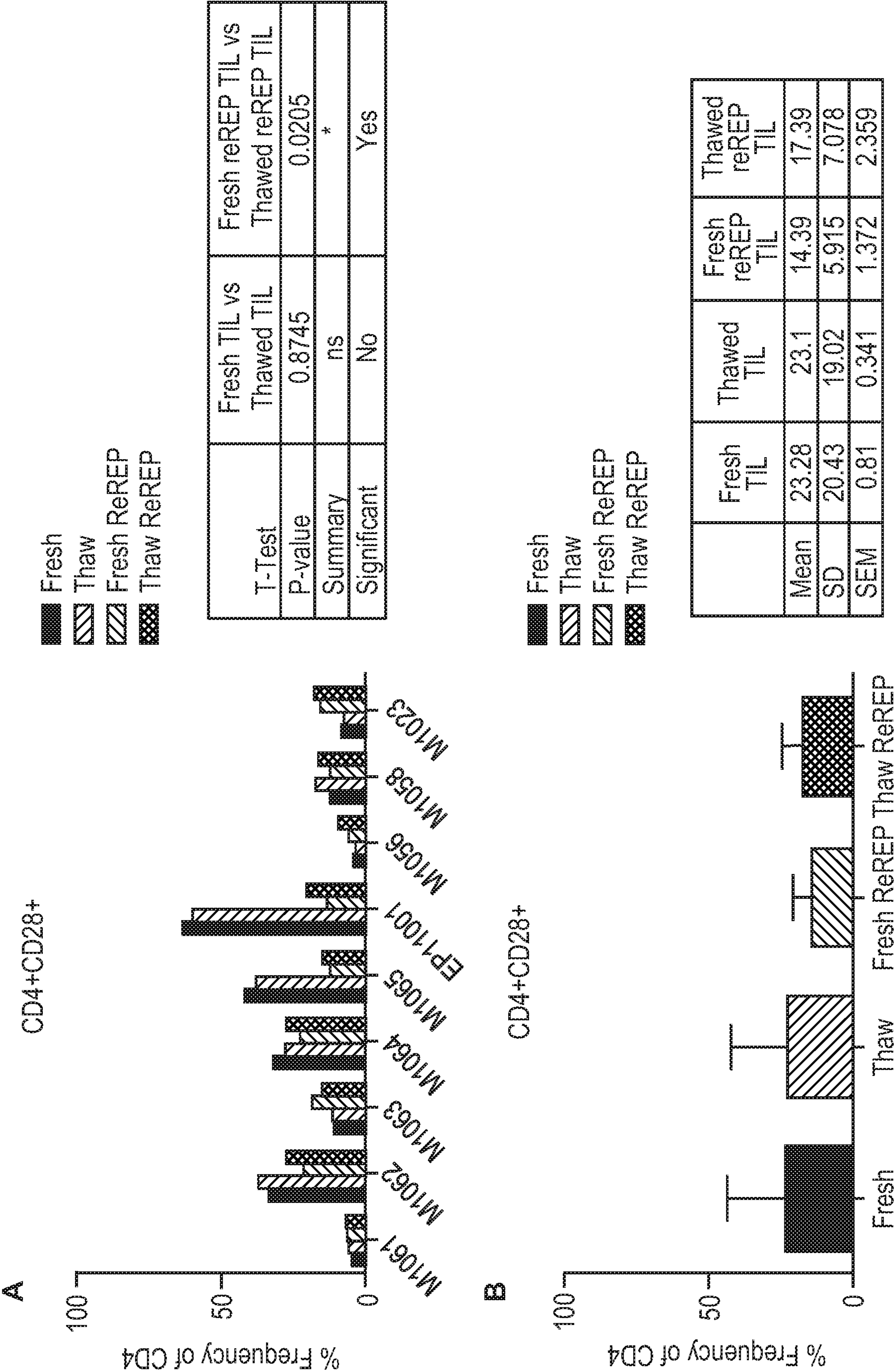


Figure 51

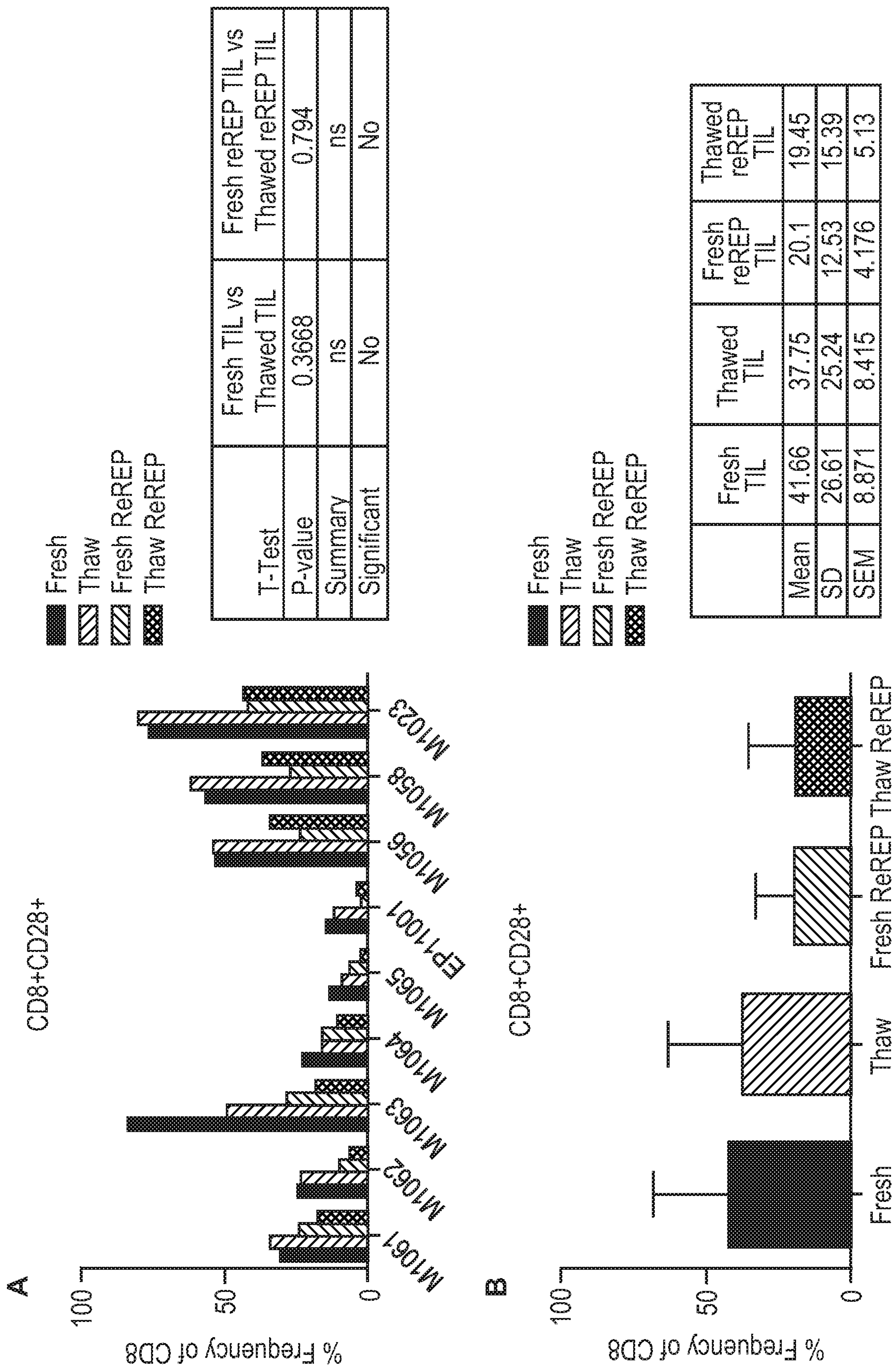


Figure 52

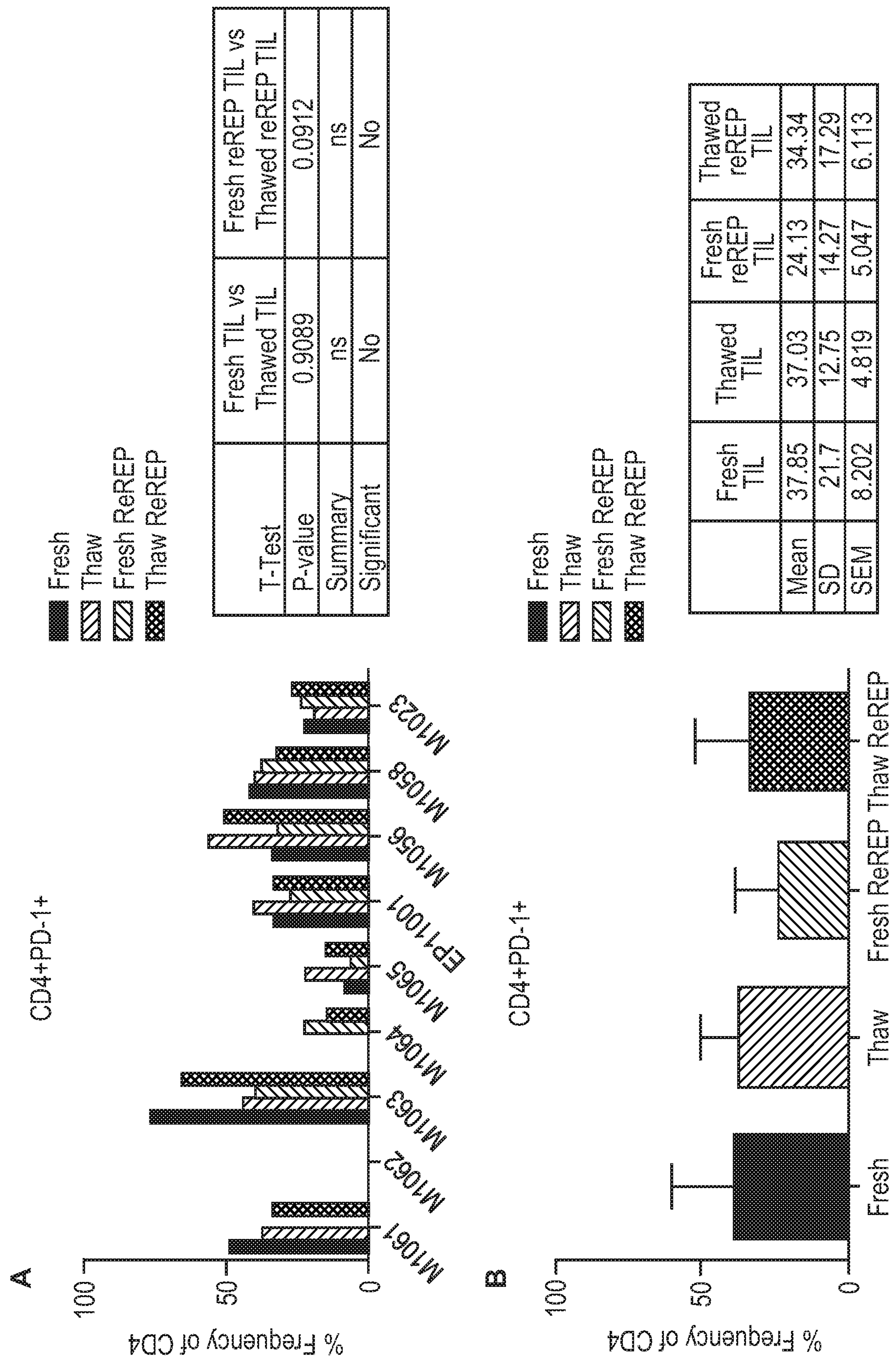
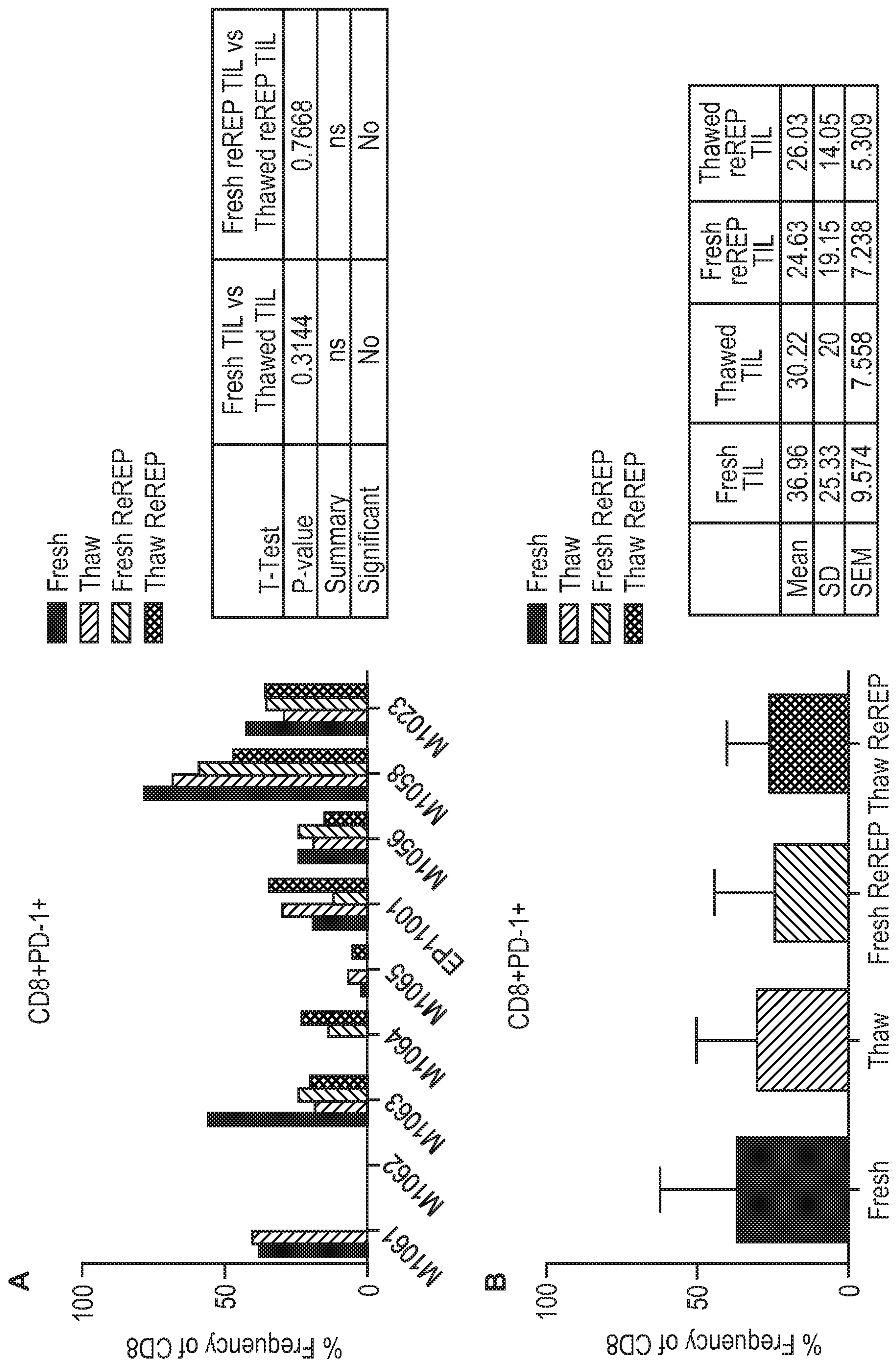


Figure 53



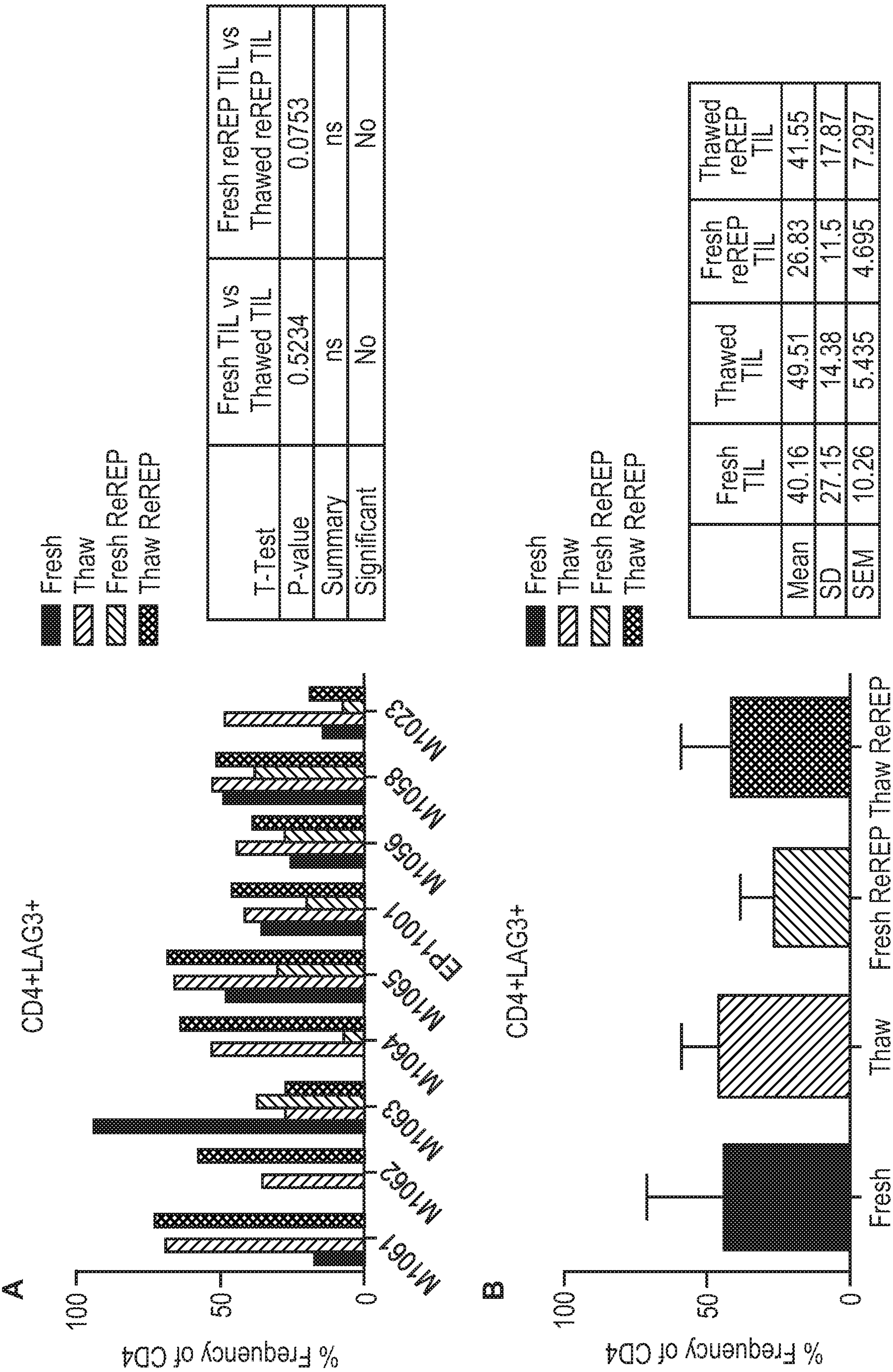


Figure 55

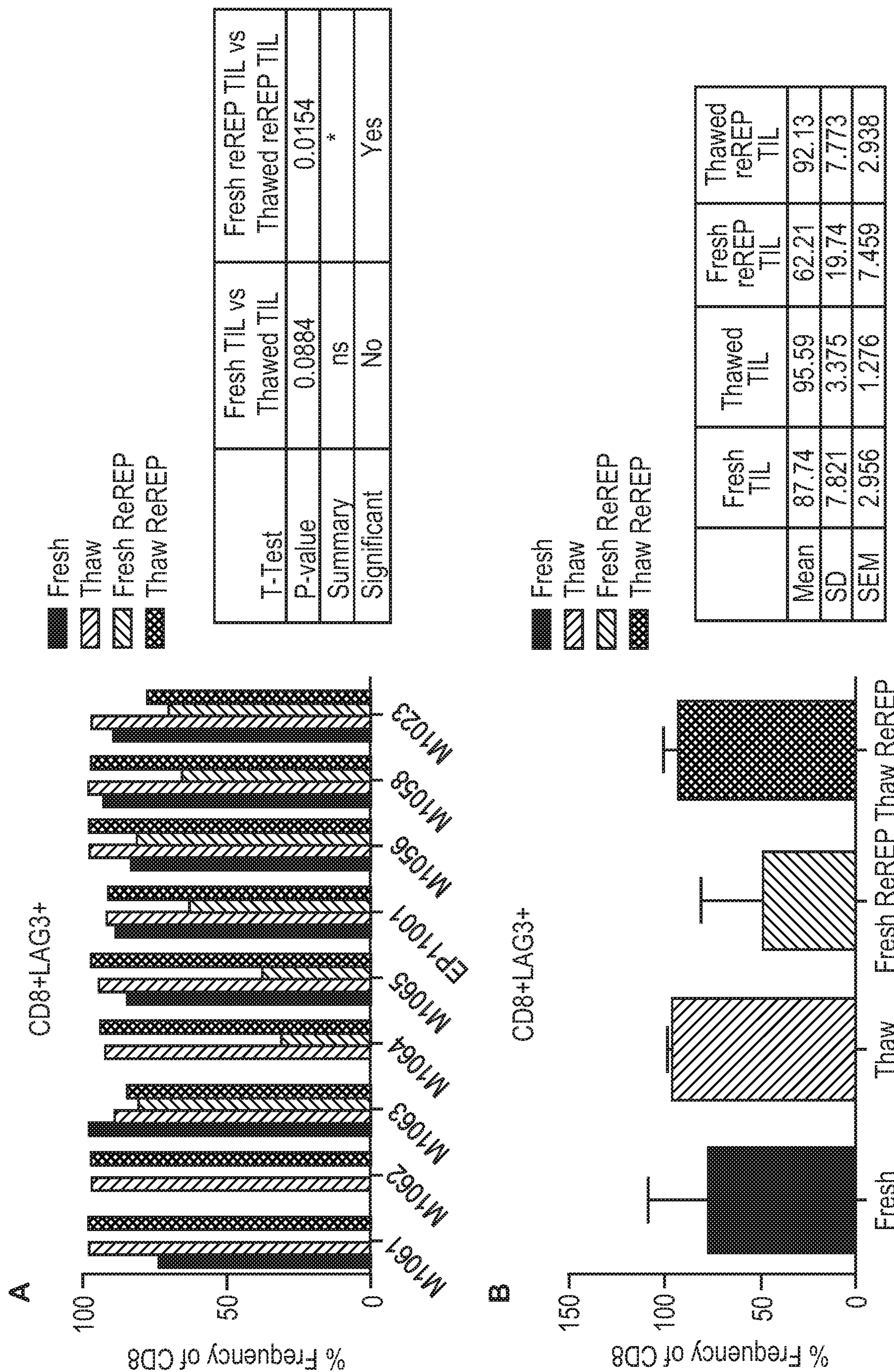
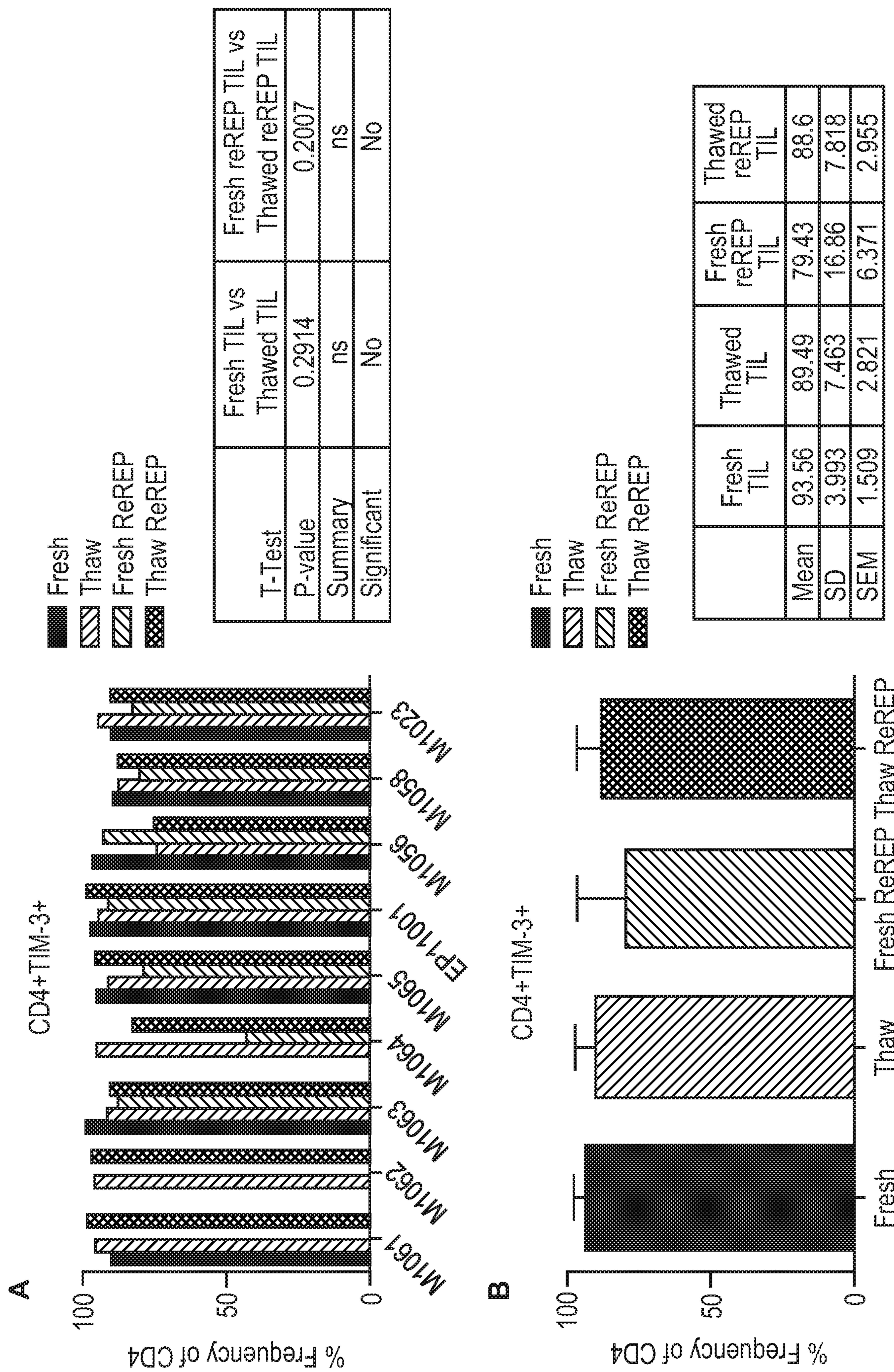


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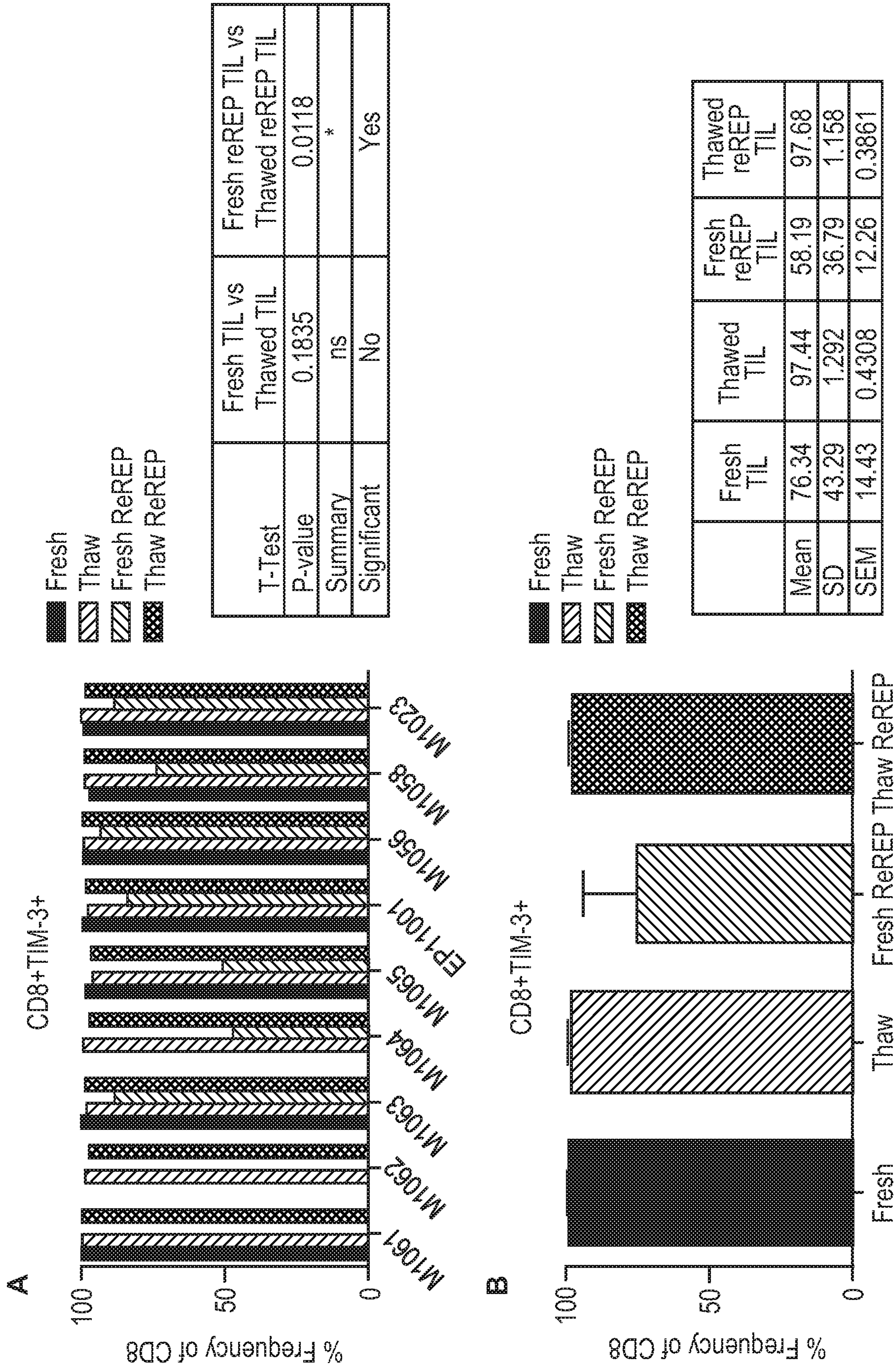


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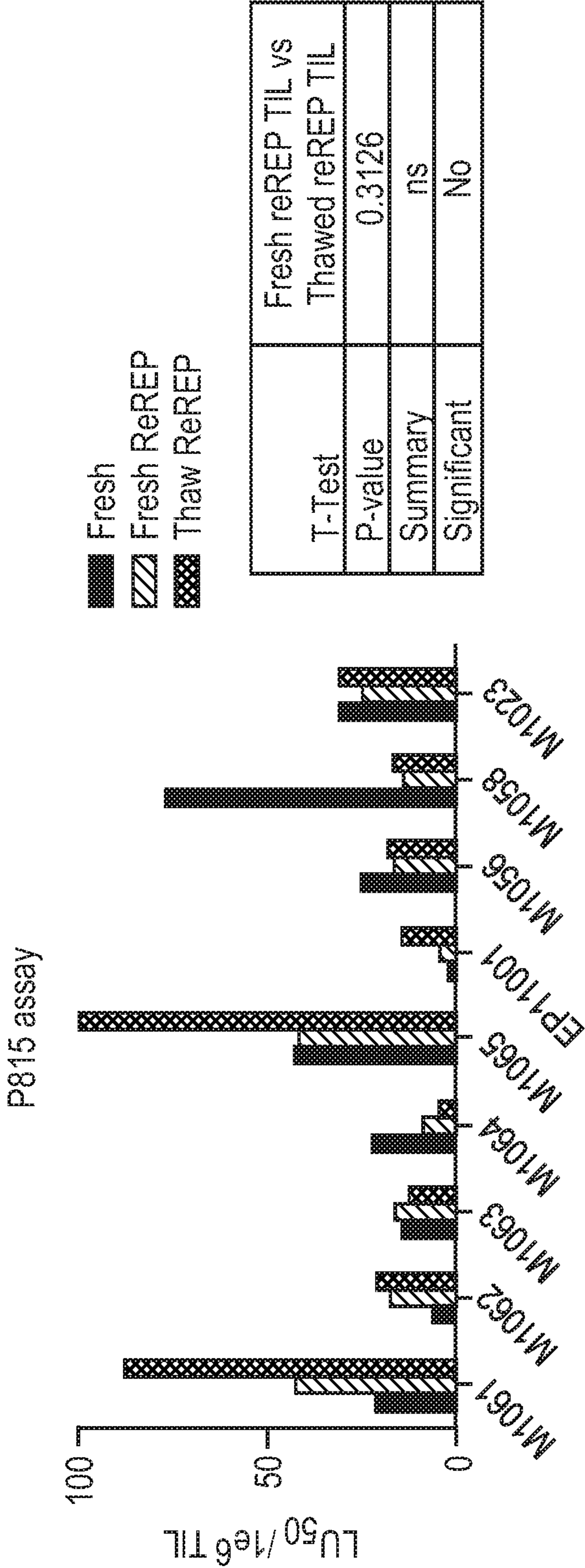


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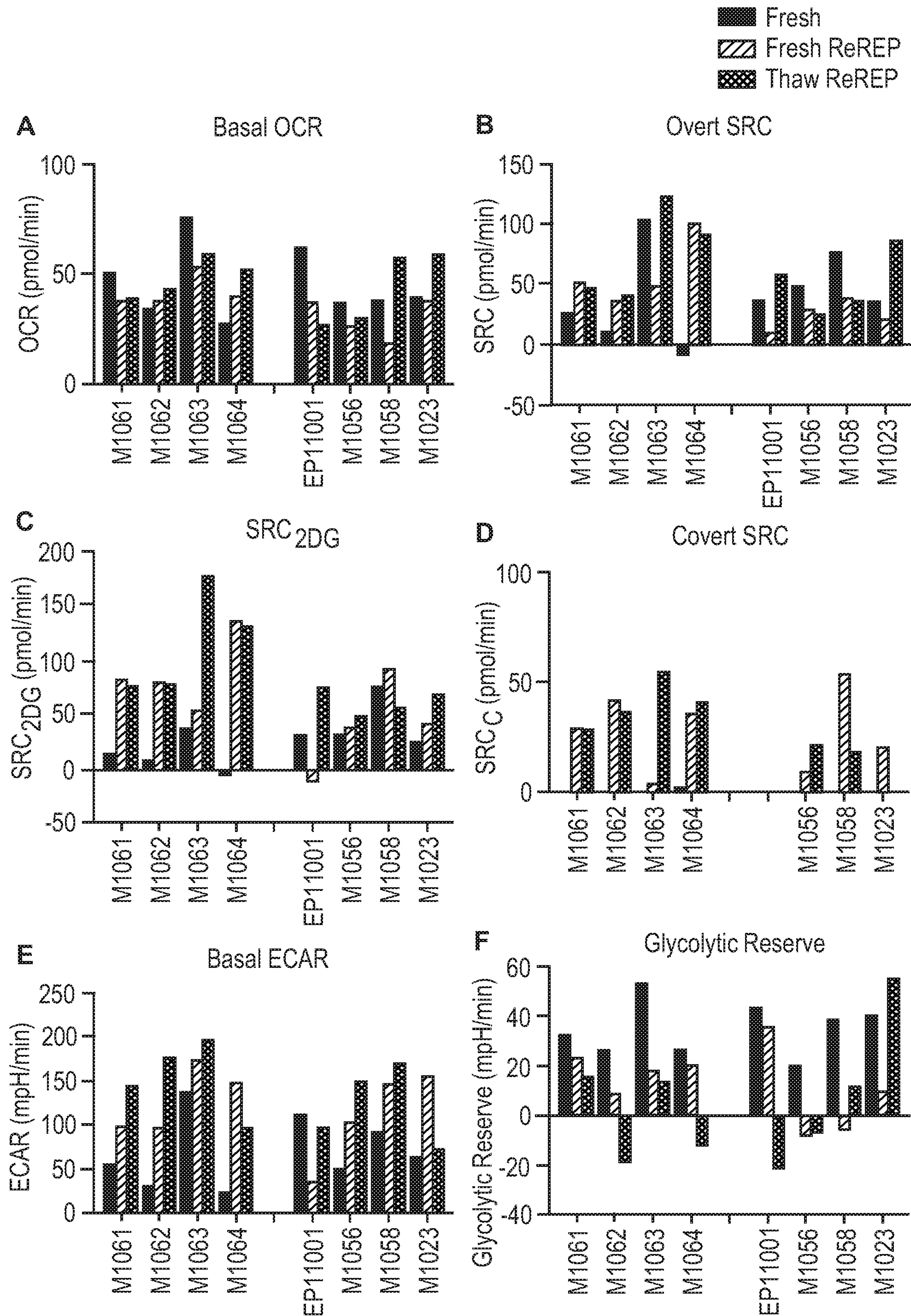


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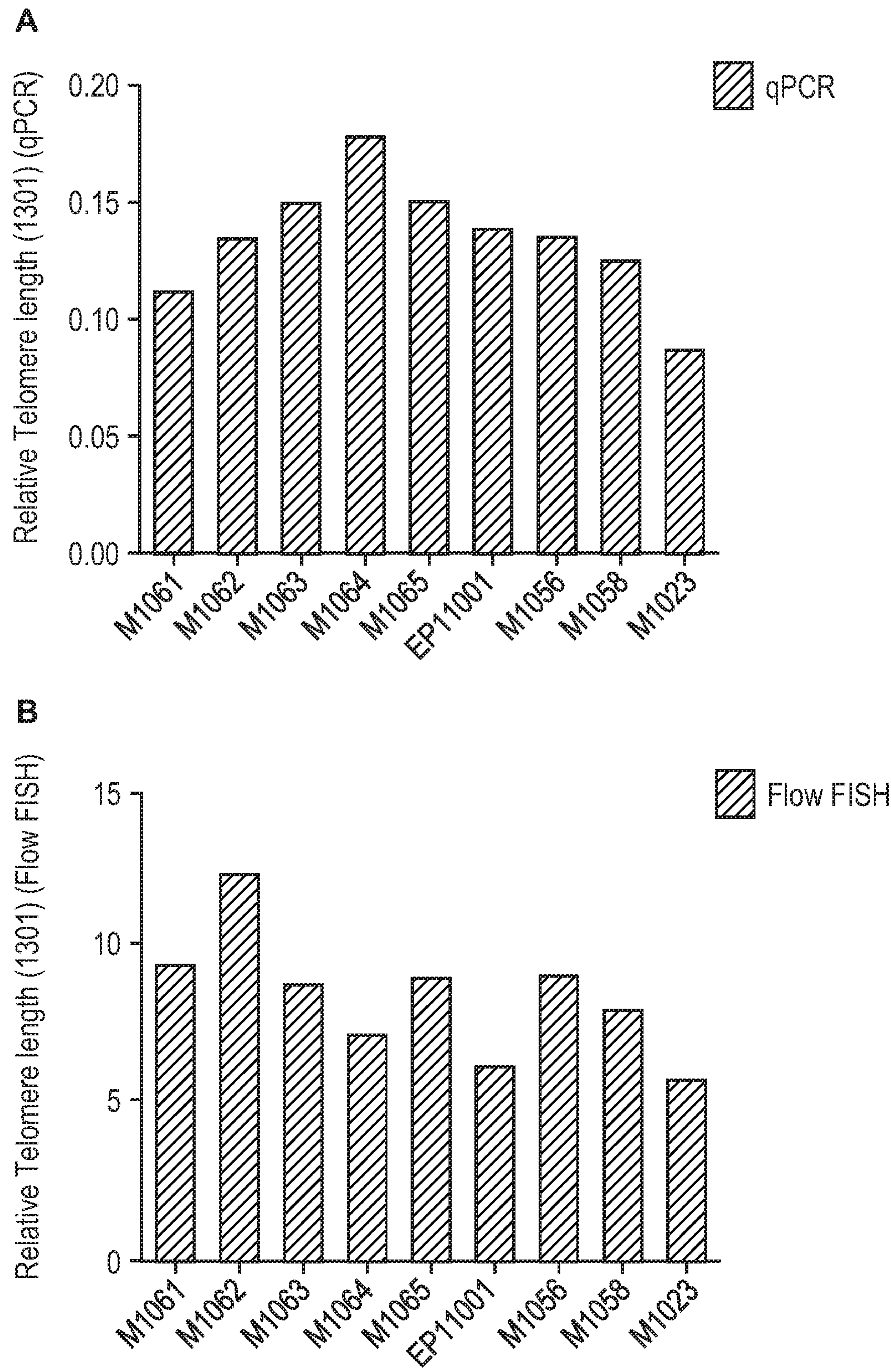
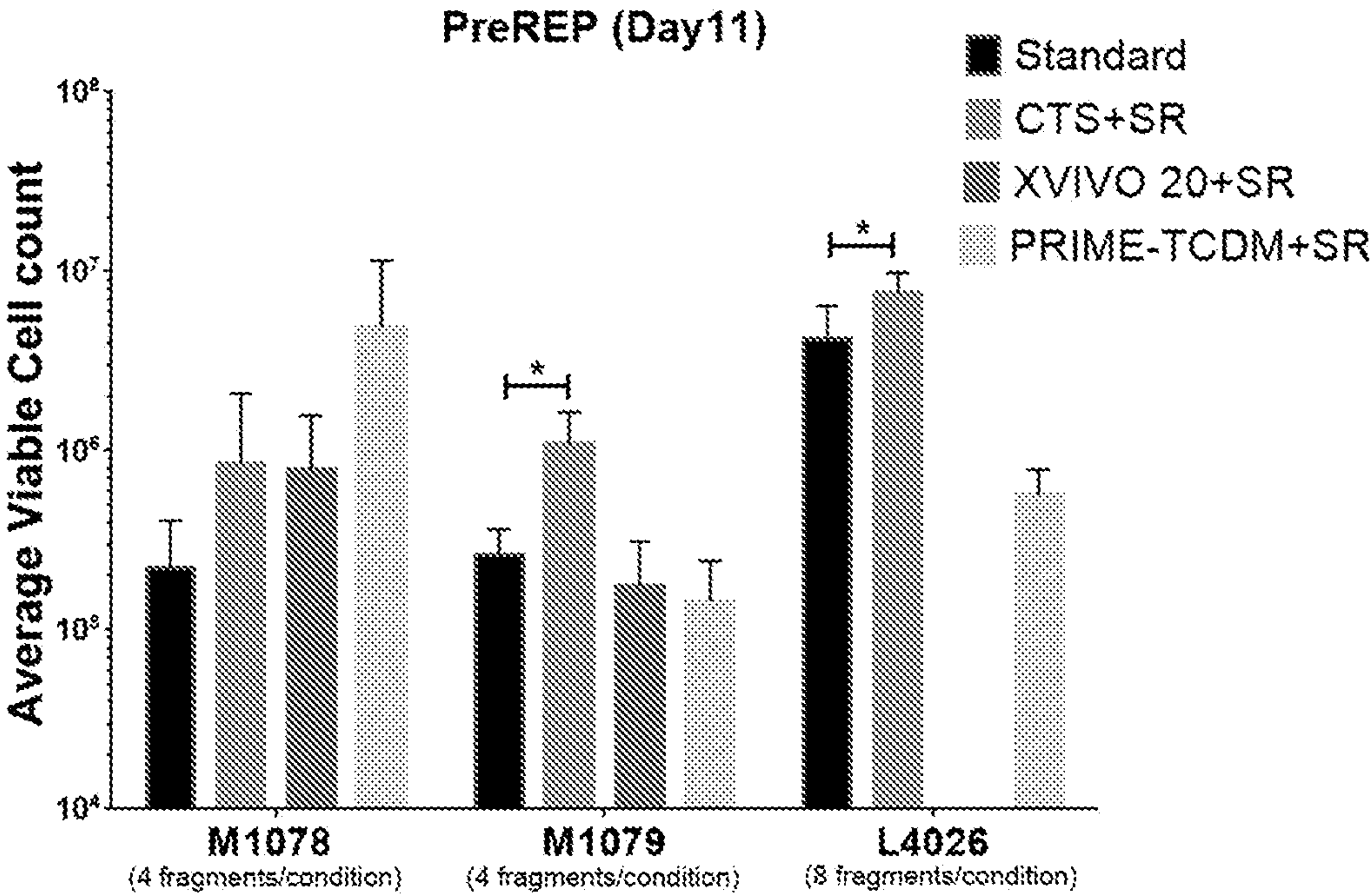


Figure 61

Figure 62

A)



B)

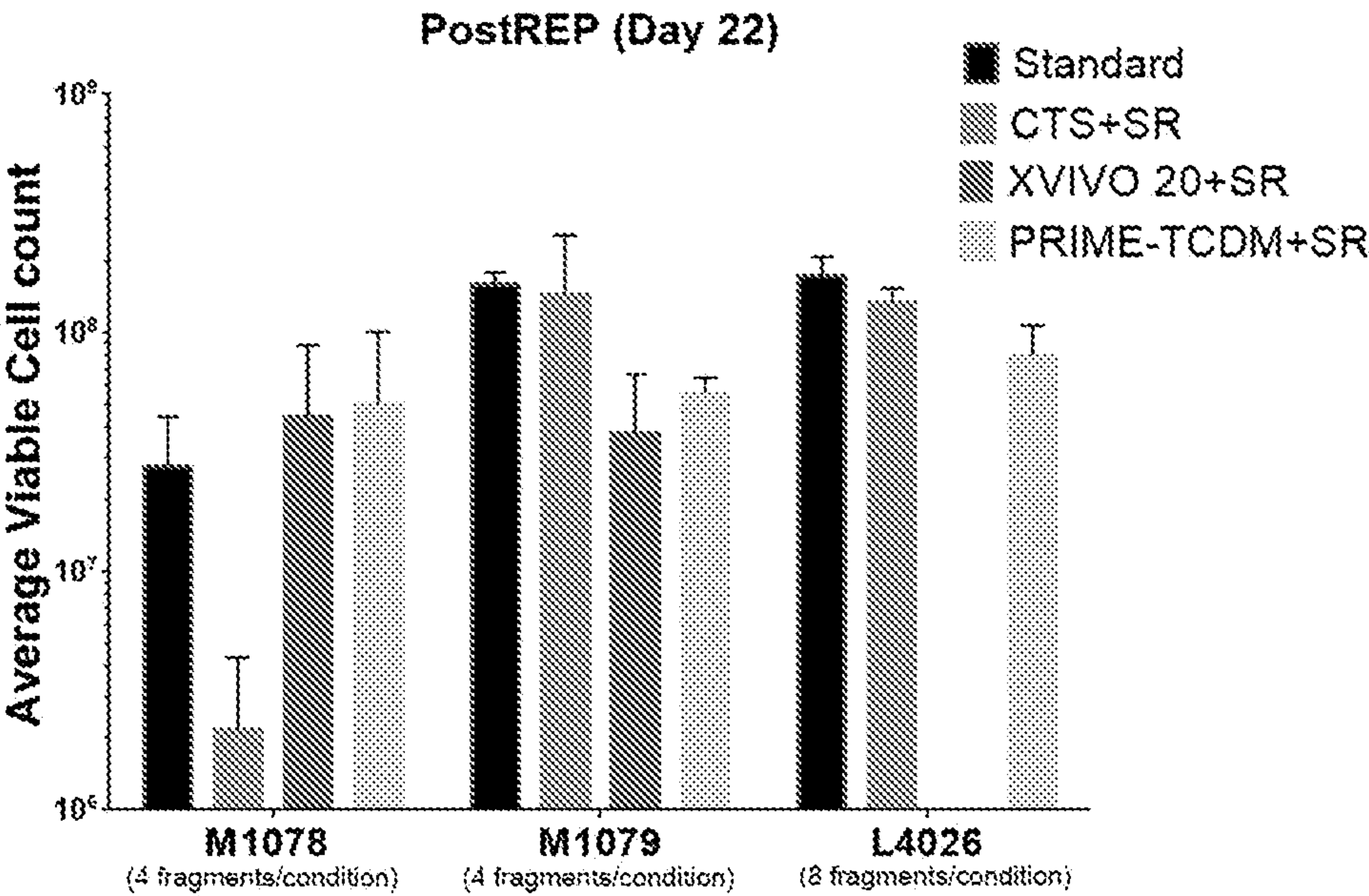
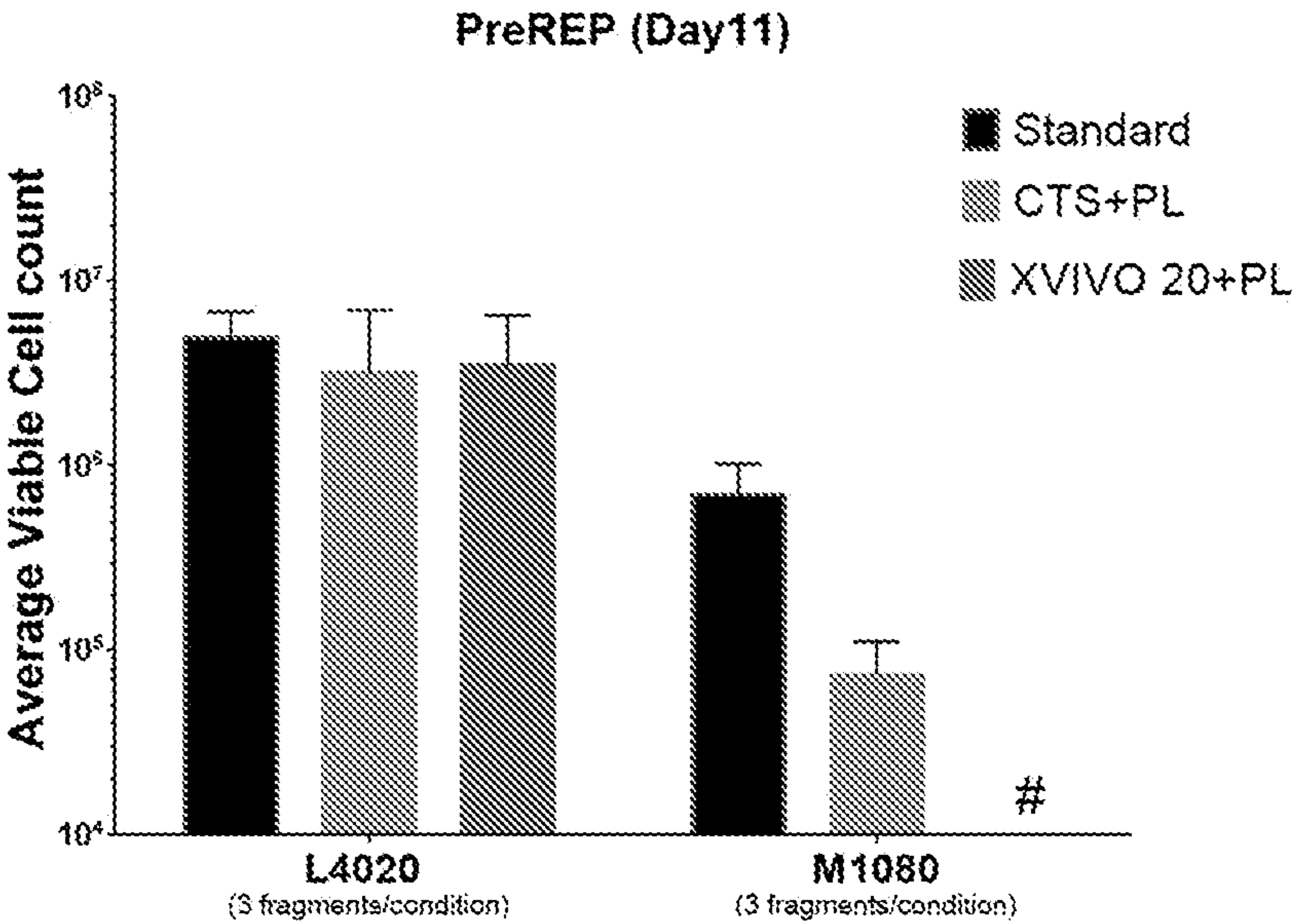


Figure 63

A)



B)

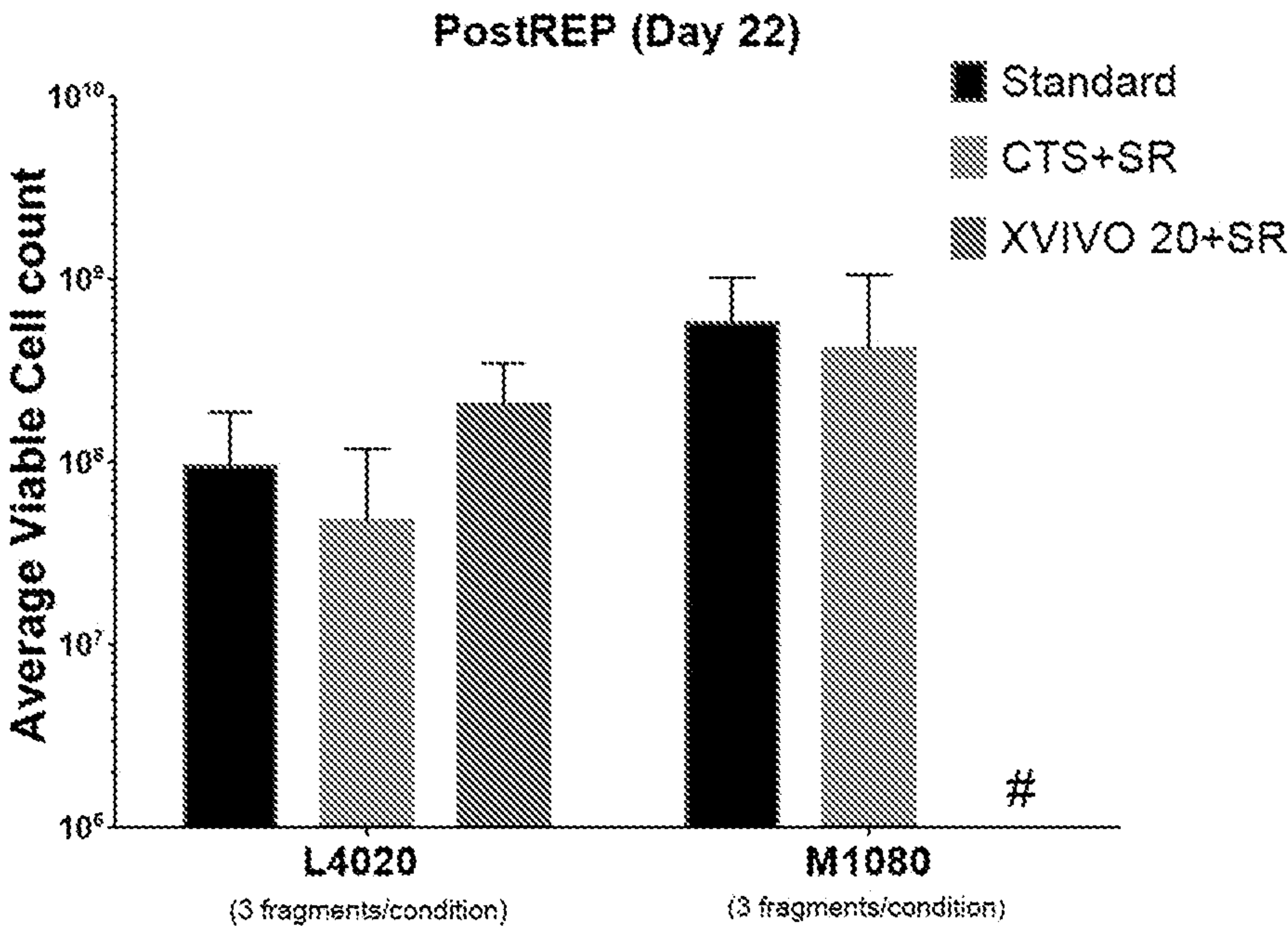


Figure 64A

A)

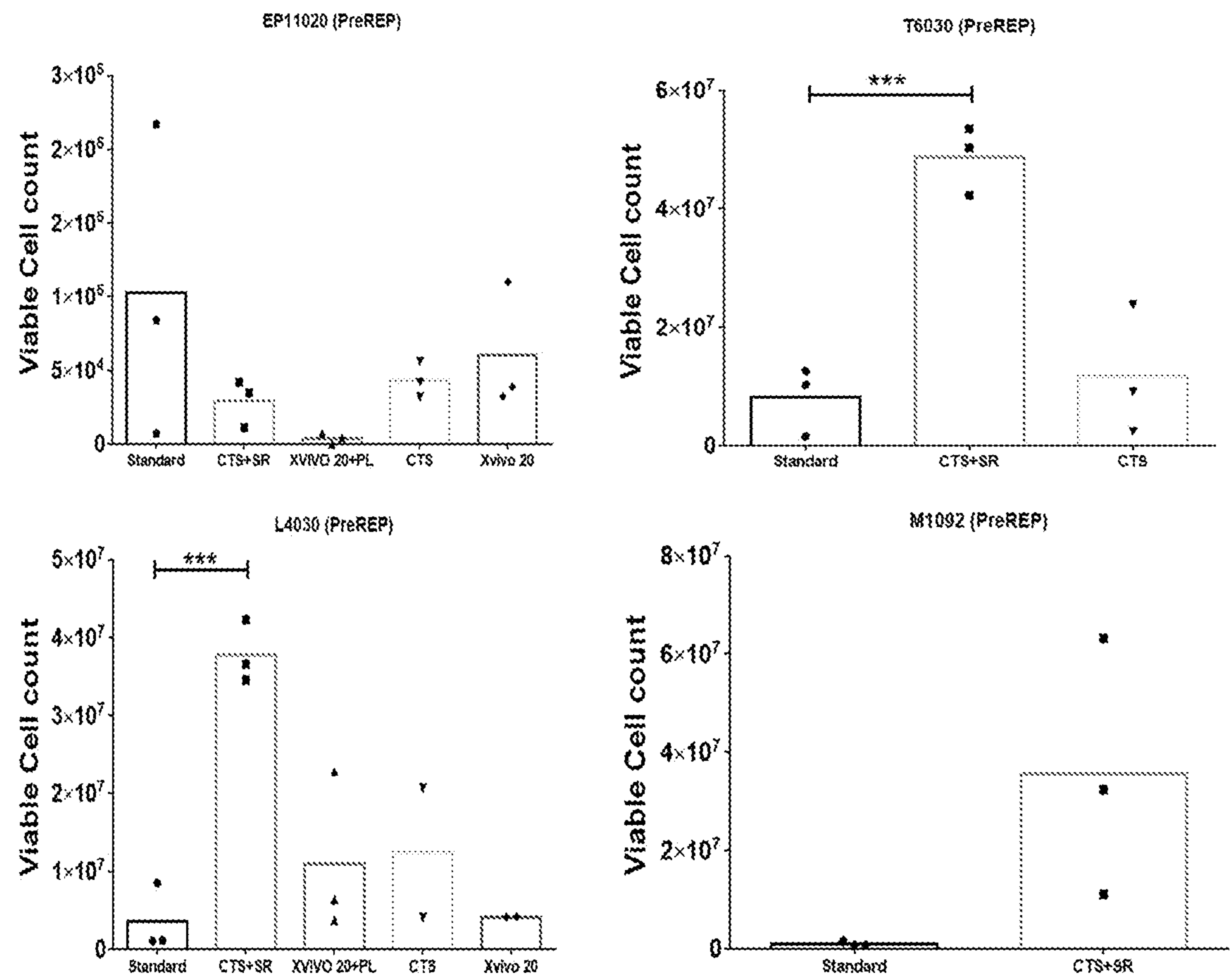


Figure 64B

B)

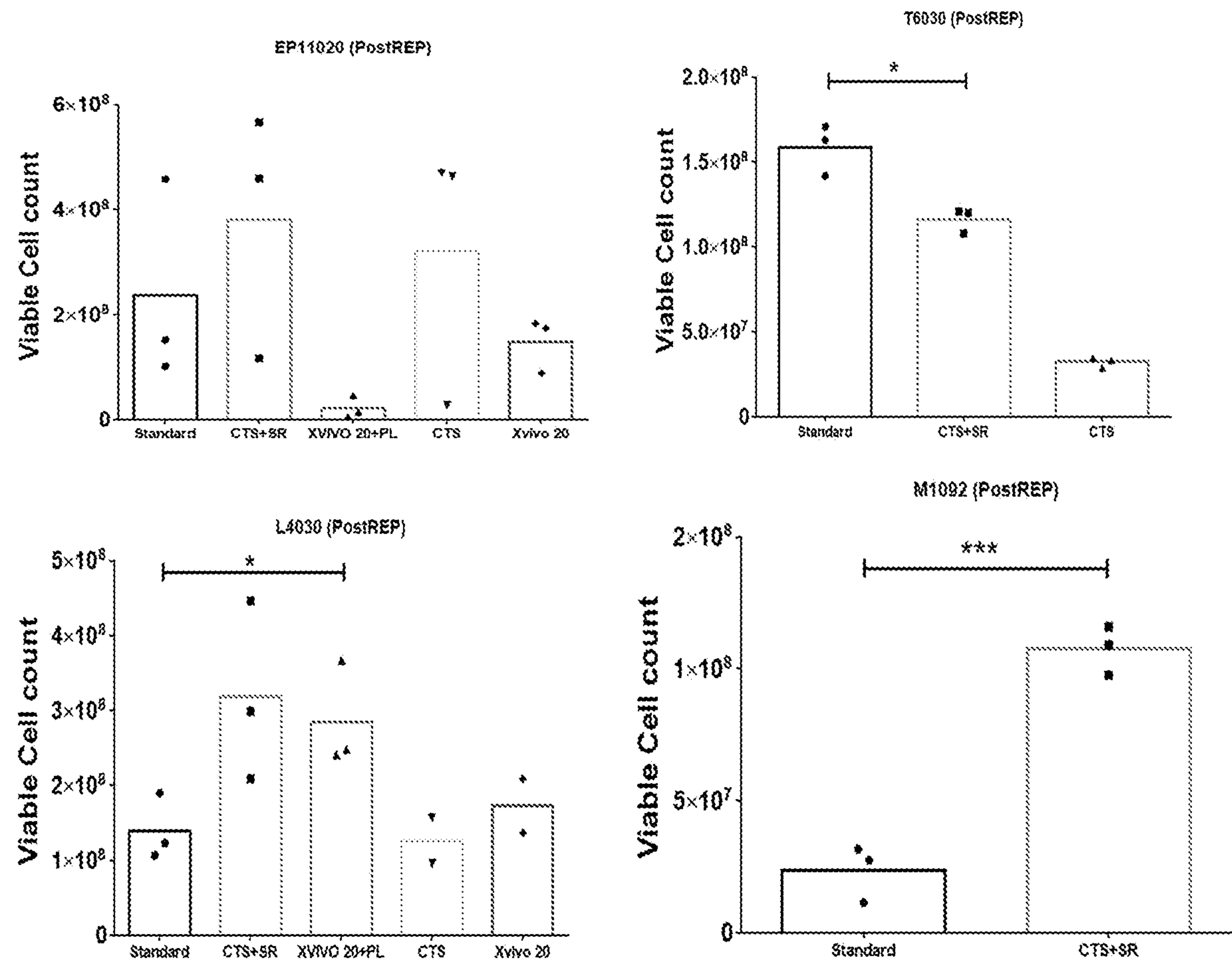
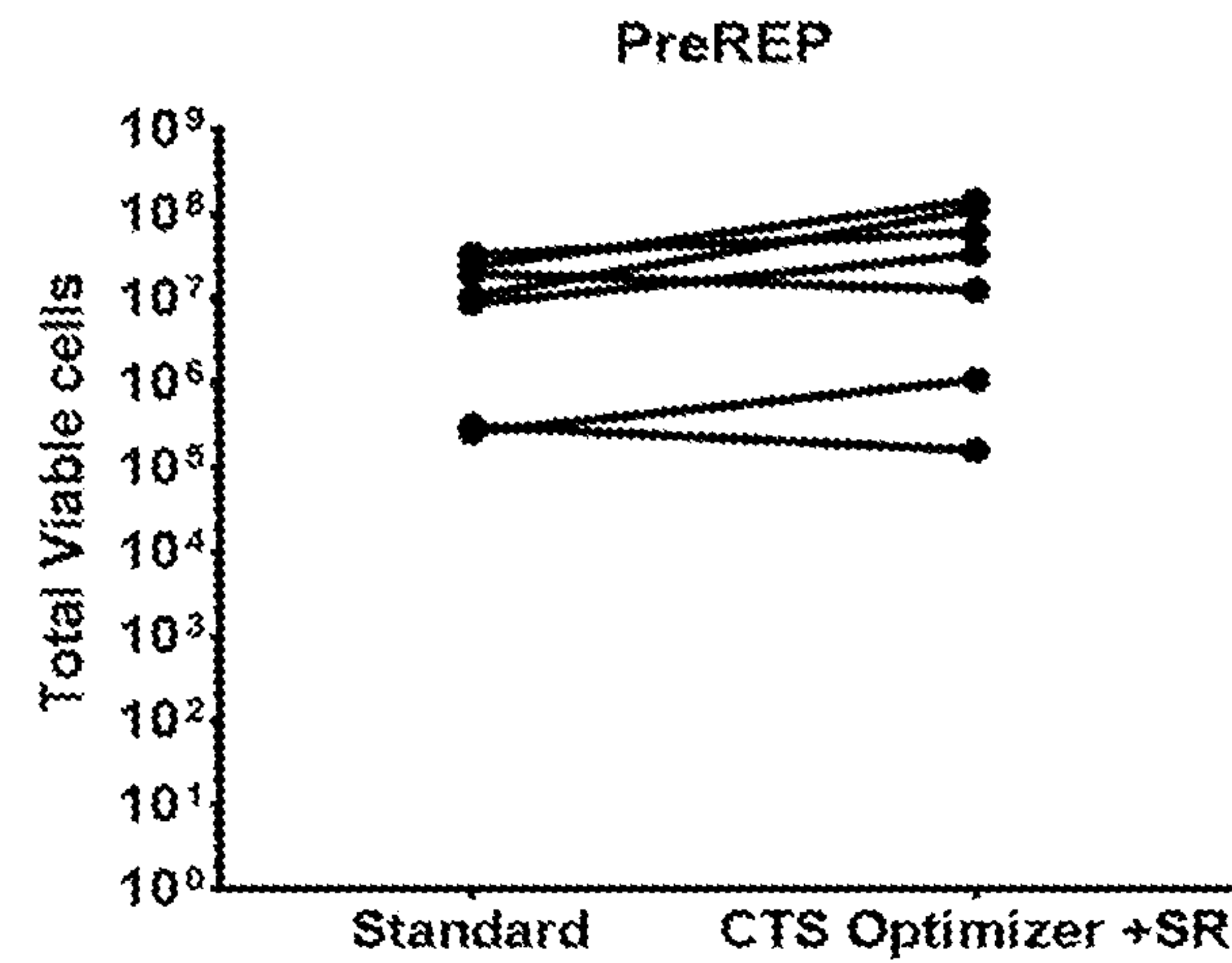


Figure 65A & 65B

A)



B)

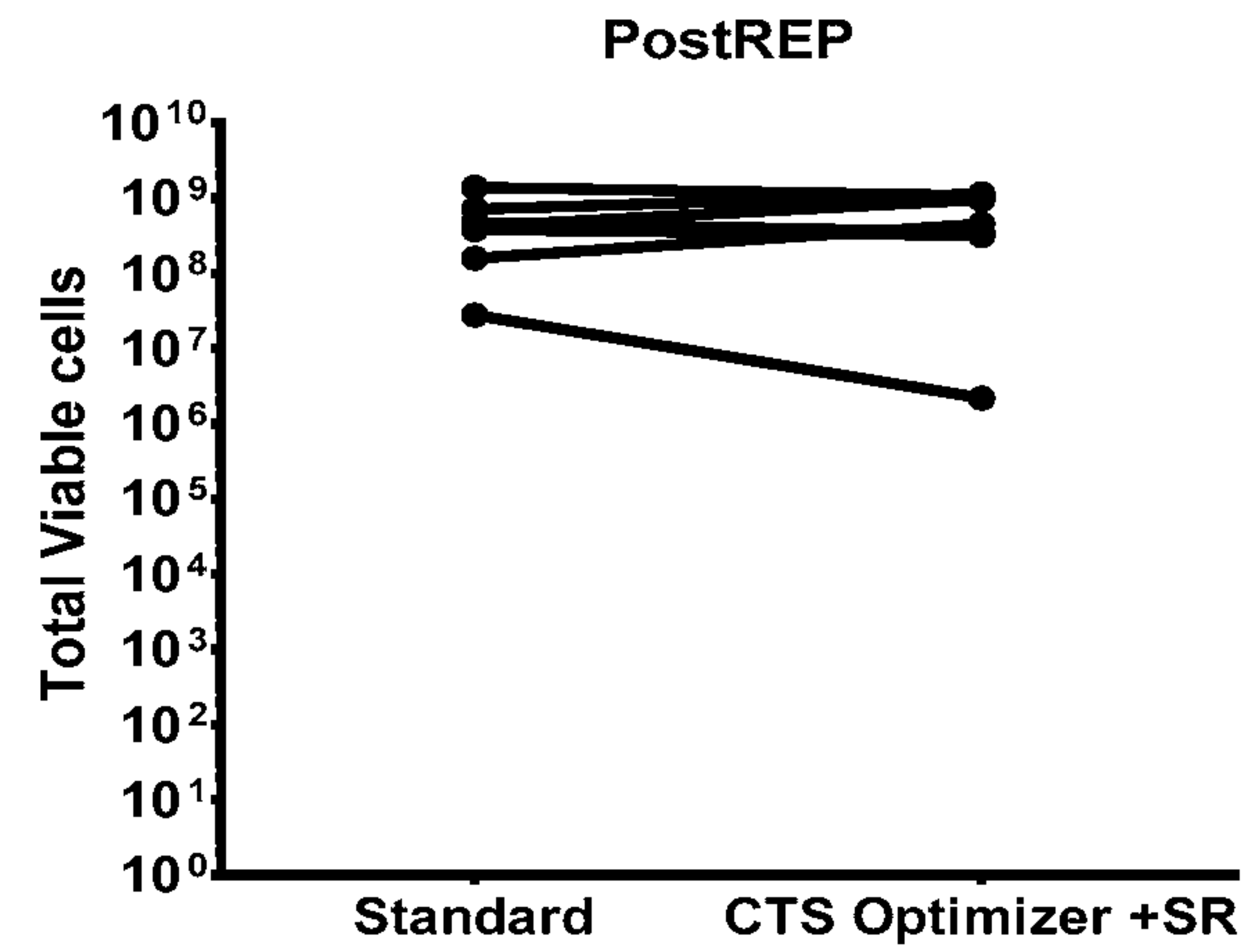


Figure 65C

C)

	Pre-REP Cell count		Post-REP Cell count	
	Standard	CTS Optimizer +SR	Standard	CTS Optimizer +SR
M1078	8.82E+07	3.38E+08	3.46E+09	2.73E+08
M1079	2.60E+06	1.09E+07	1.99E+10	5.61E+10
M1080				
L4020	1.98E+08	1.27E+08	4.75E+10	3.99E+10
L4026	1.68E+08	3.02E+08	8.63E+10	6.69E+10
L4030	7.05E+07	7.48E+08	2.63E+10	5.96E+10
EP11020	2.04E+06	1.06E+06	4.44E+10	7.14E+10
T6030	1.61E+08	9.64E+08	2.98E+10	2.18E+10
M1092	2.00E+07	7.05E+08	4.41E+09	2.02E+10

Figure 66

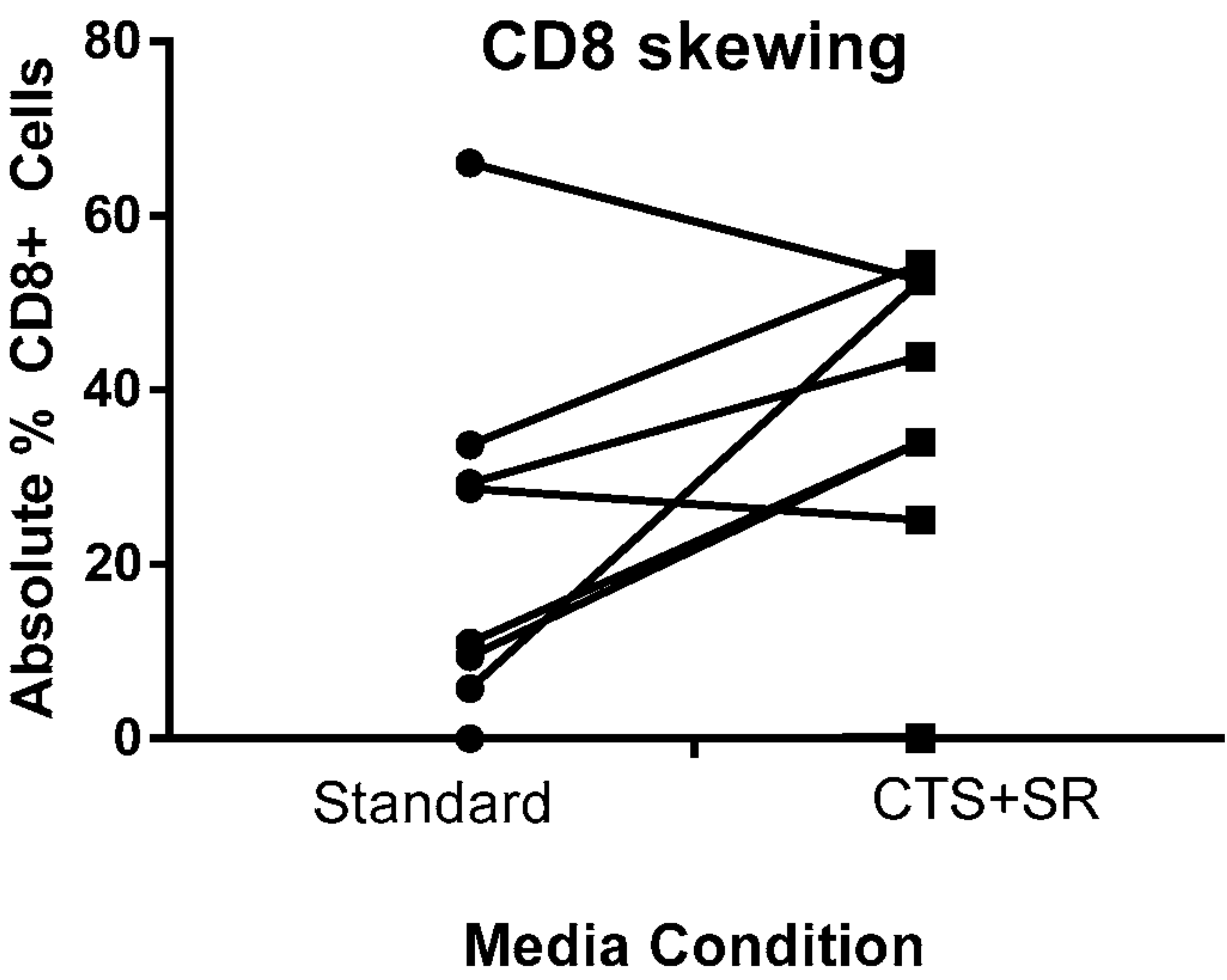
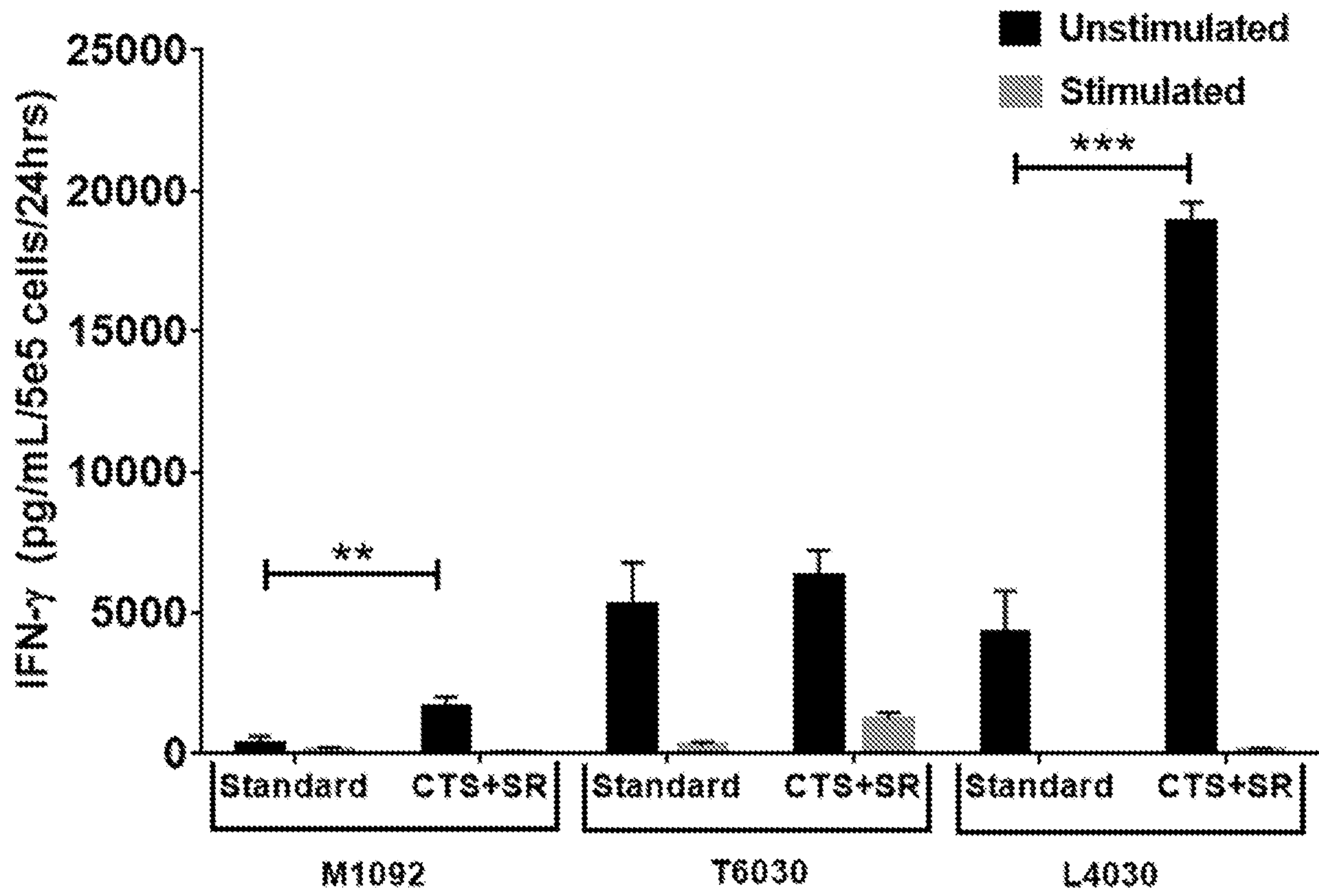


Figure 67



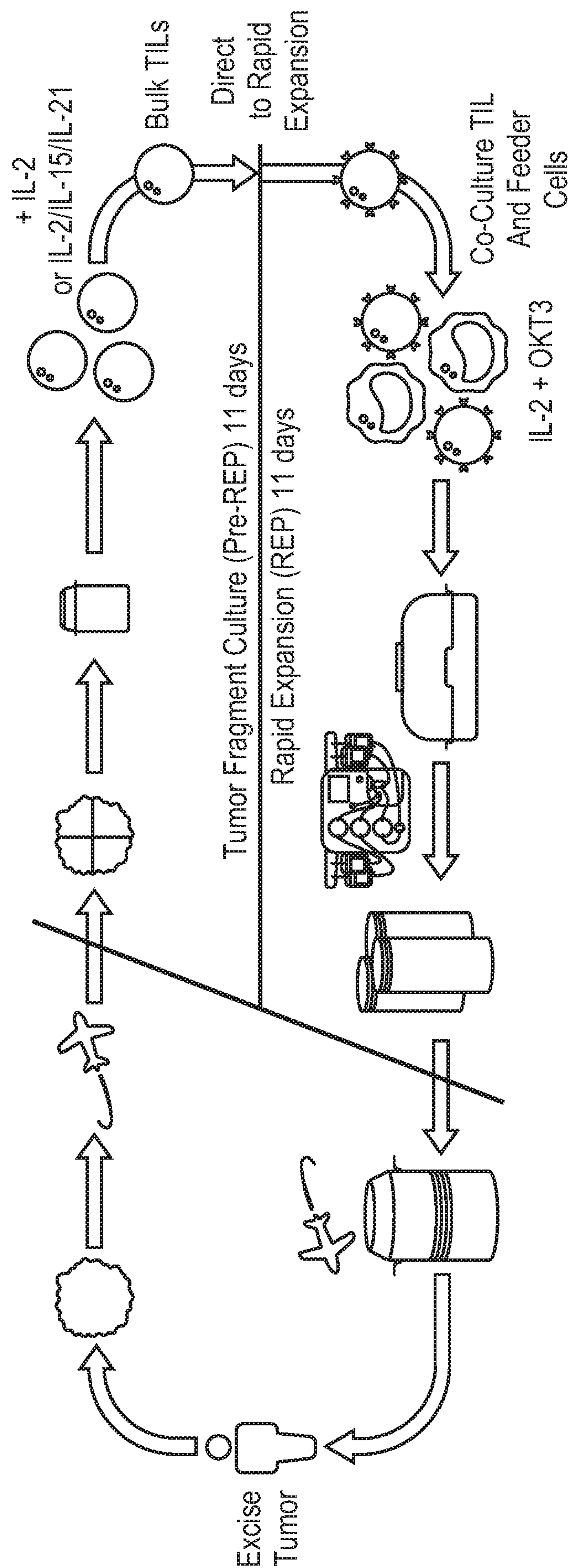


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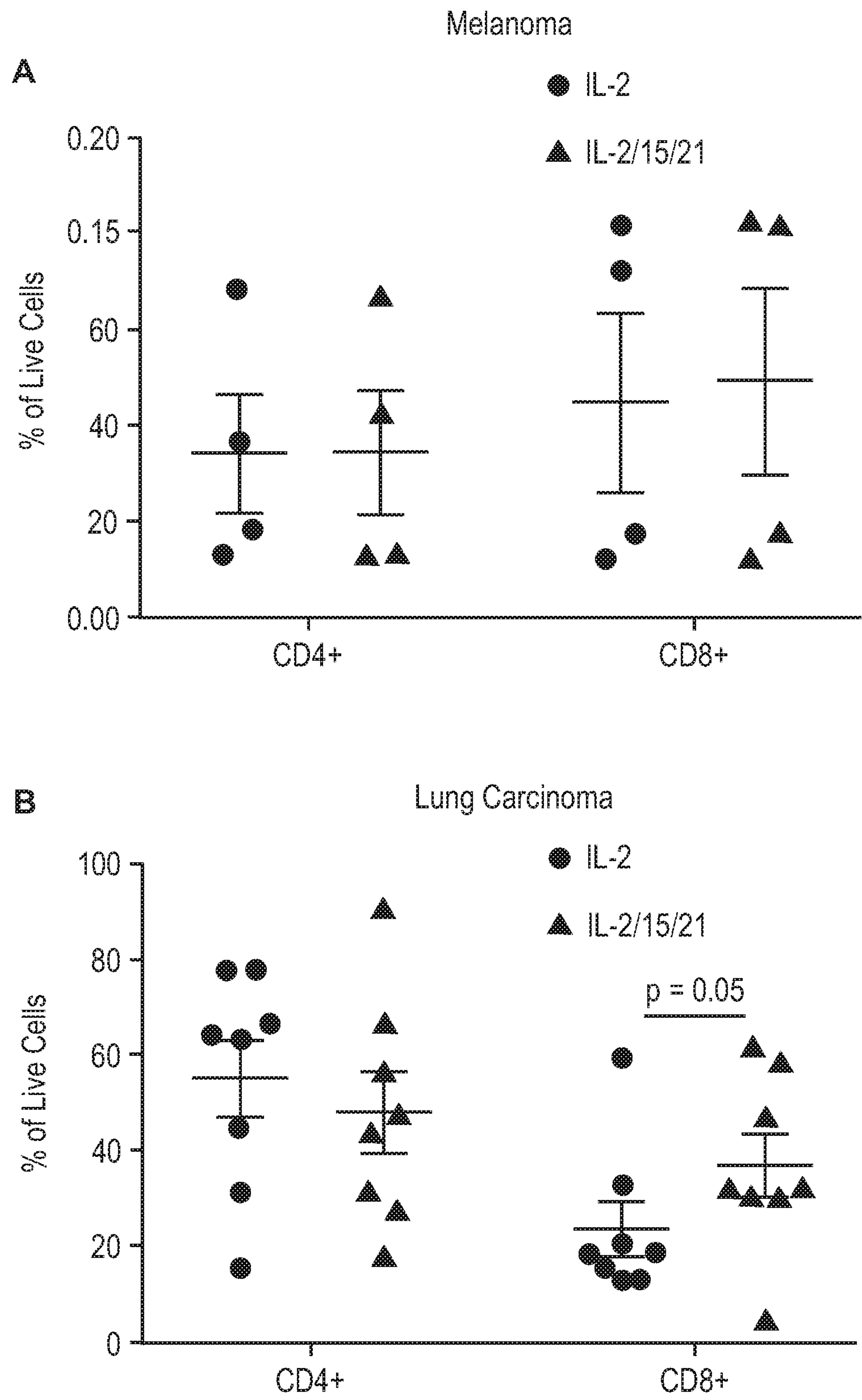


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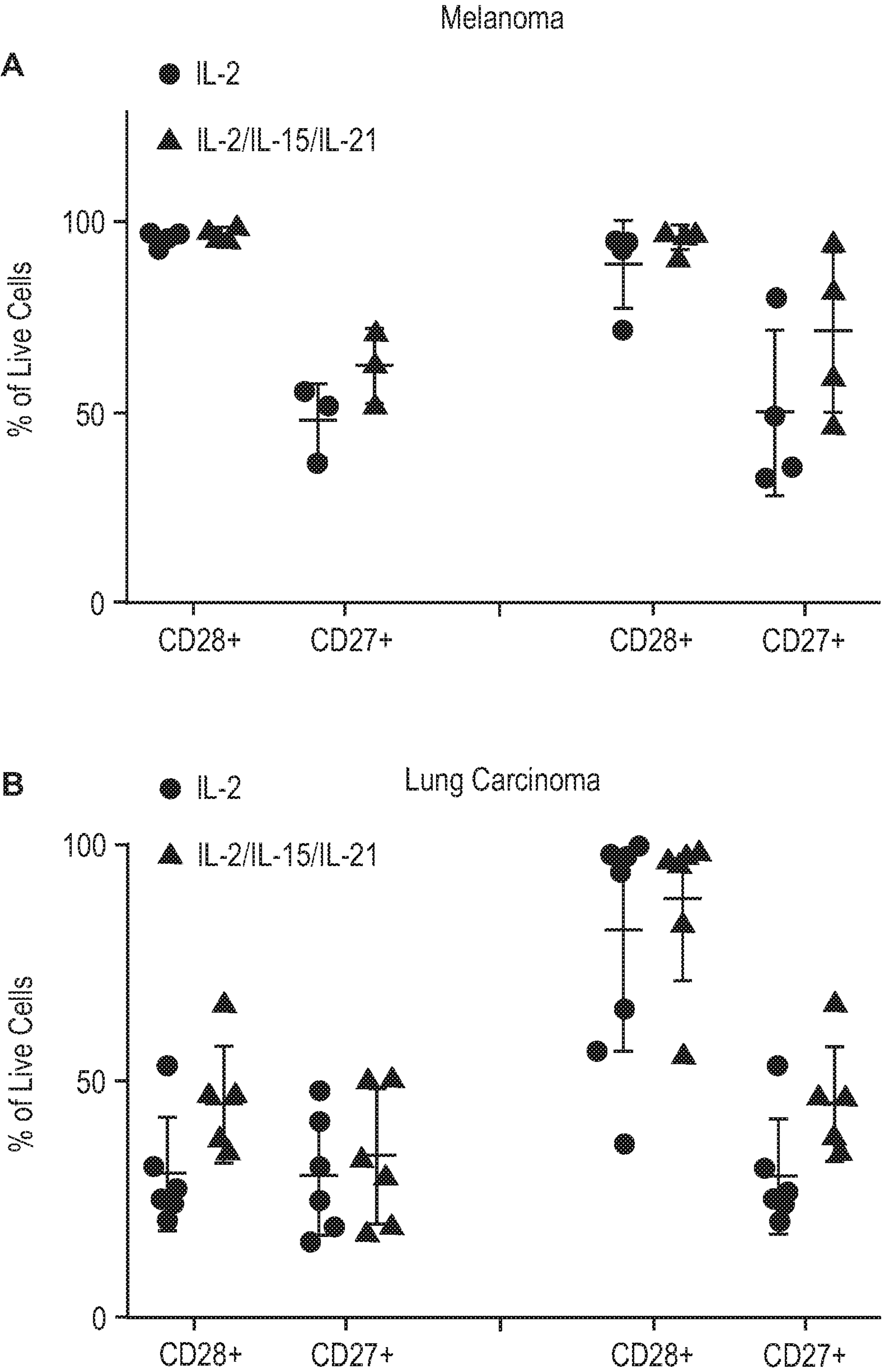


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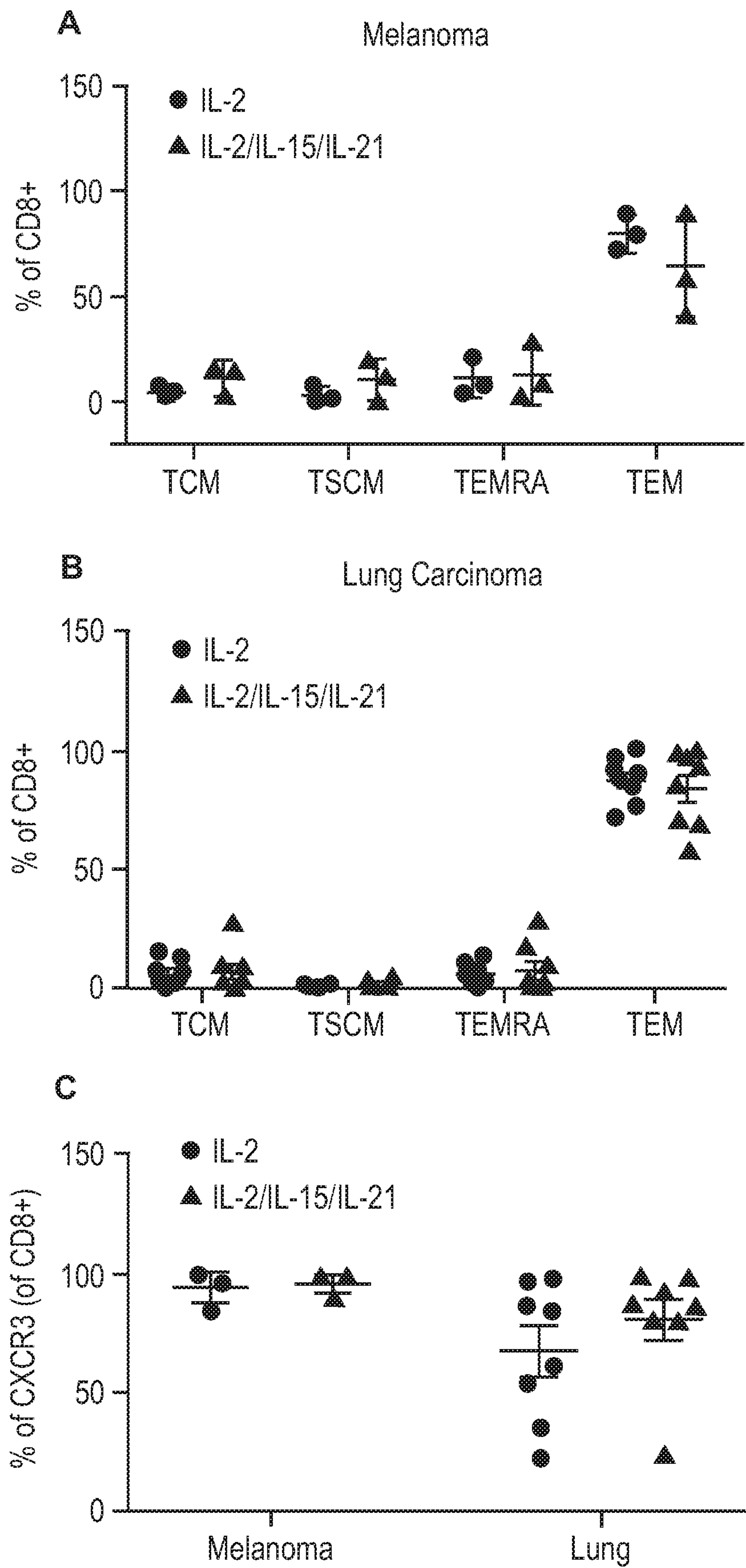


Figure 71

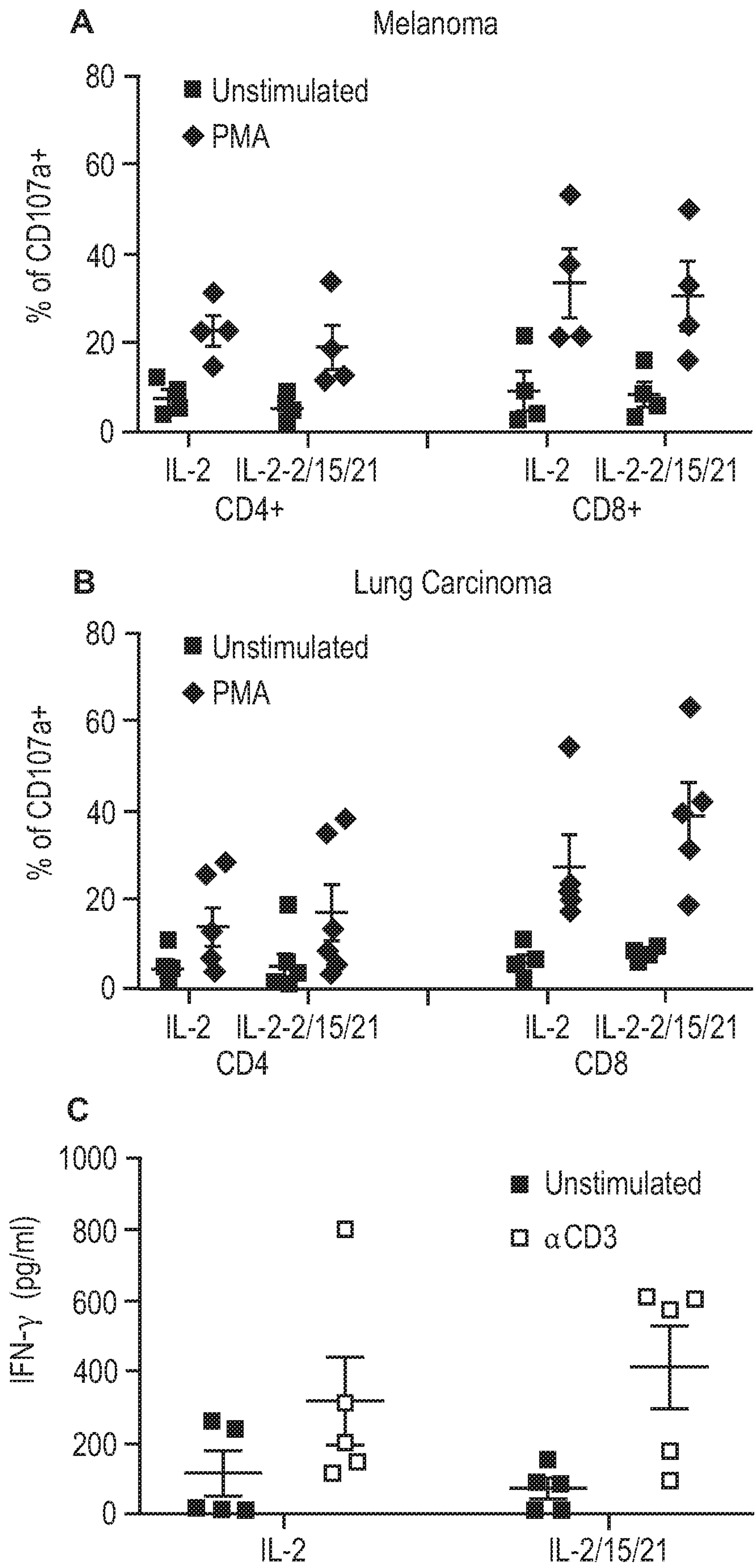


Figure 72

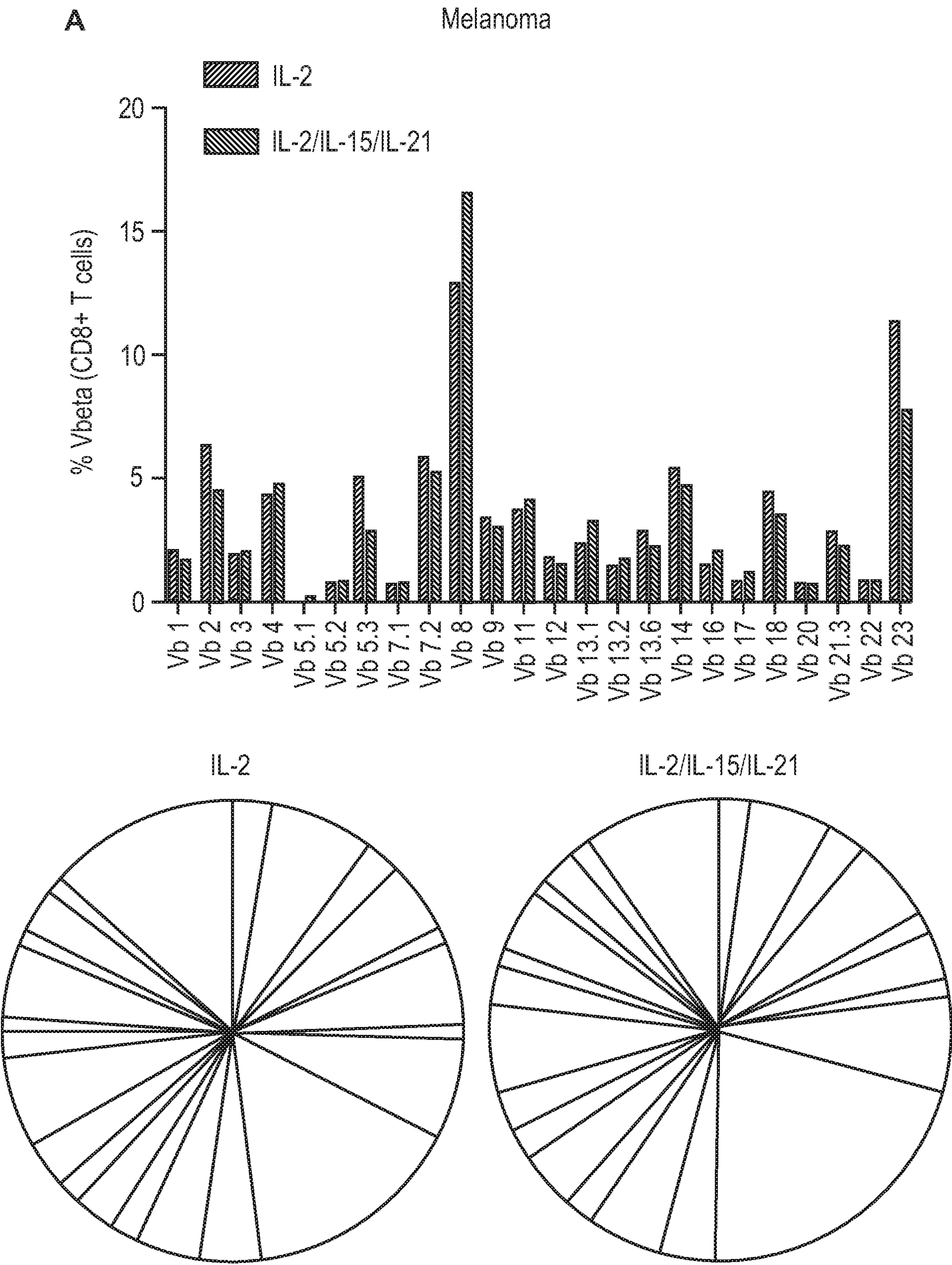


Figure 73

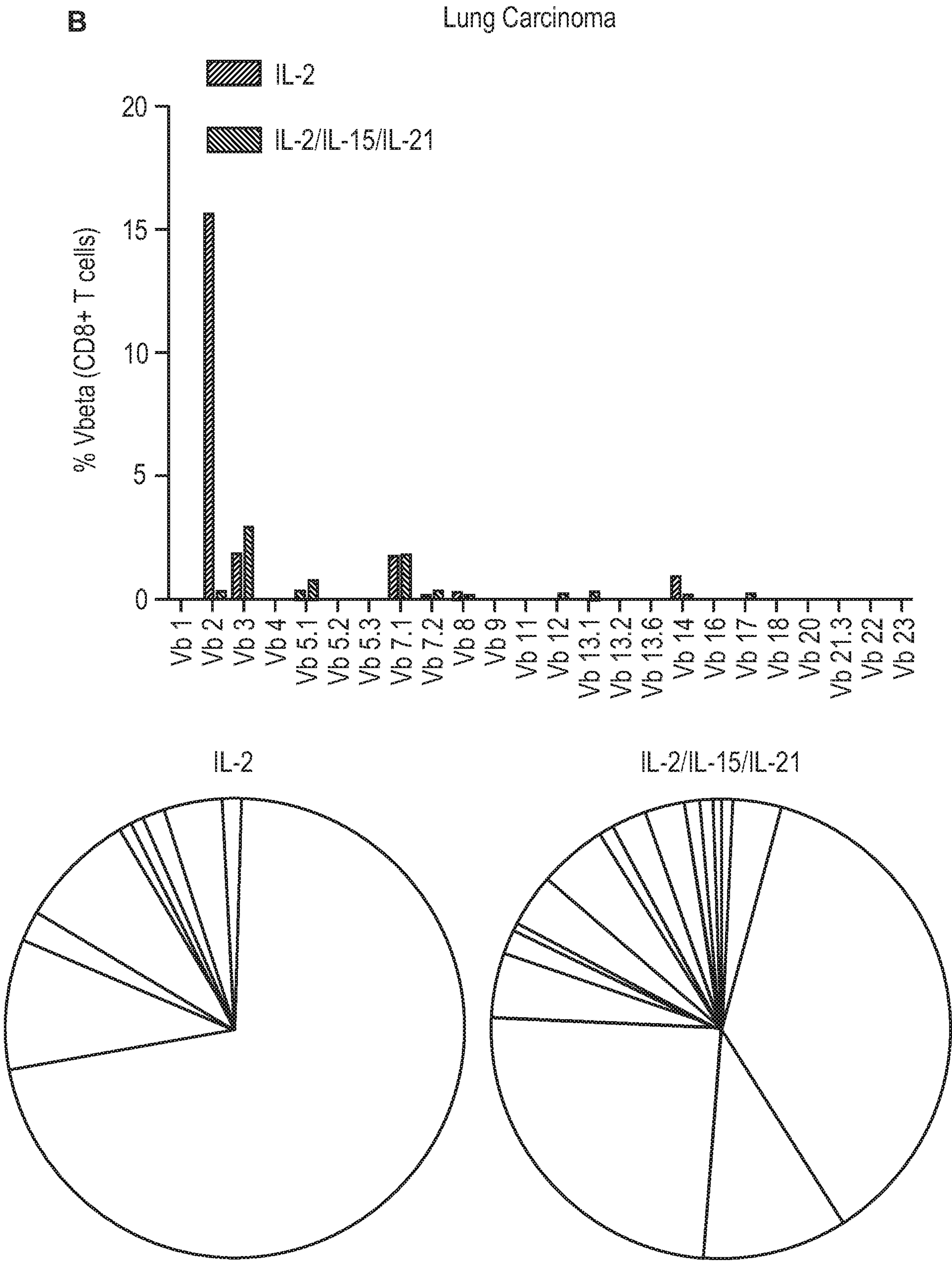


Figure 73

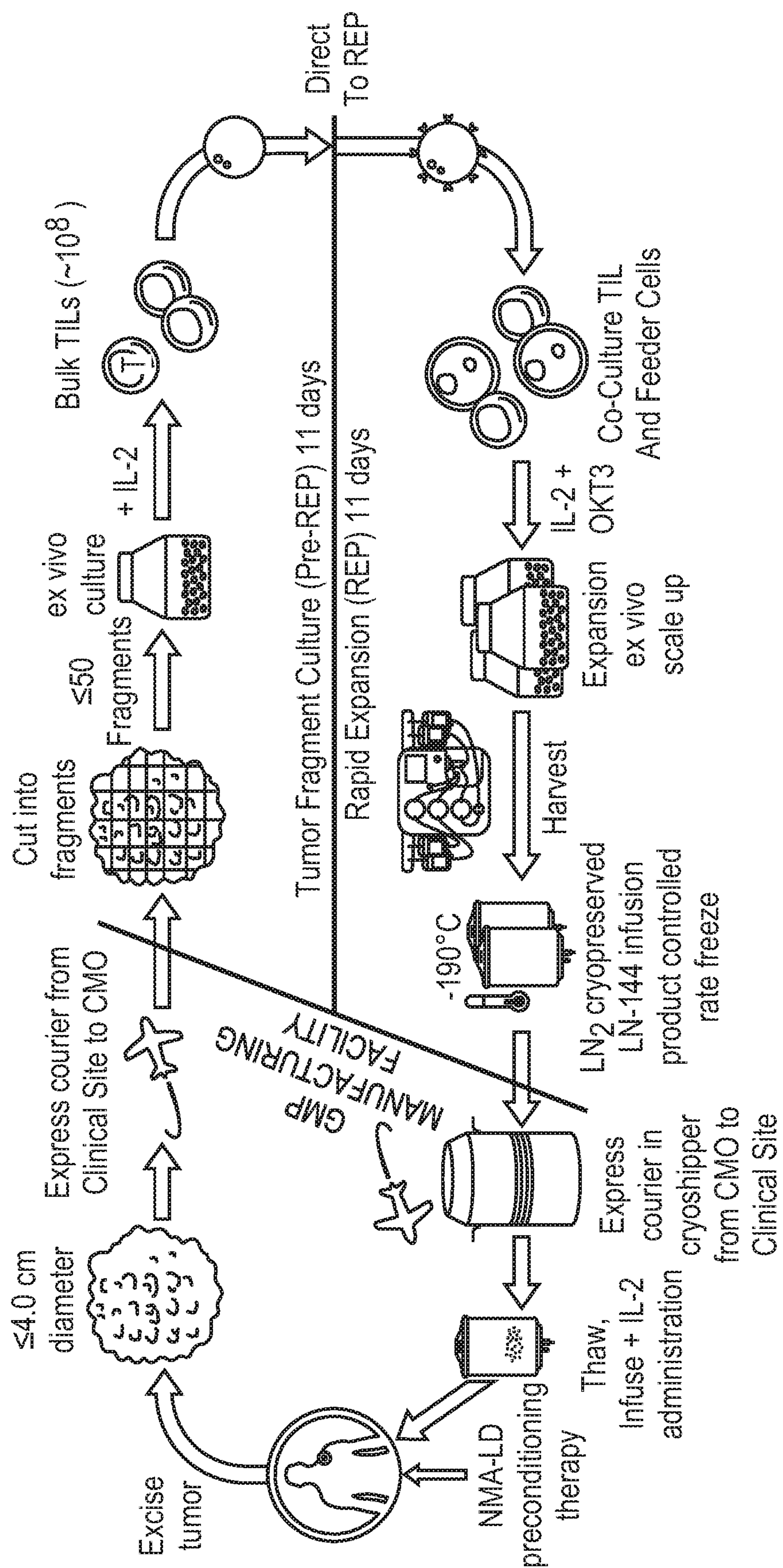


Figure 74

Figure 75

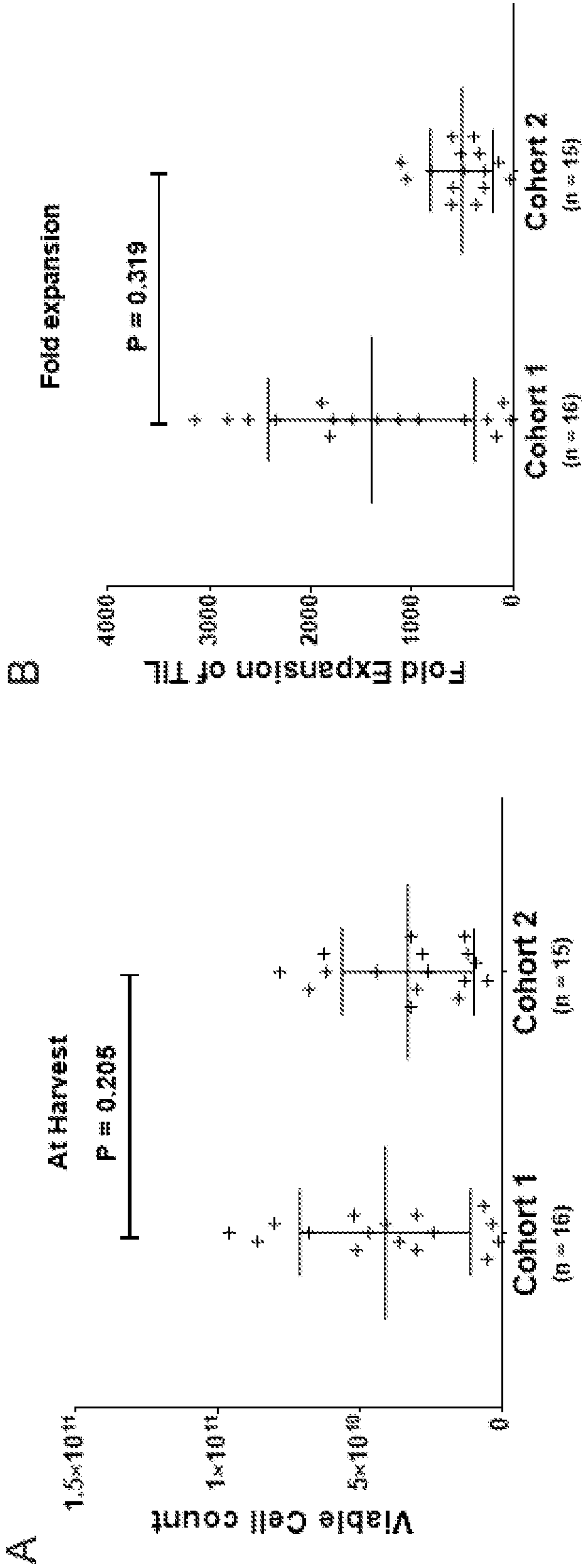


Figure 76

%CD45 CD3: Gen 1 vs. Gen 2

p=0.3 (ns)

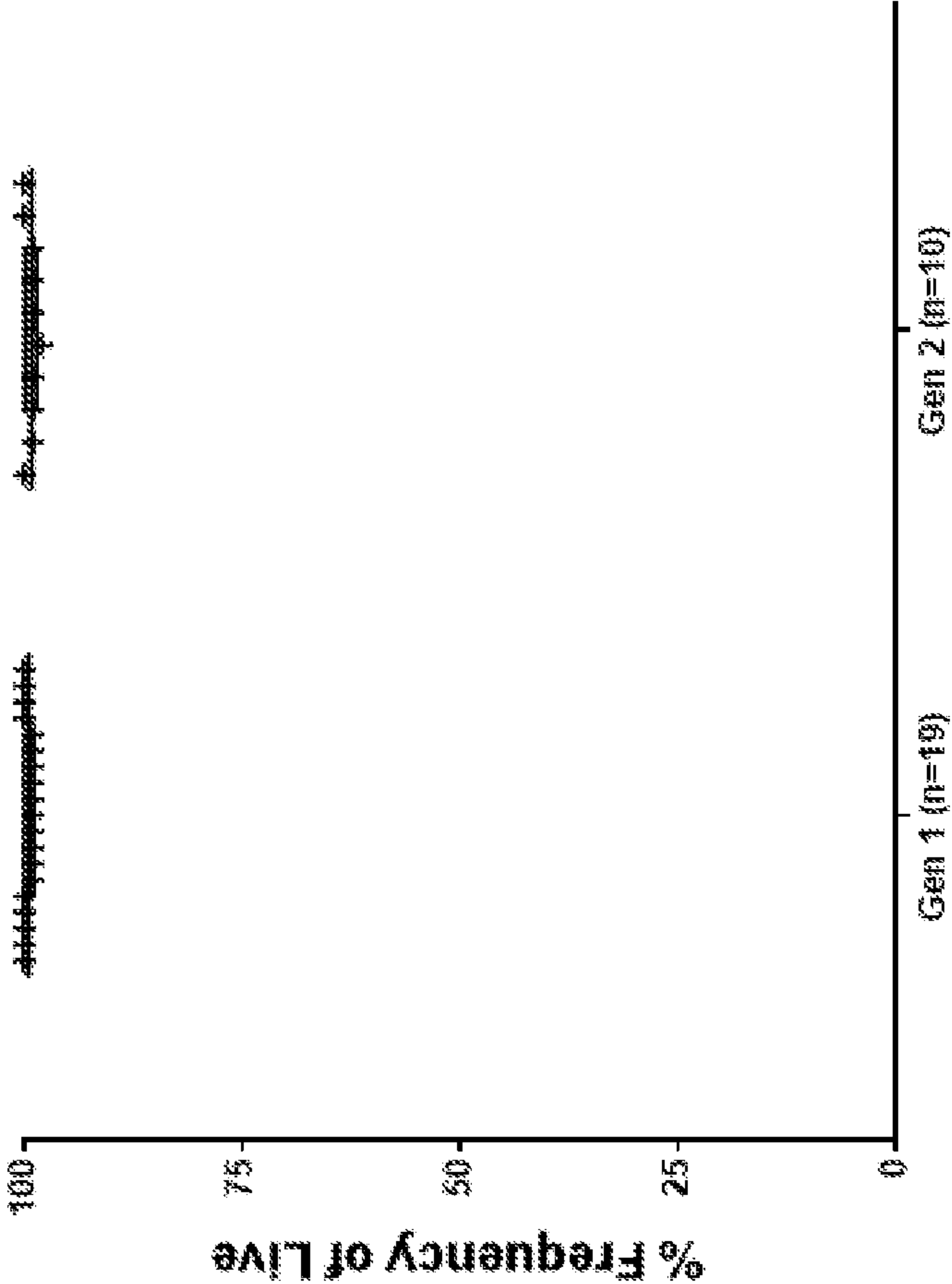


Figure 77

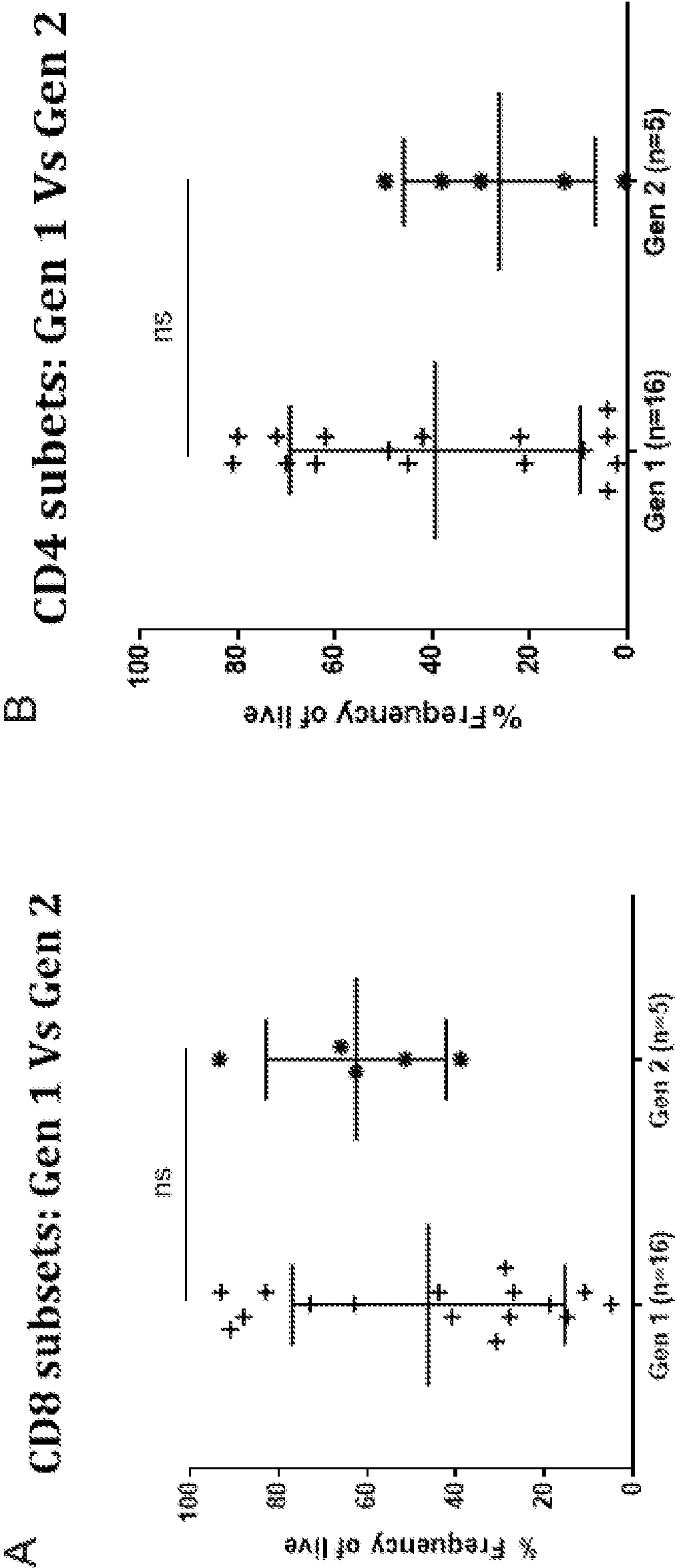


Figure 78

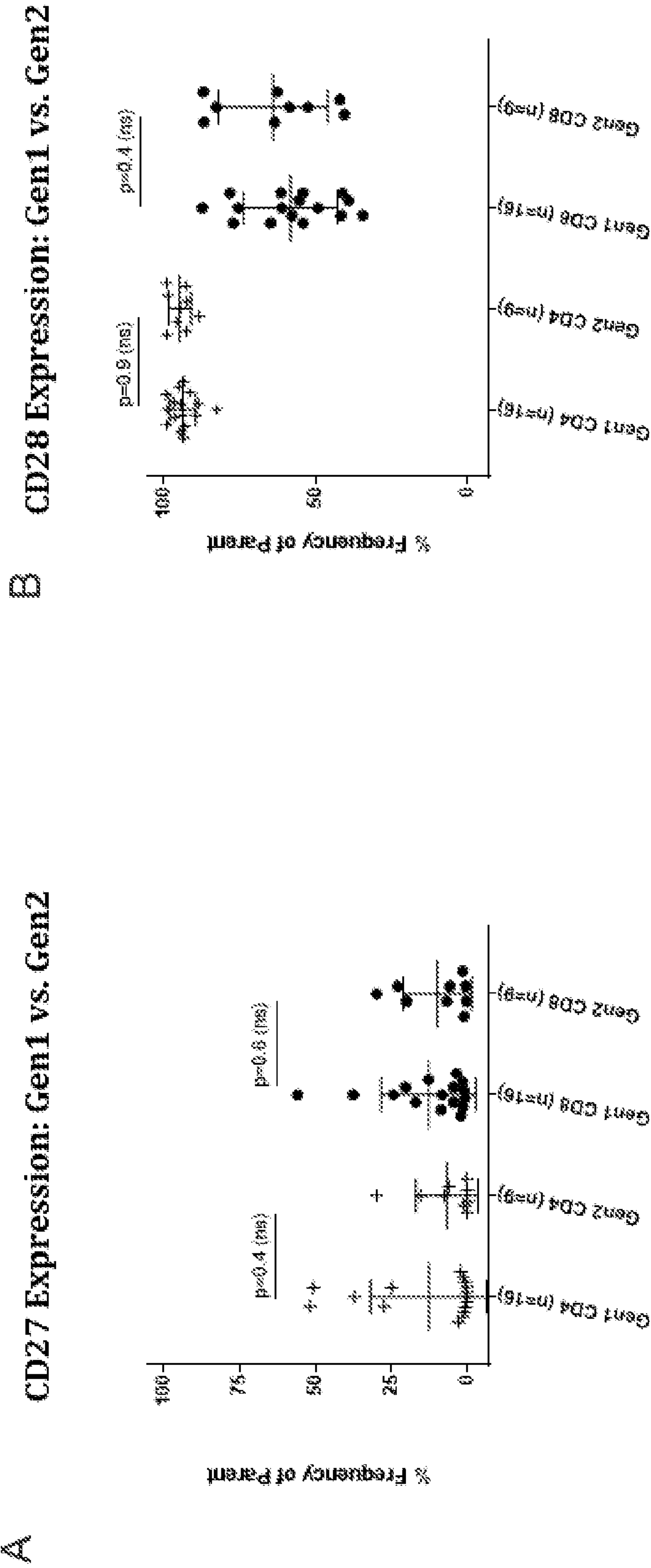


Figure 79

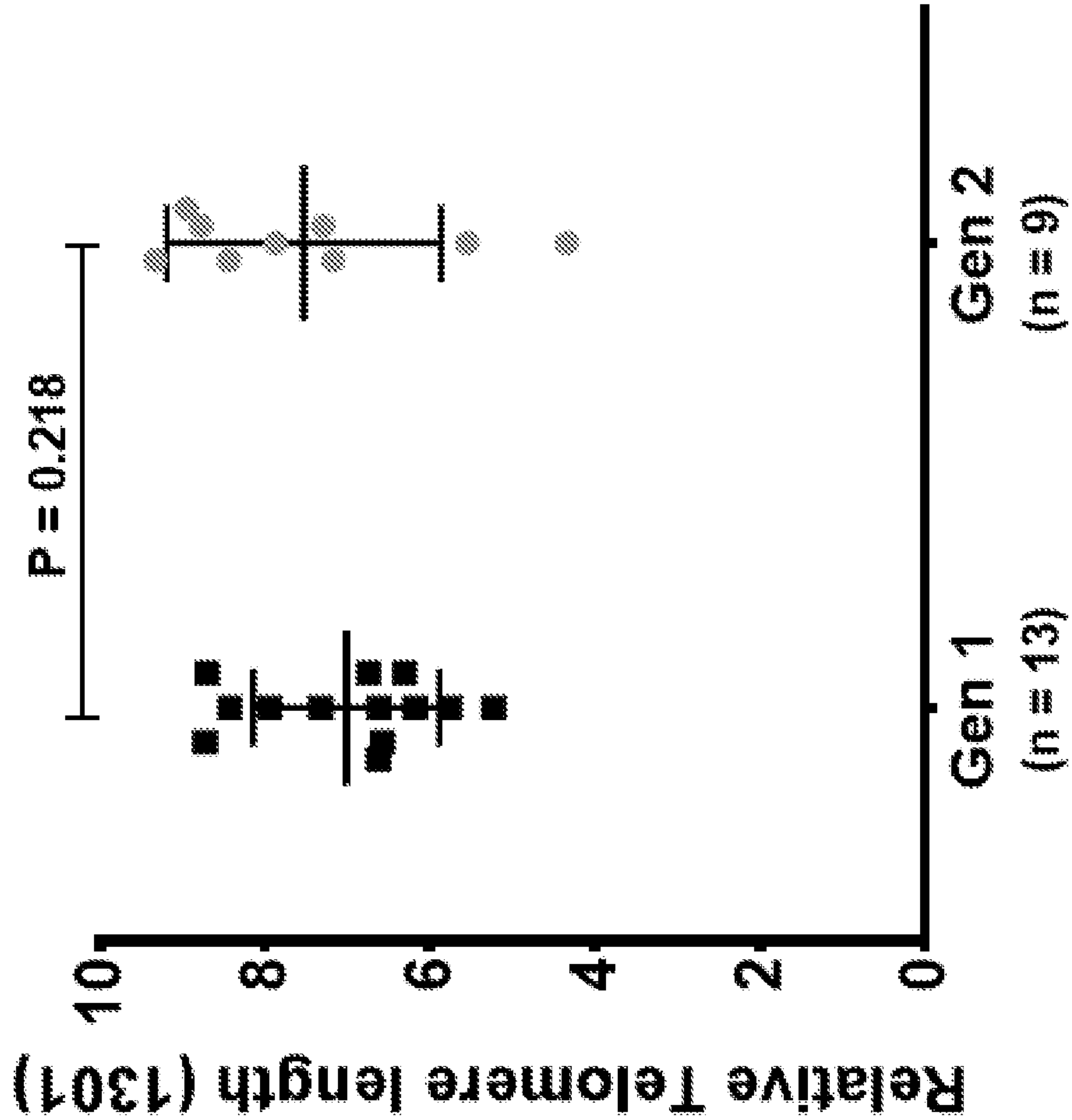


Figure 80

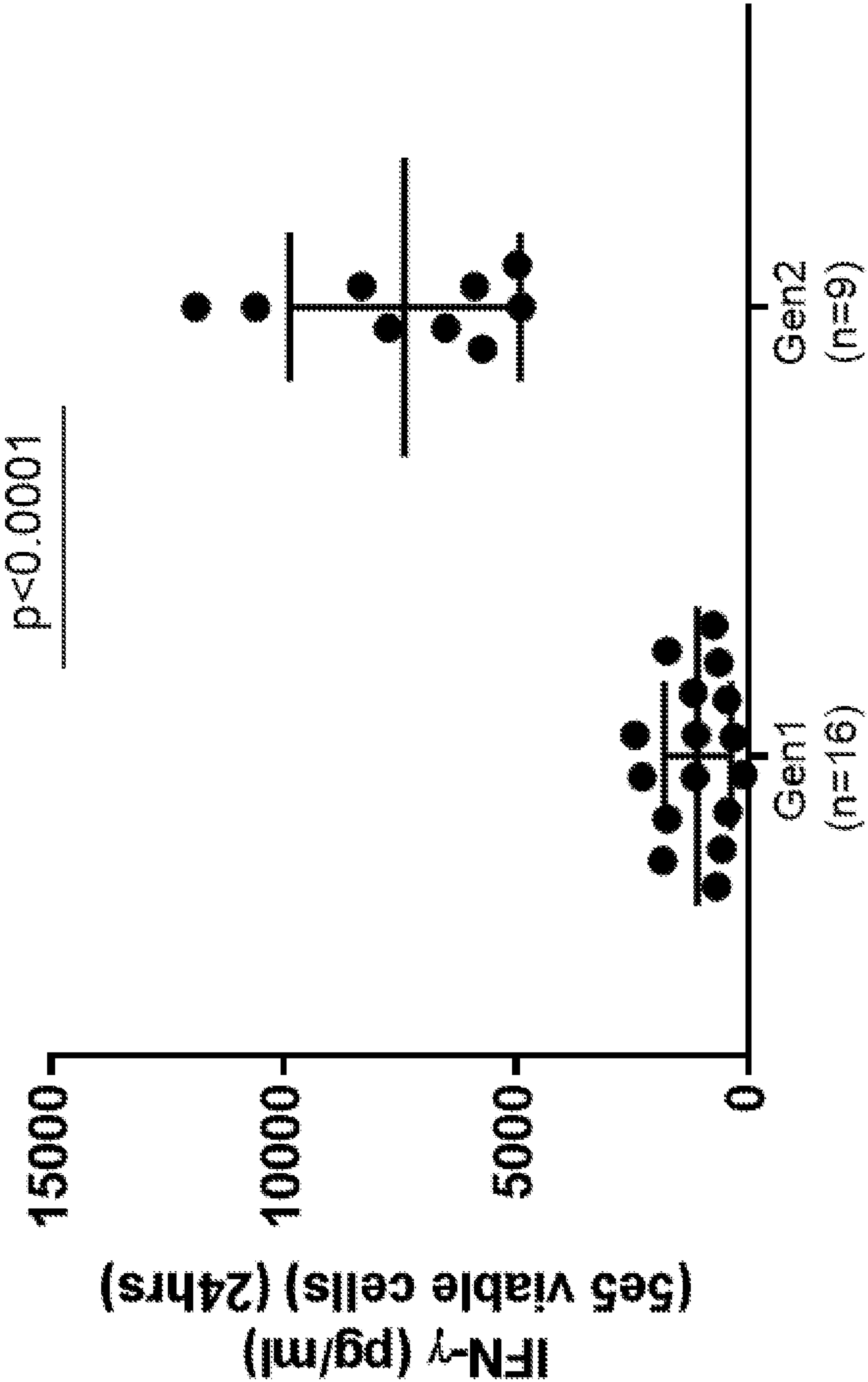
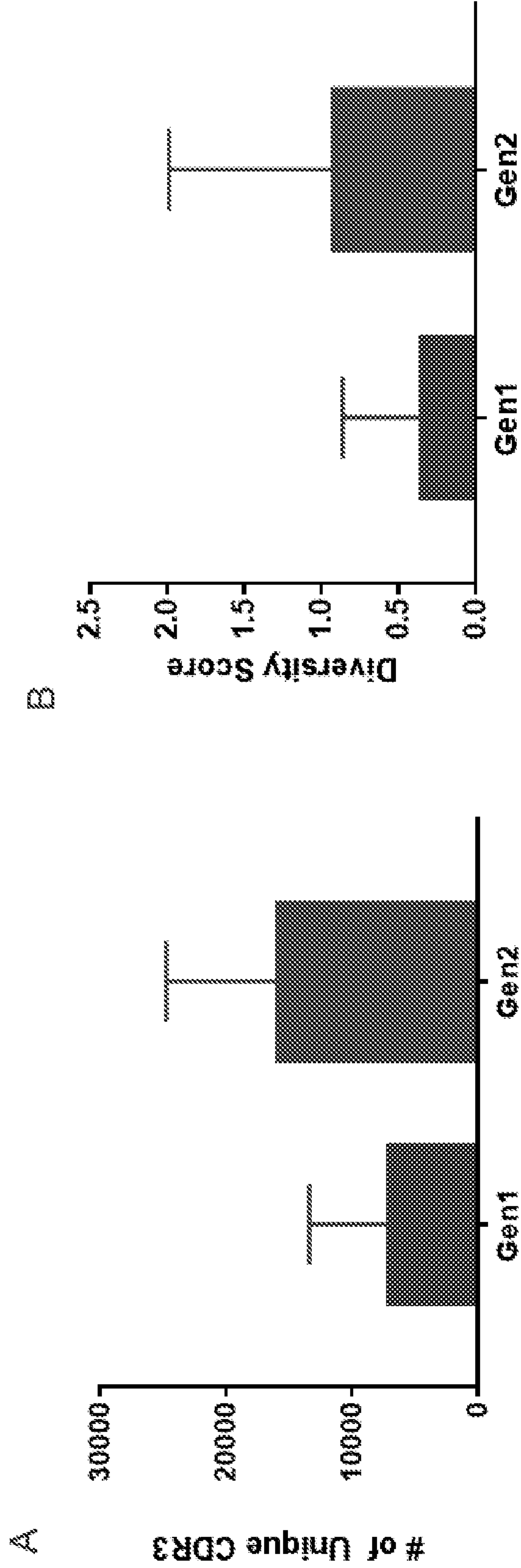


Figure 81



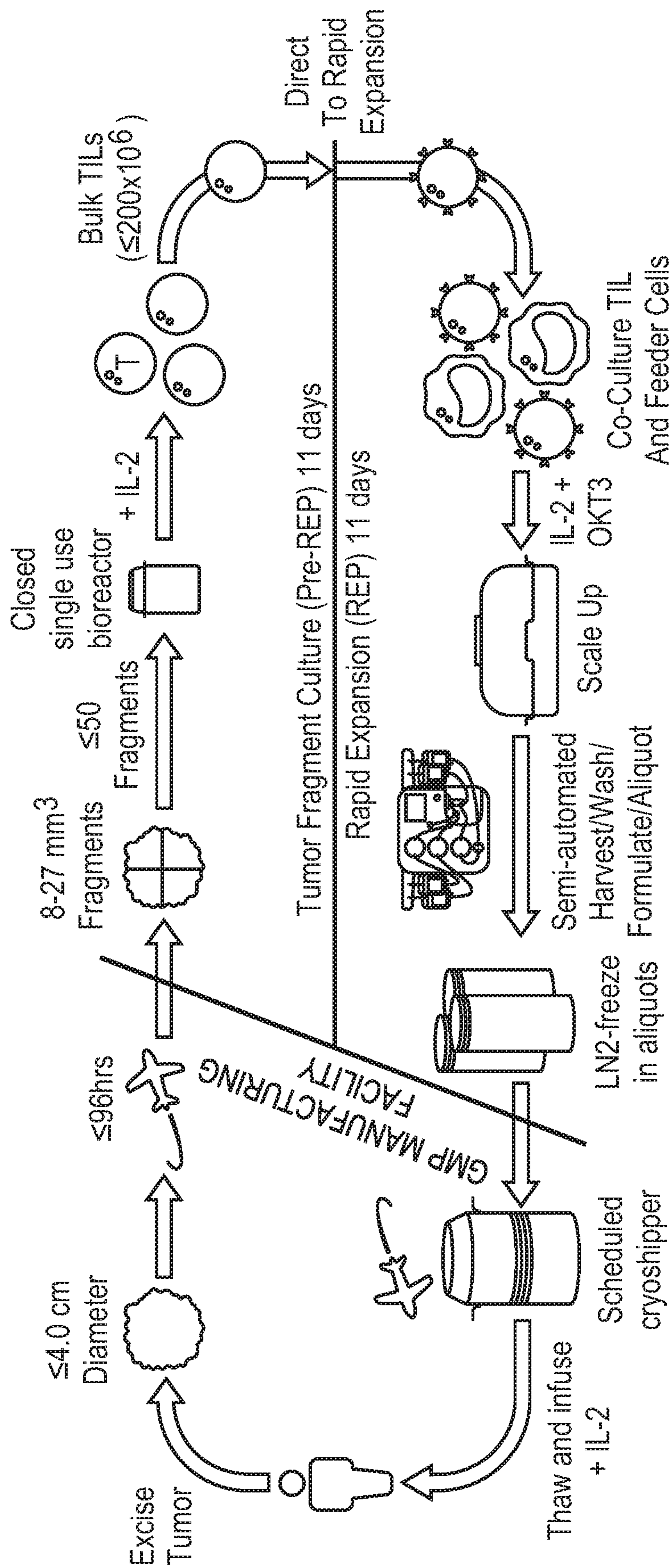


Figure 82

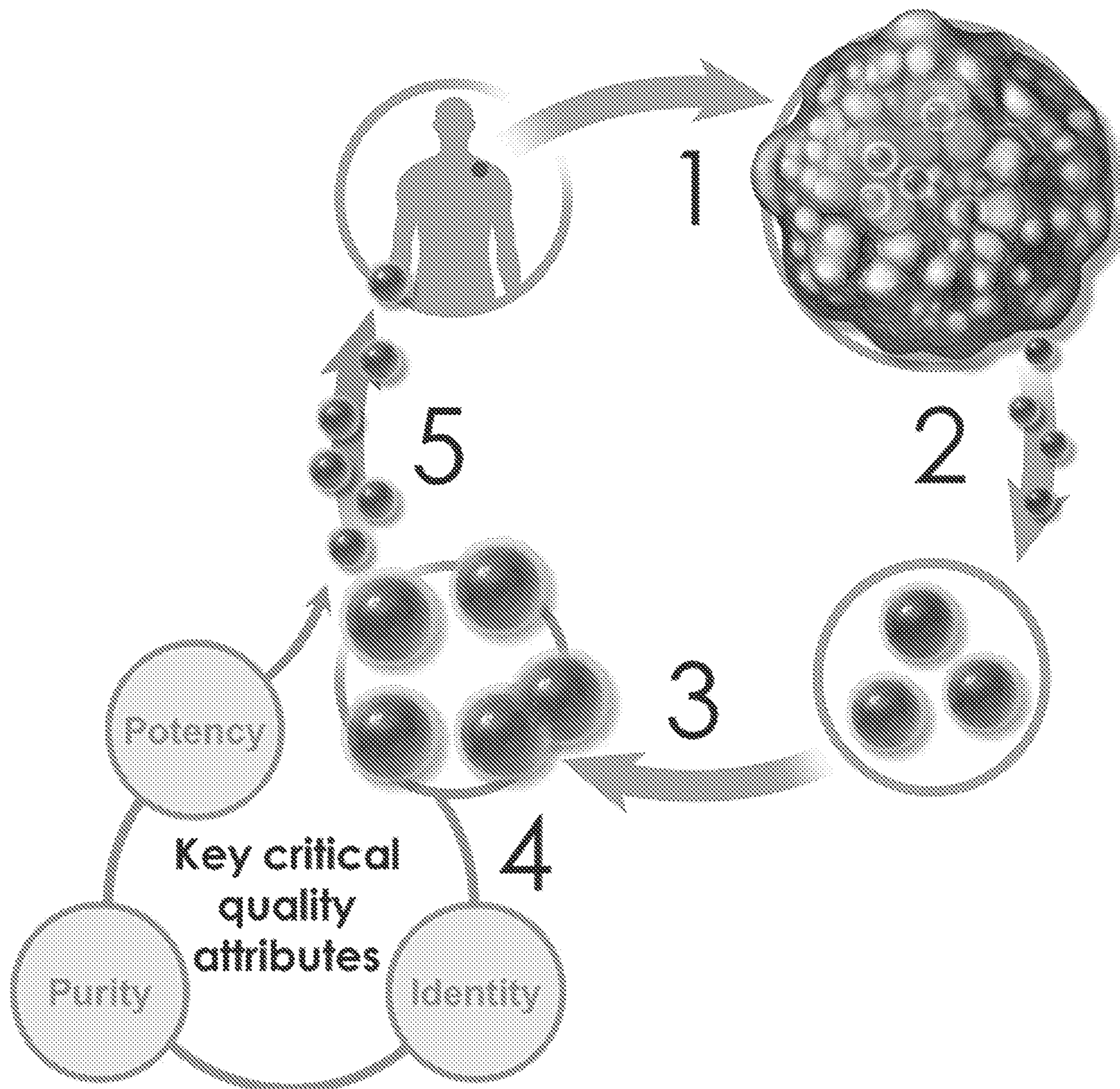
Figure 83

Process 1C: 43-55 Days for Steps A - E	Process 2A: about 22 days from Steps A - E
1. <u>STEP A</u> Obtain Patient Tumor Sample	2. <u>STEP A</u> Obtain Patient Tumor Sample
3. <u>STEP B</u> Fragmentation and First Expansion 11 days to 21 days	3. <u>STEP B</u> Fragmentation and First Expansion 3 days to 14 days
3. <u>STEP C</u> First Expansion to Second Expansion Transition Optional Storage until Selection	4. <u>STEP C</u> First Expansion to Second Expansion Transition No Storage and Closed System
5. <u>STEP D</u> Second Expansion IL-2, OKT-3, antigen-presenting feeder cells Optionally repeat one or more times	5. <u>STEP D</u> Second Expansion IL-2, OKT-3, and antigen-presenting feeder cells Closed System
6. <u>STEP E</u> Harvest TILS from Step D	7. <u>STEP E</u> Harvest TILS from Step D Closed System
6. <u>STEP F</u> Final Formulation and/or Transfer to Infusion Bag	8. <u>STEP F</u> Final Formulation and/or Transfer to Infusion Bag (optionally cryopreserve)

Figure 84

Process Step	Process 1C Embodiment	Process 2A Embodiment	Advantages
Pre-REP	4 fragments per 10 GREX-10 flasks 11-21 day duration	40 fragments per 1 GREX-100M flask 11 day duration	- Increased tumor fragments per flask - Shortened culture time - Reduced number of steps - Amenable to closed system
Pre-REP to REP Transition	- Pre-REP TIL are frozen until phenotyped for selection then thawed to proceed to the REP (~day 30) - REP requires $>40 \times 10^6$ TIL	- Pre-REP TIL directly move to REP on day 11 - REP requires 25-200×10^6 TIL	- Shortened pre-REP-to-REP process - Reduced number of steps - Eliminated phenotyping selection - Amenable to closed system
REP	6 GREX-100M flasks on REP day 0 5×10^6 TIL and 5×10^8 PBMC feeders per flask on REP day 0 - Split to 18-36 flasks on REP day 7 14 day duration	1 GREX-500M flask on day 11 $25-200 \times 10^6$ TIL and 5×10^9 PBMC feeders on day 11 - Split to ≤ 6 GREX-500M flasks on day 16 11 day duration	- Reduced number of steps - Shorter REP duration - Closed system transfer of TIL between flasks - Closed system media exchanges
Harvest	TIL harvested via centrifugation	TIL harvested via LOVO automated cell washing system'	- Reduced number of steps - Automated cell washing - Closed system - Reduced loss of product during wash
Final Formulation	- Fresh product in Hypothermosol - Single infusion bag - Limited shipping stability	- Cyropreserved product in PlasmaLyte-A + 1% HSA and CS10 stored in LN₂ - Multiple aliquots - Longer shipping stability	- Shipping flexibility - Flexible patient scheduling - More timely release testing
Overall Estimated Process Time	43-55 days	22 days	Faster turnaround to patient

Figure 85



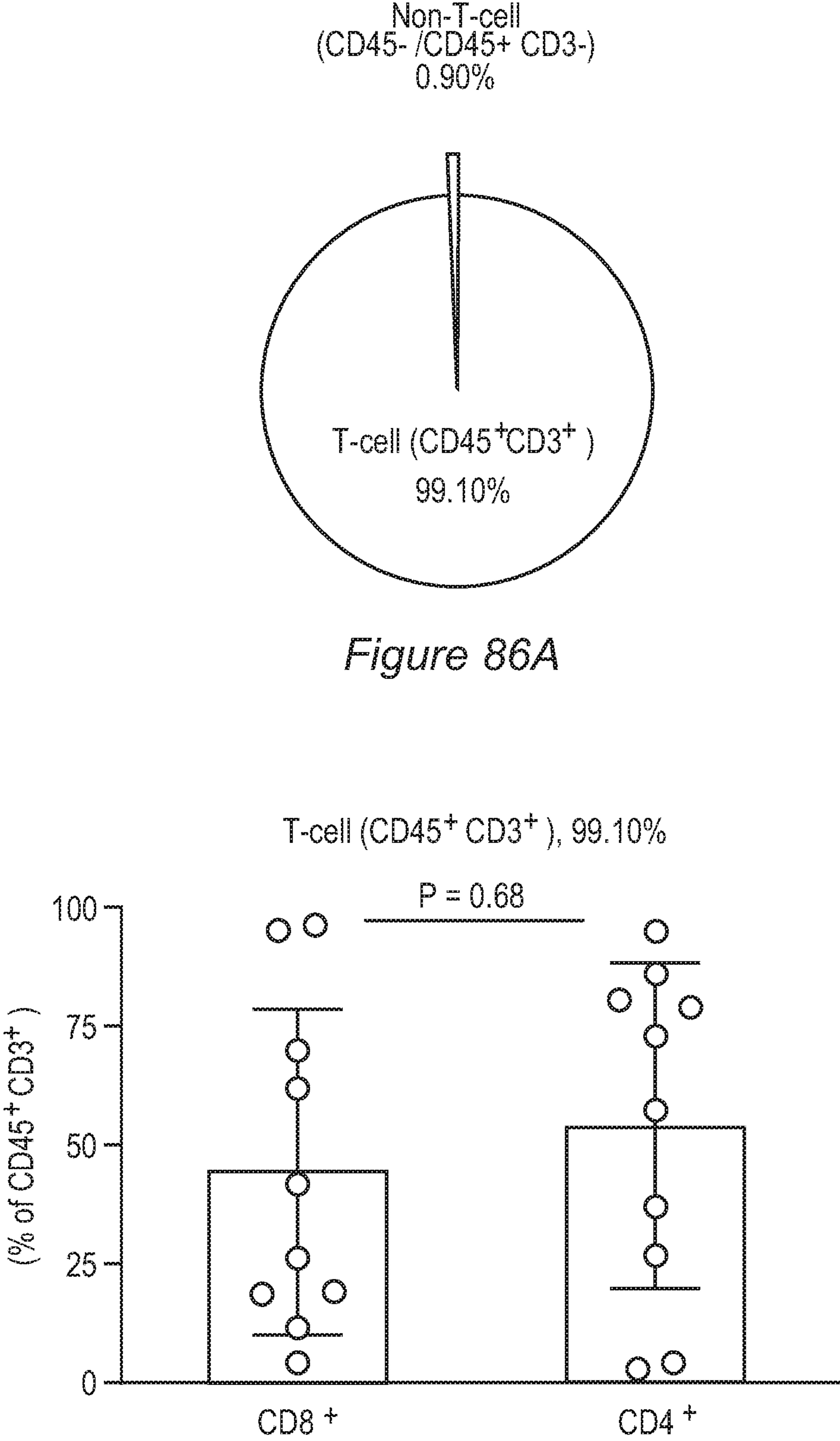


Figure 86B

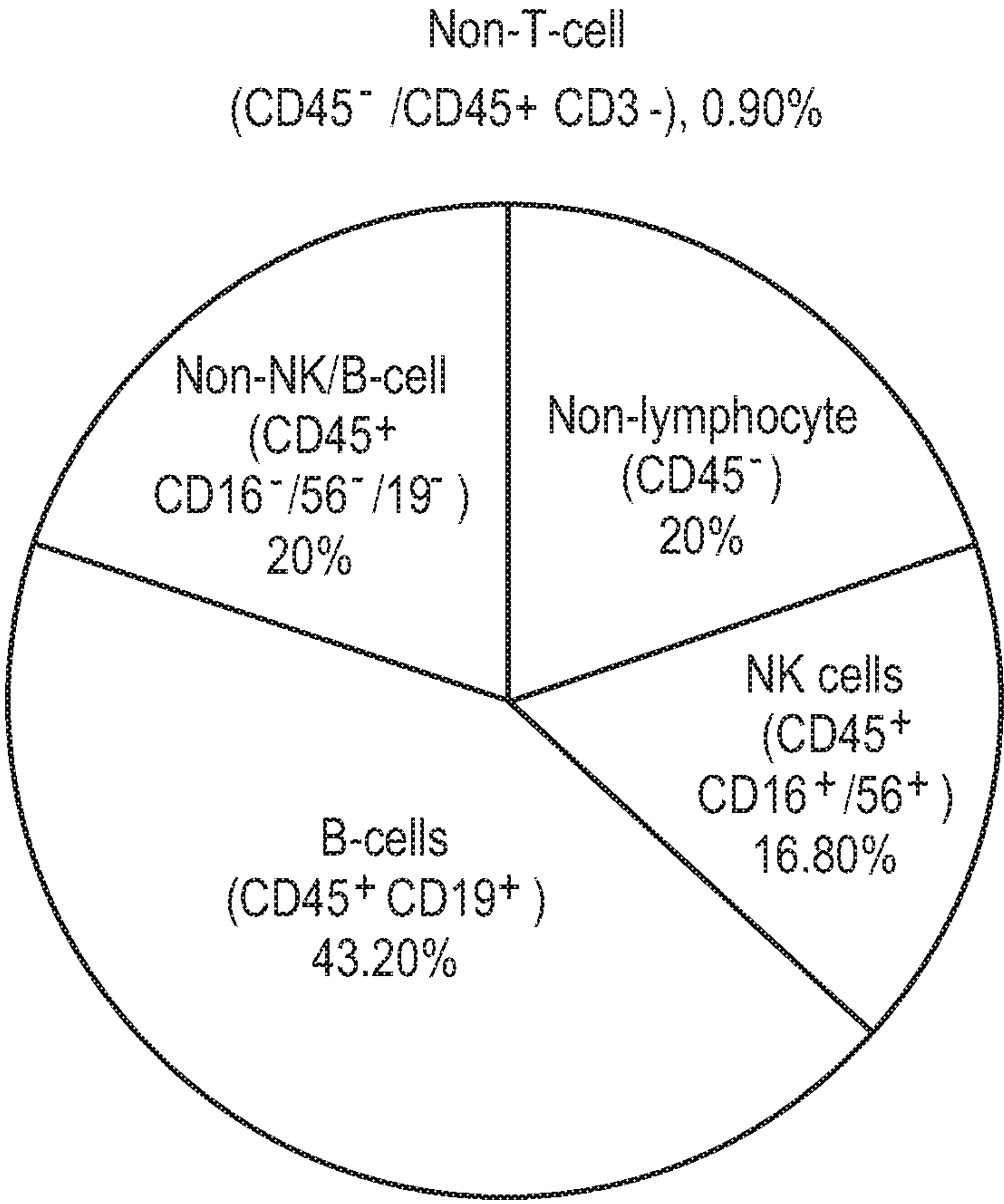


Figure 86C

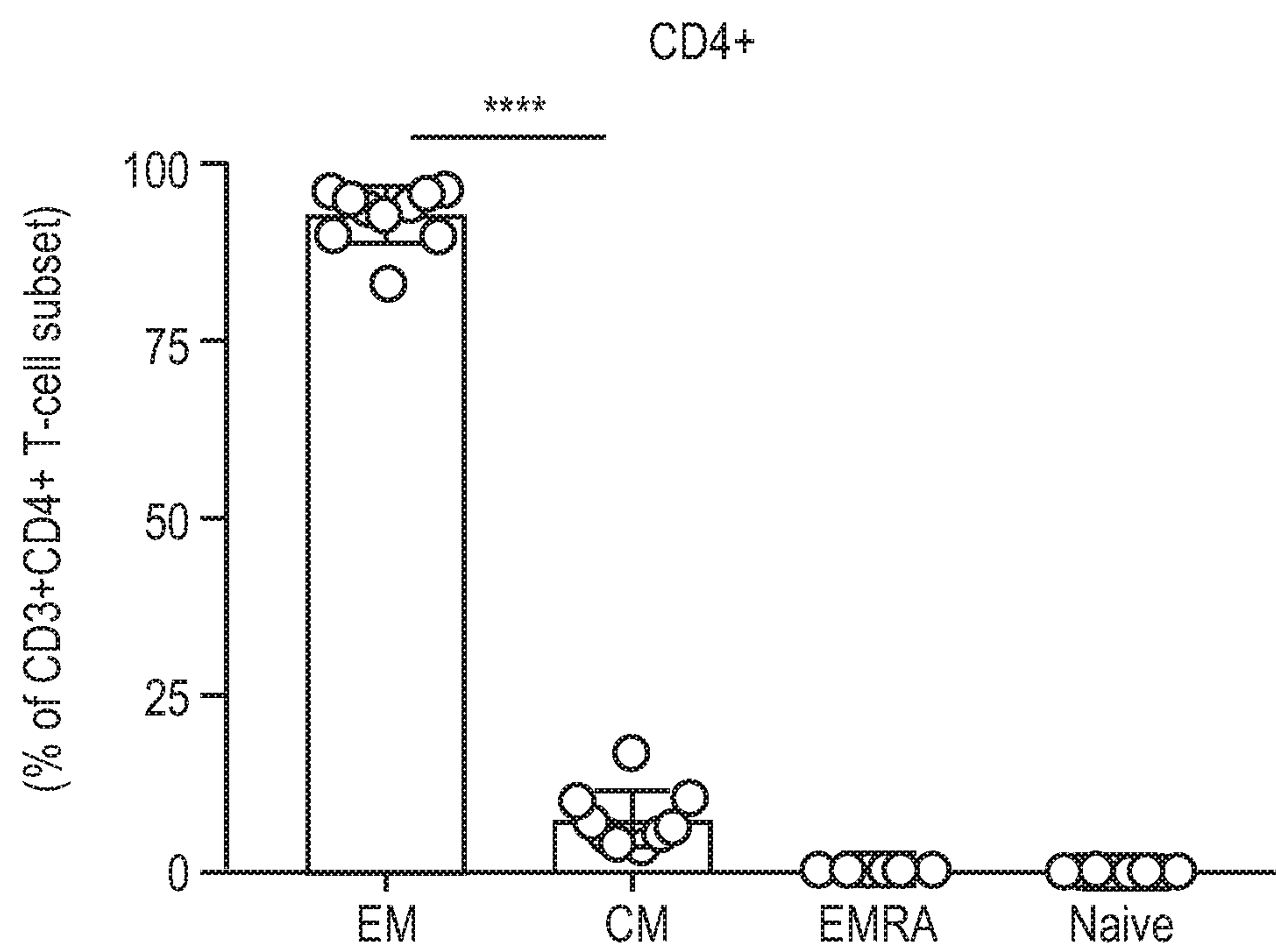


Figure 87A

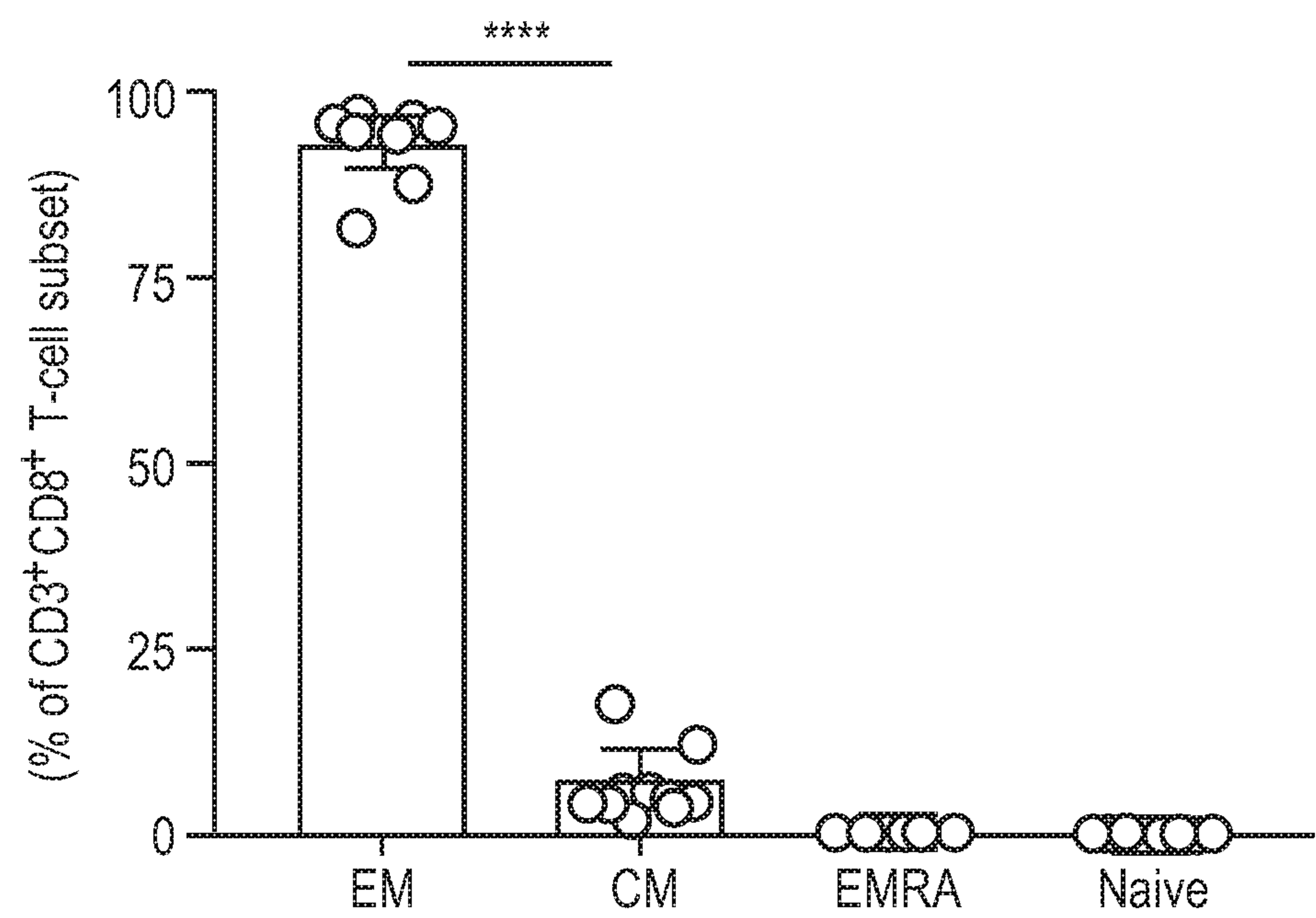


Figure 87B

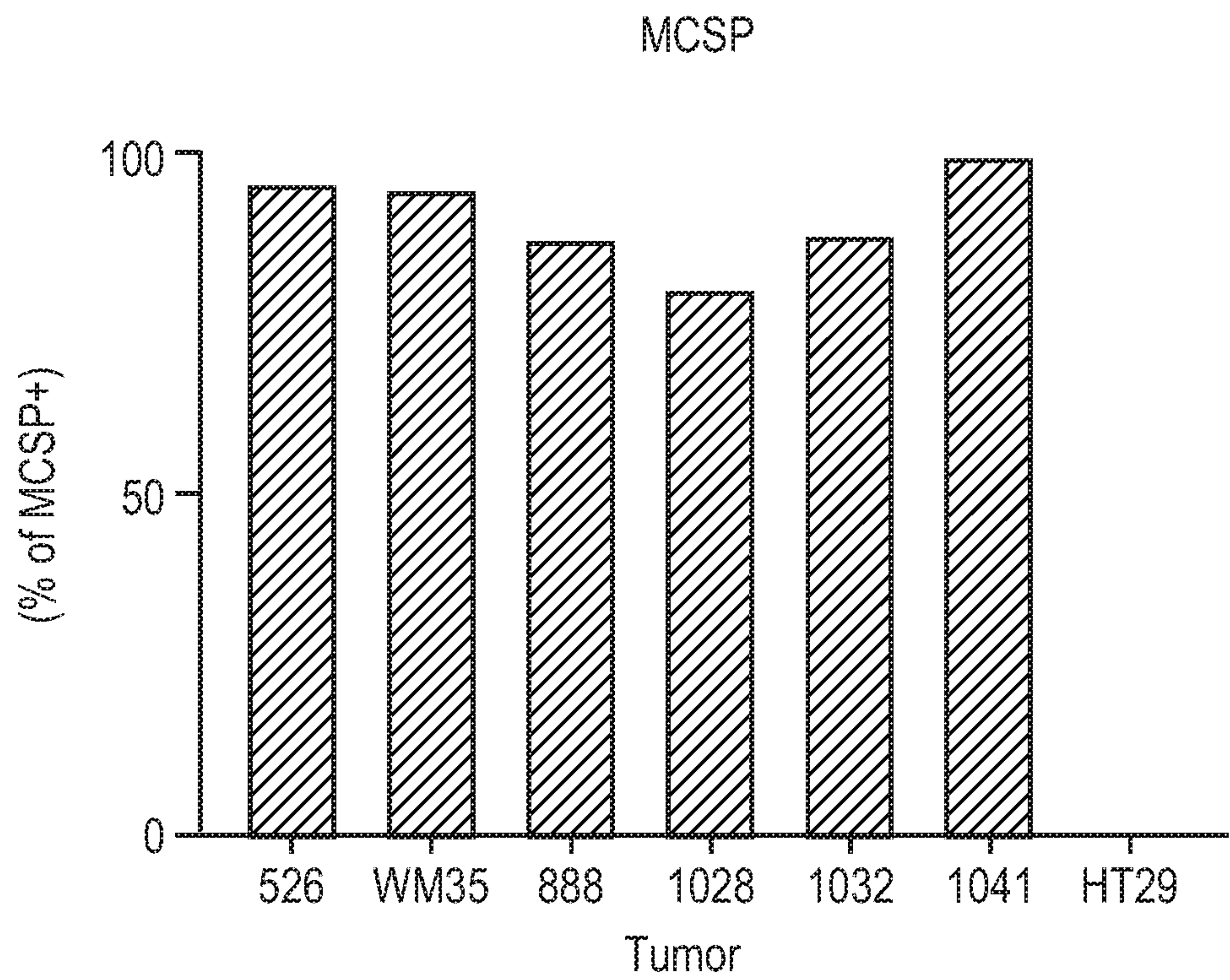


Figure 88A

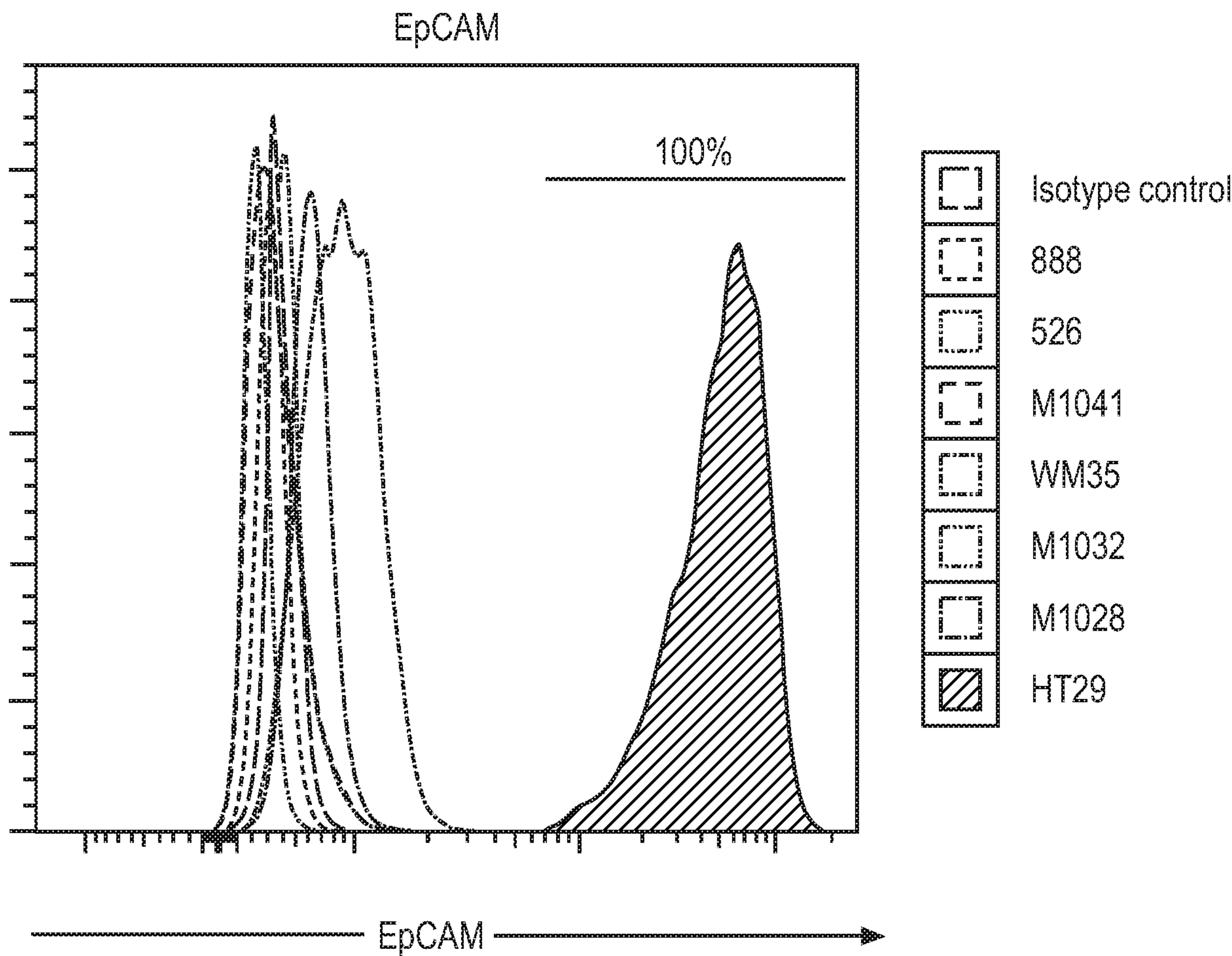


Figure 88B

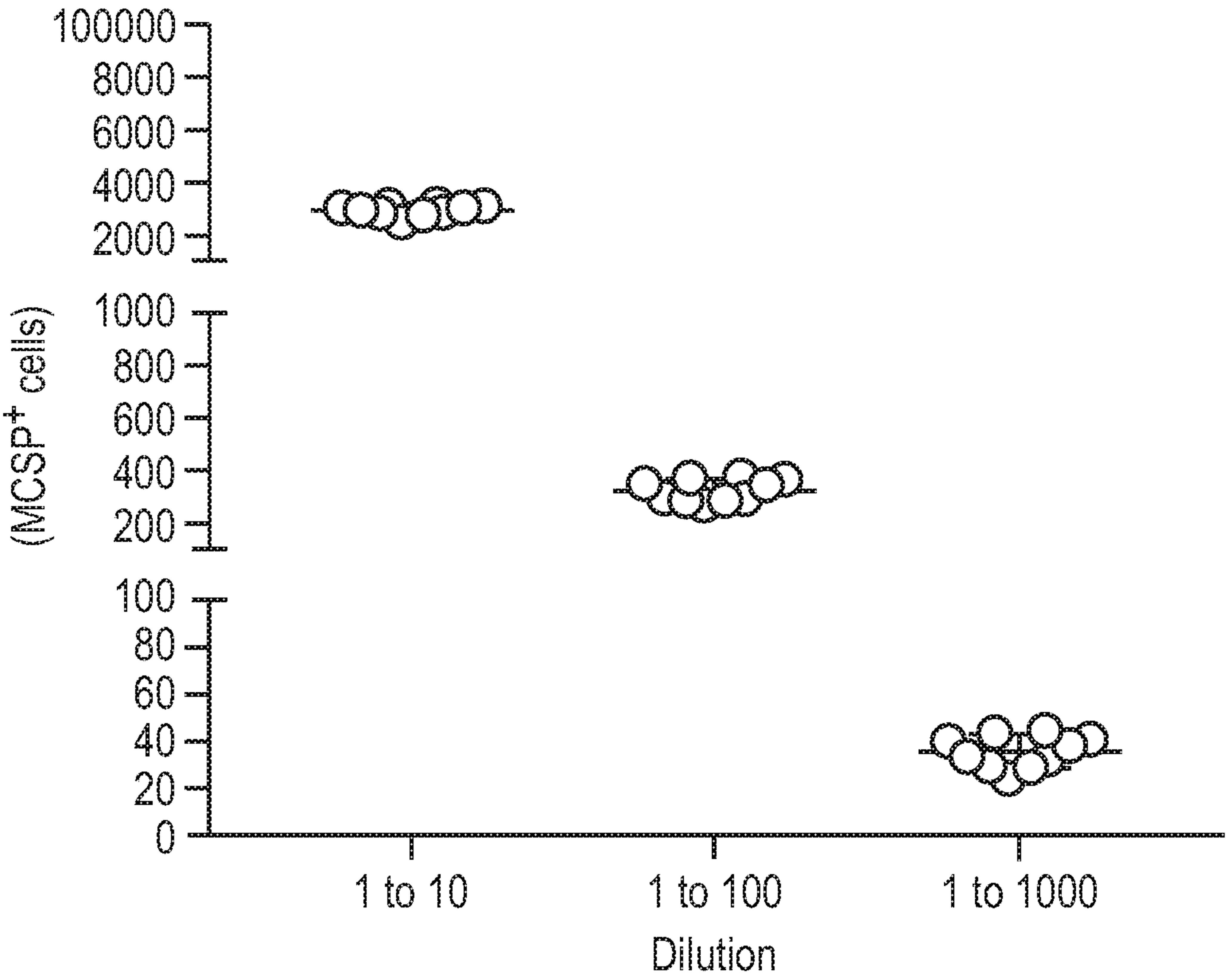


Figure 89A

DILUTION	AV	SD	UPPER LIMIT (AV + 3SD)	LOWER LIMIT (AV - 3SD)
1 to 10	2976	203	3585	2367
1 to 100	322	39	440	204
1 to 1000	36	7	56	16

Figure 89B

DILUTION	RANGE (UPPER- LOWER)	EXP#1 (AV)	EXP#2 (AV)	EXP#3 (AV)
1 to 10	3585-2367	2814	3282	2367
1 to 100	440-204	227	320	239
1 to 1000	56-16	27	25	32

Figure 90A

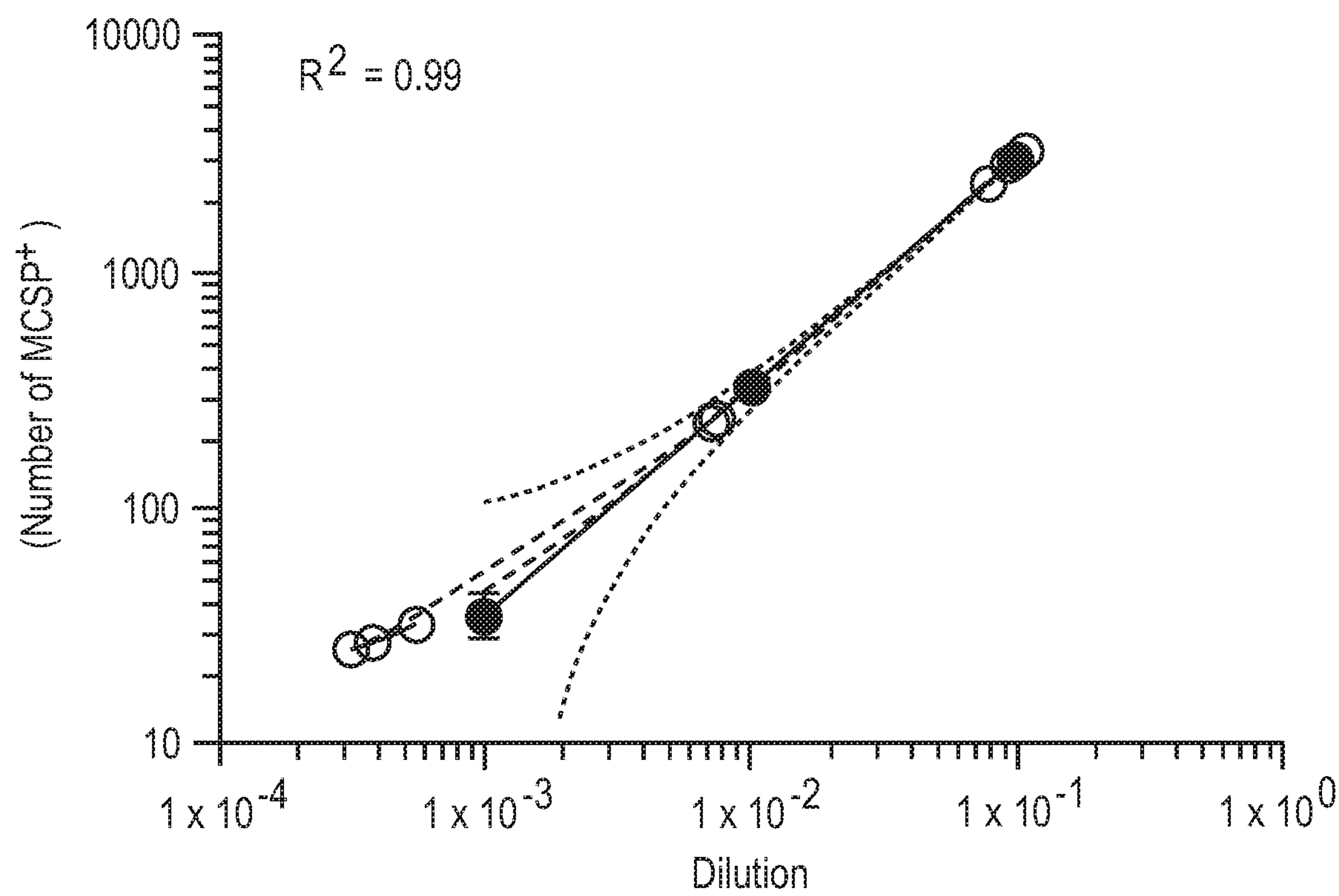


Figure 90B

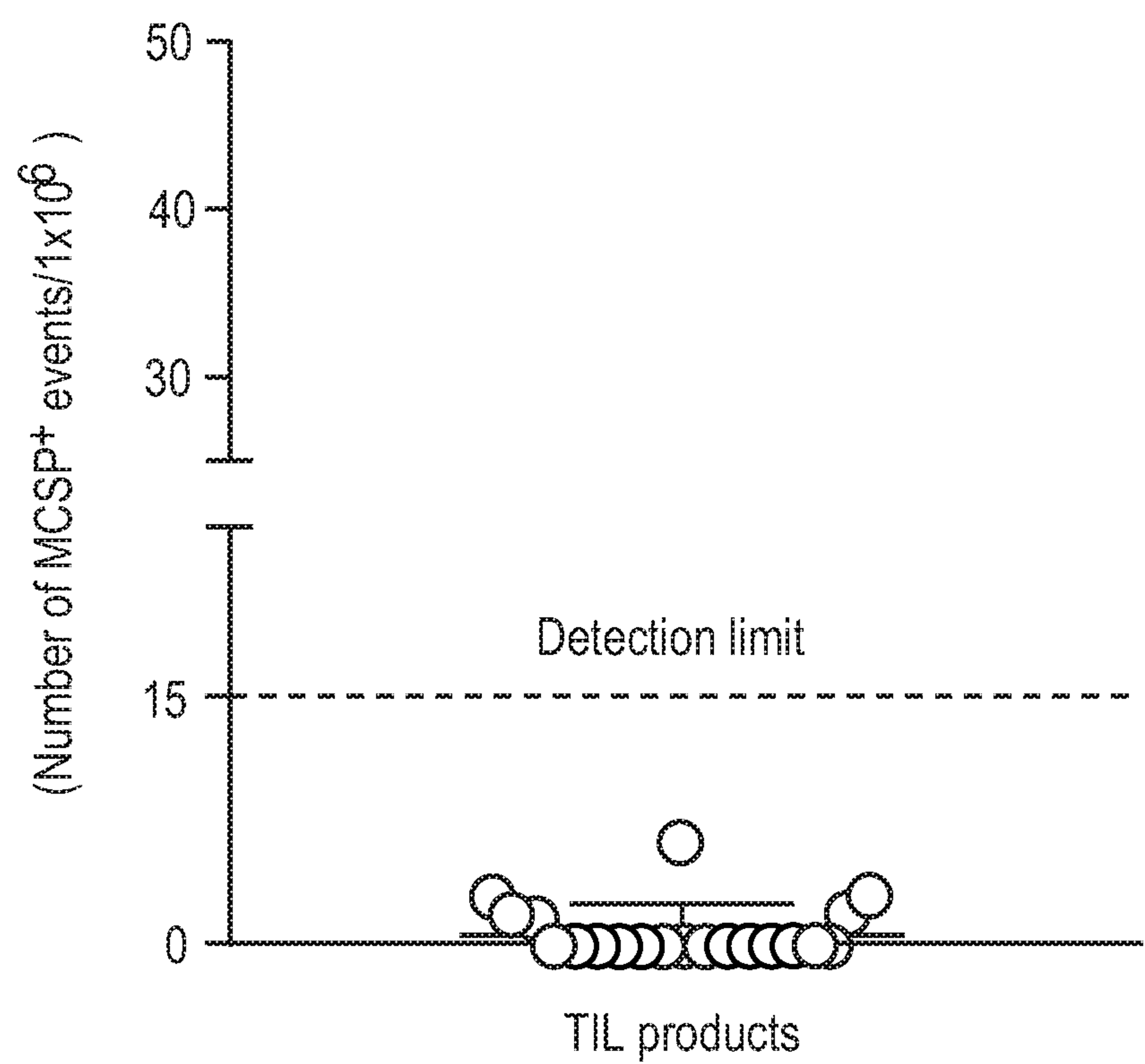


Figure 91A

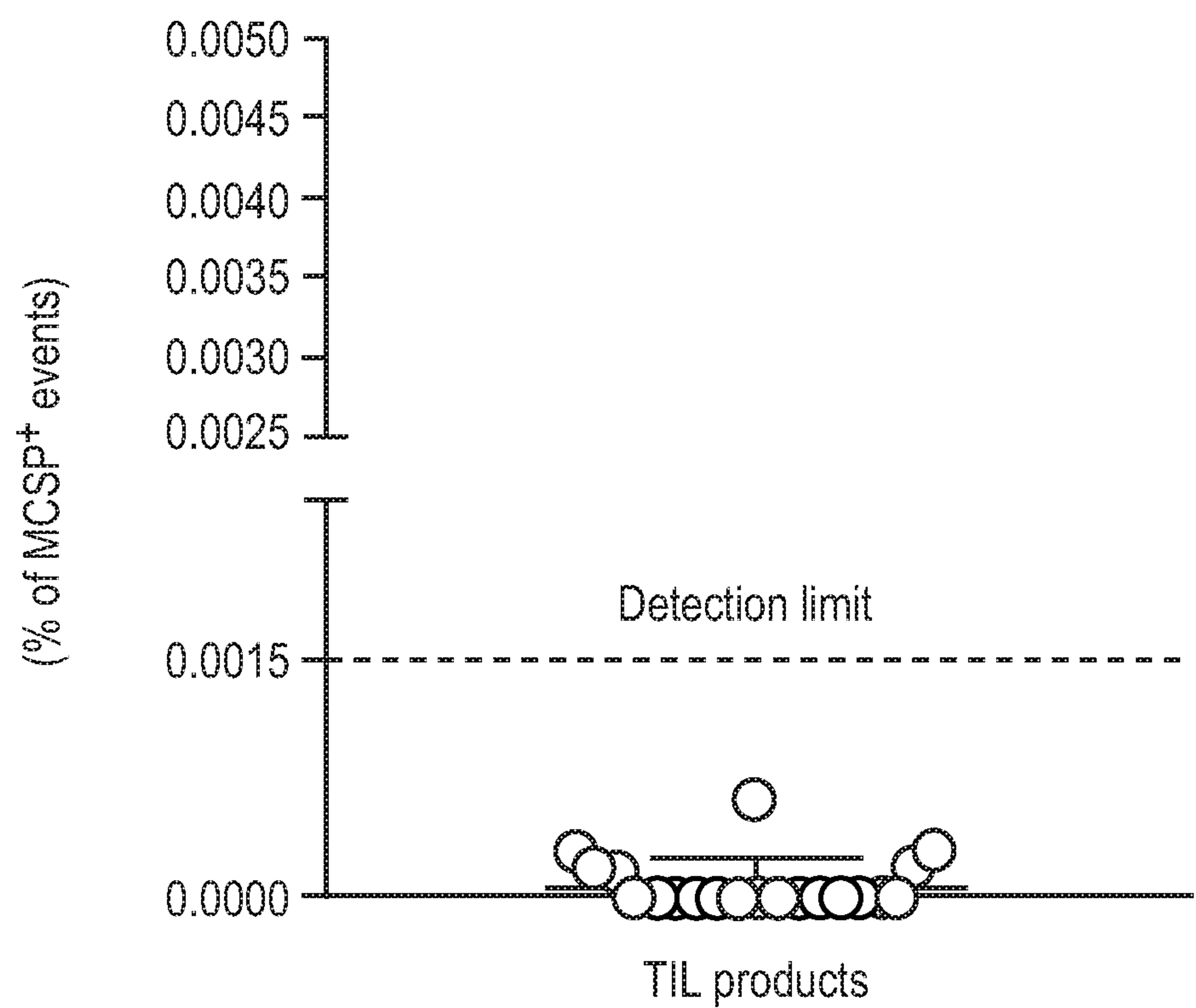


Figure 91B

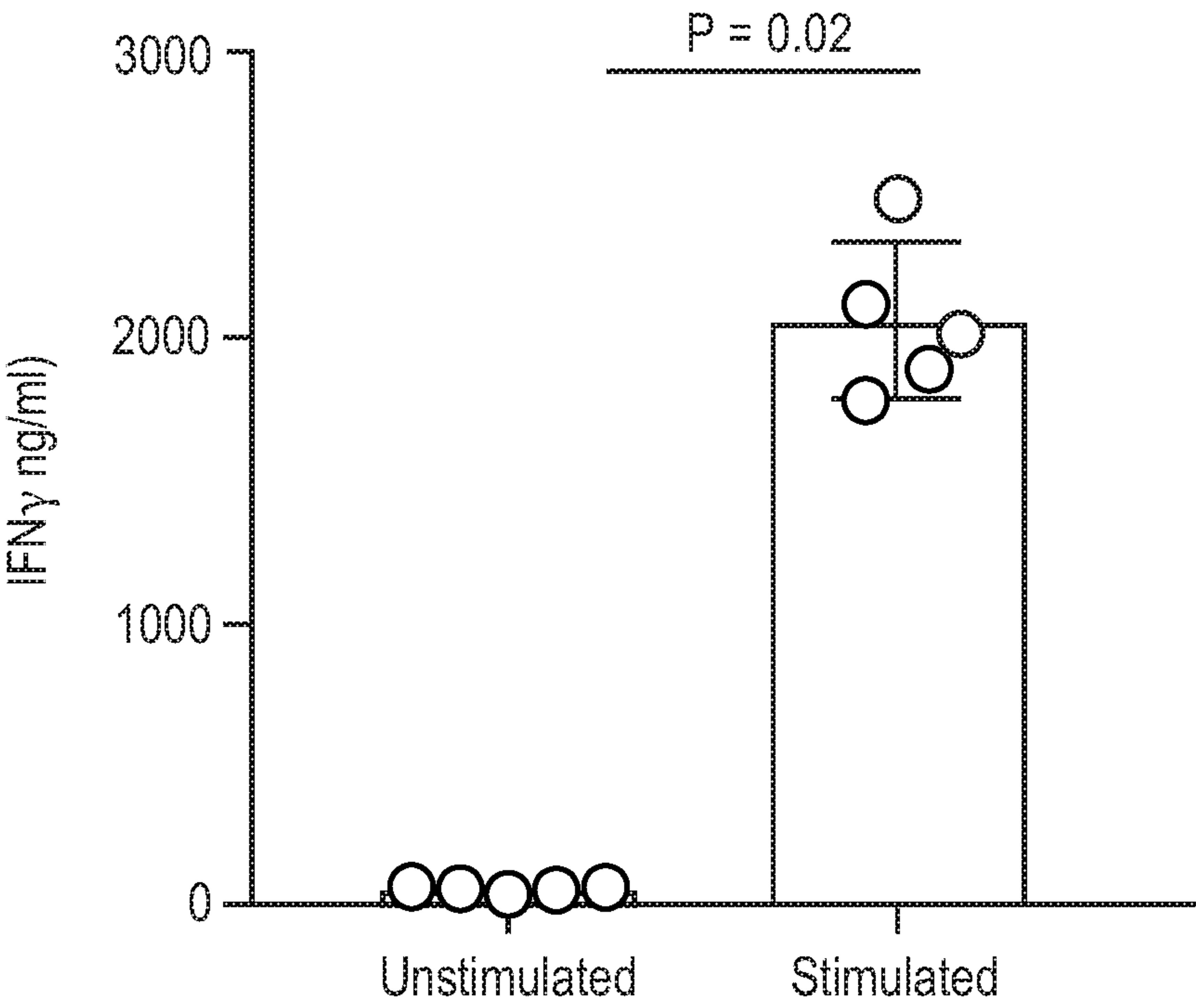


Figure 92

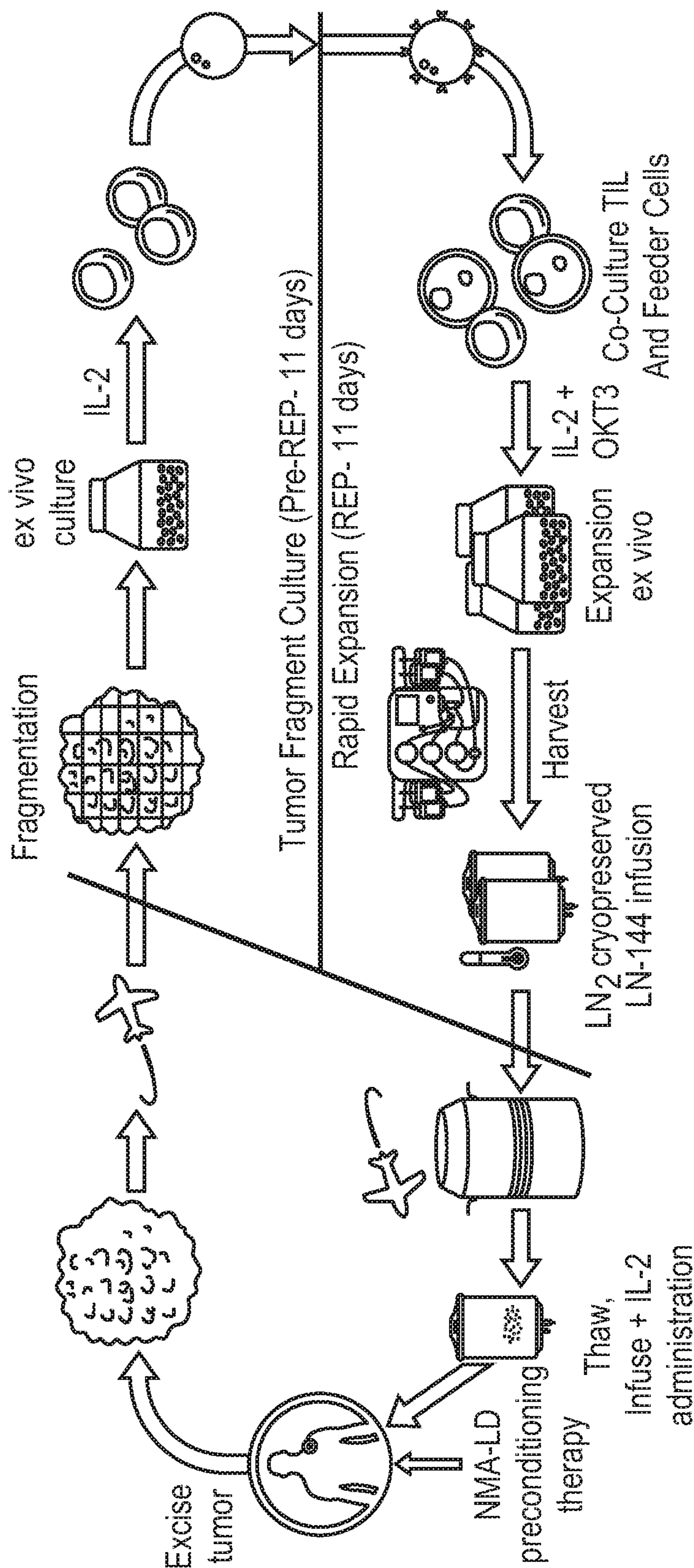


Figure 93

Figure 94

PROCESS STEP	GEN 1	GEN 2	IMPACT
Fragment Culture	≤21 days, multiple bioreactors, multiple operator interventions	≤11 days, single closed bioreactor, no intervention	Shortens culture, reduces interventions
TIL selection	IL-2 expanded TIL cryopreserved, tested, selection based on phenotype, thaw, rest, co-culture	Bulk TIL direct to co-culture	Reduces steps, eliminates testing, increases clonal diversity
Harvest/ Wash	Manual volume reduction and harvest. Manual wash and concentration	Closed semi-automated volume reduction and harvest. Automated wash and concentration	Reduces operator interventions, reduces processing time, maintains functionally closed system
Formulation	Fresh hypothermic product (2- 8°C)	Cryopreserved product (≤ -150°C)	Allows for global trials through increased flexibility in shipping and patient scheduling
Manufacturing Time	38 day process time	22 day process time	Turnaround to patient, clean room throughput, lower cost of goods

Figure 95A

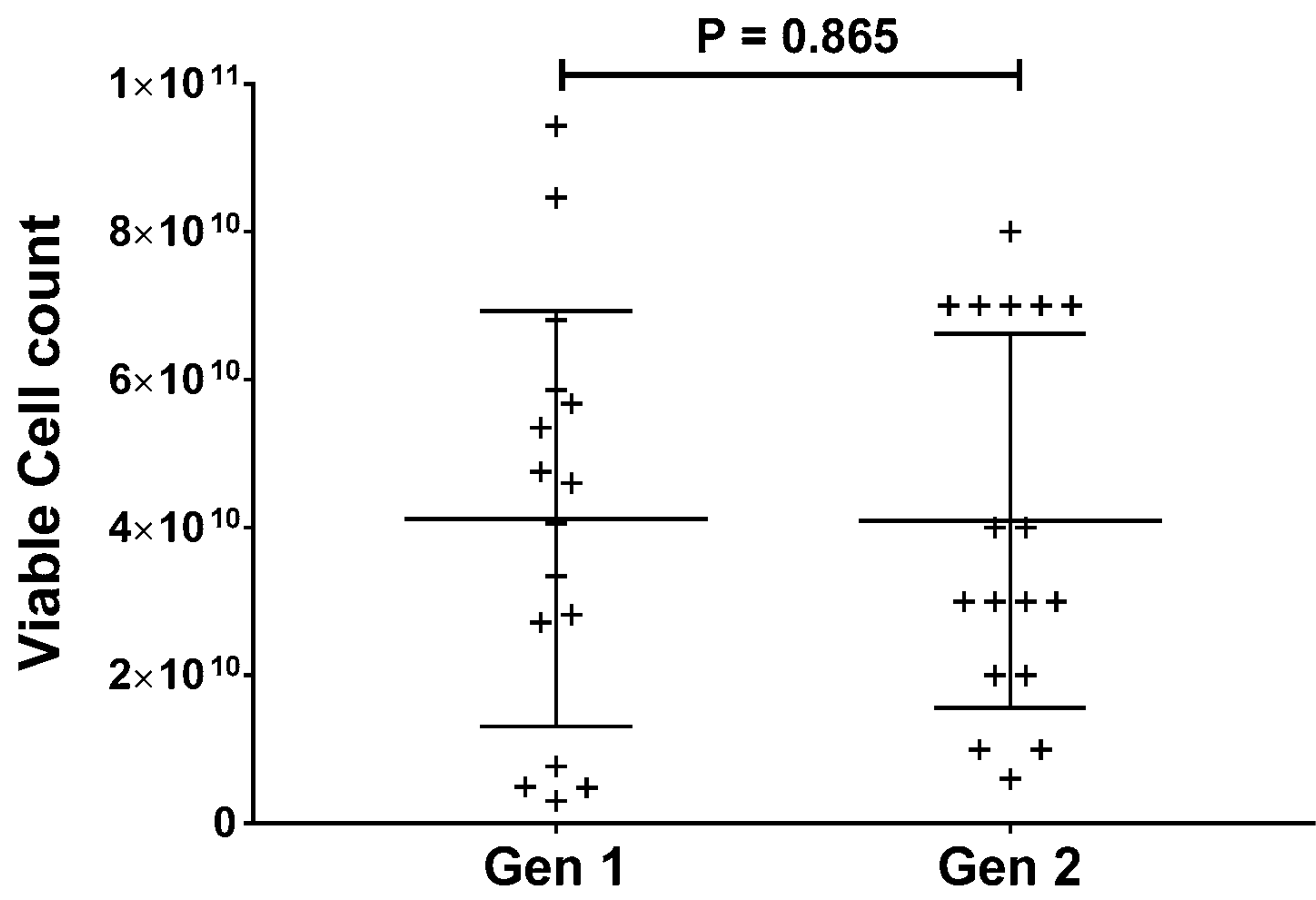


Figure 95B

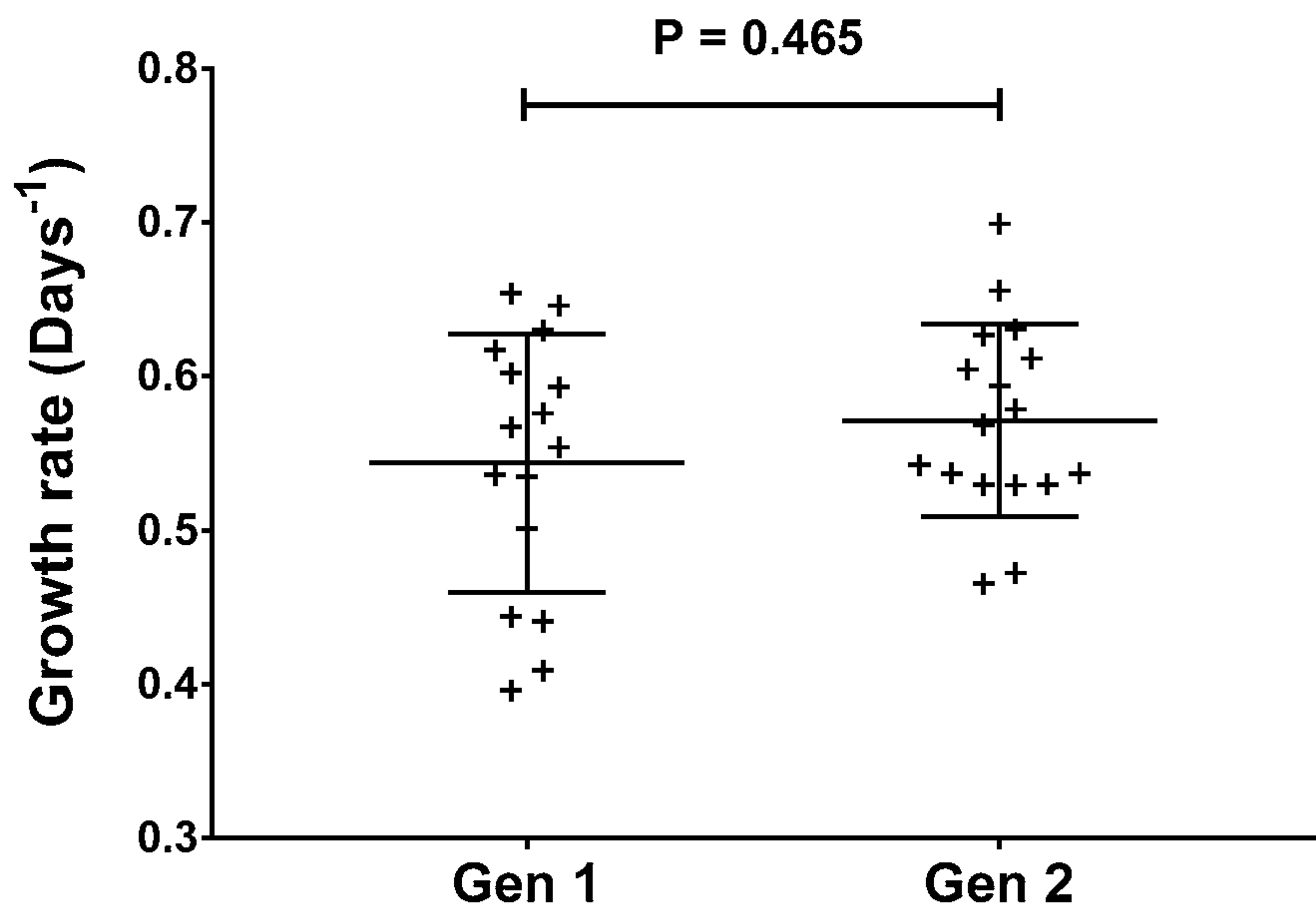


Figure 95C

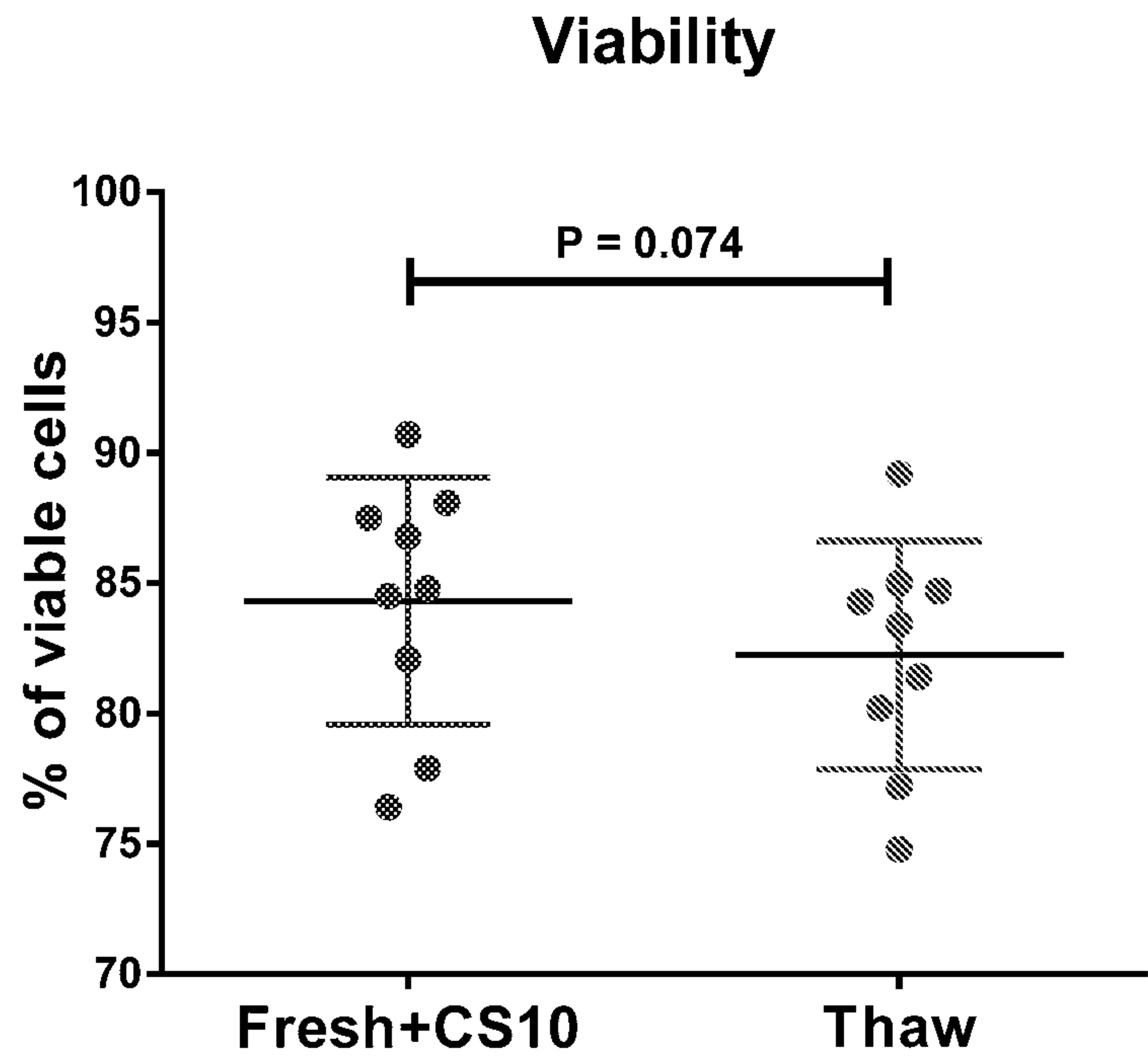


Figure 96A

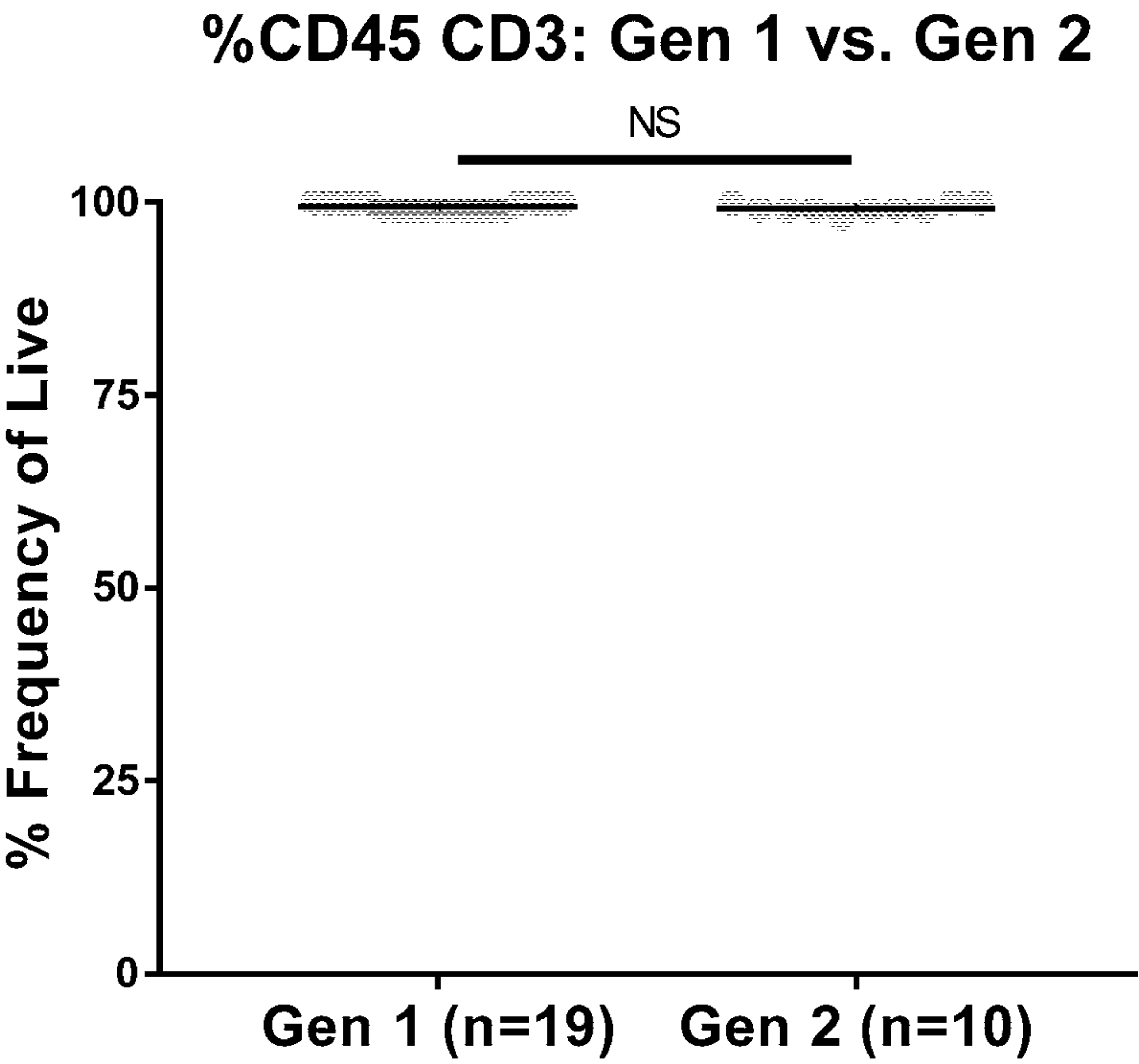


Figure 96B

CD27 Expression: Gen1 vs. Gen2

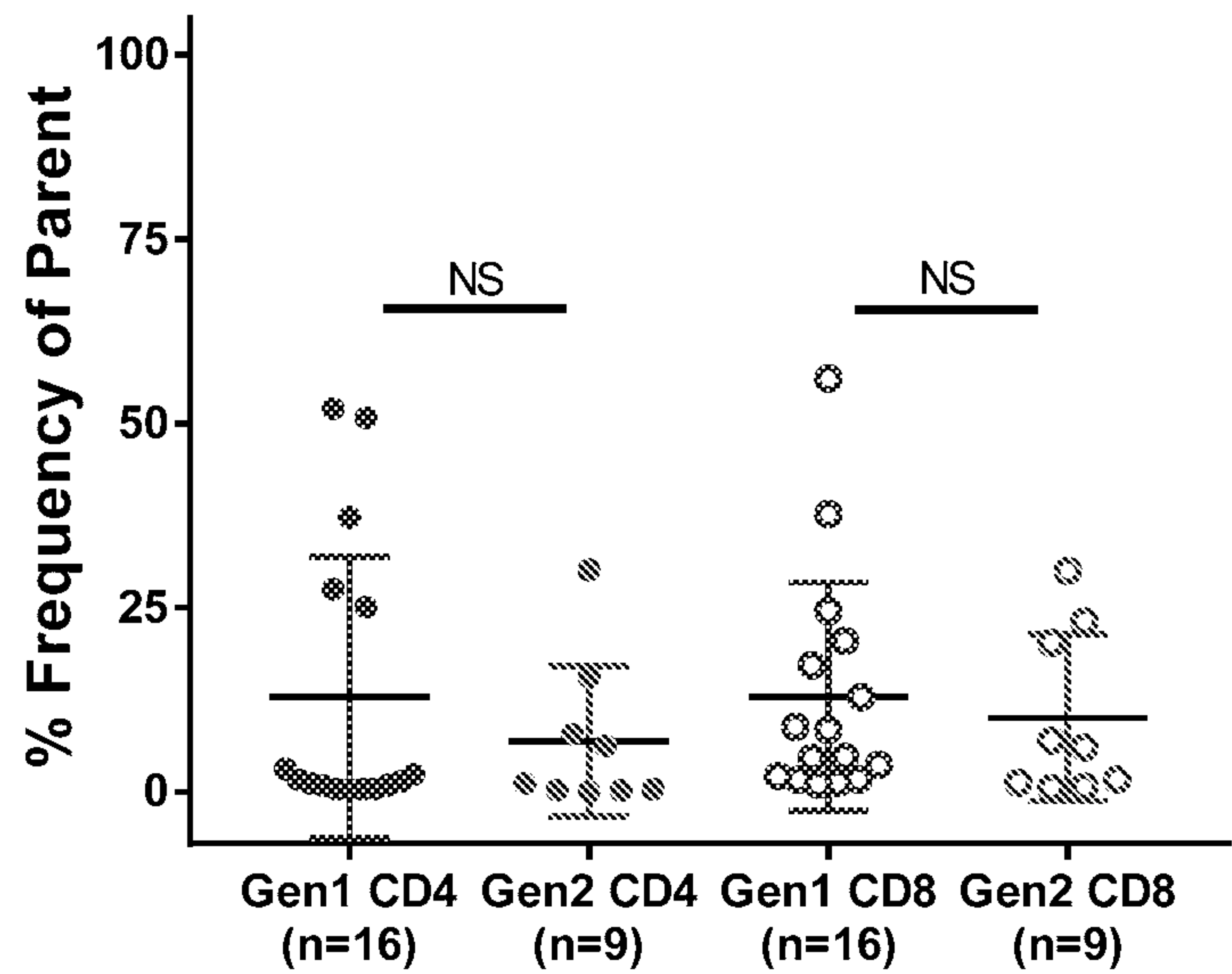


Figure 96C

CD28 Expression: Gen1 vs. Gen2

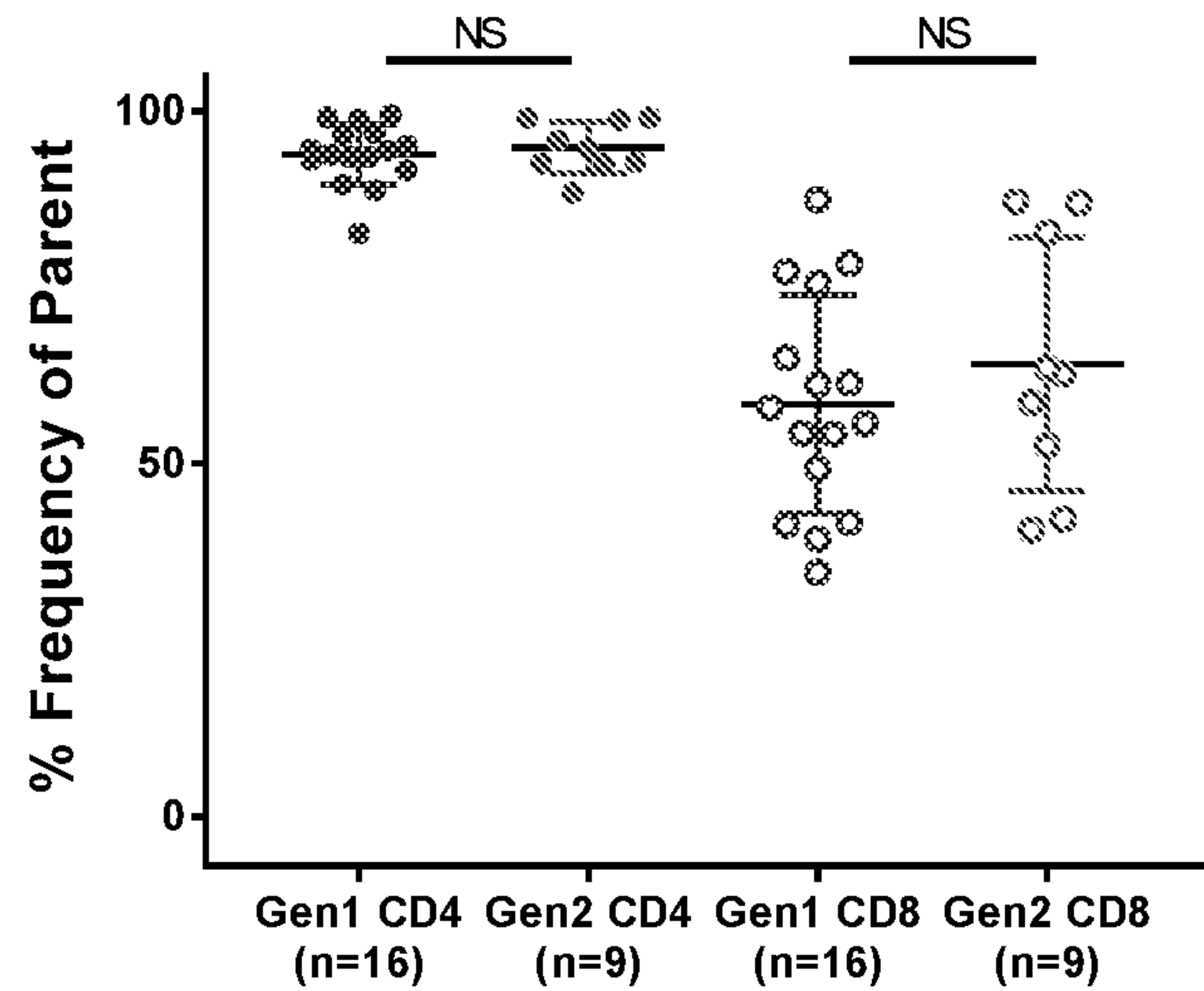


Figure 97

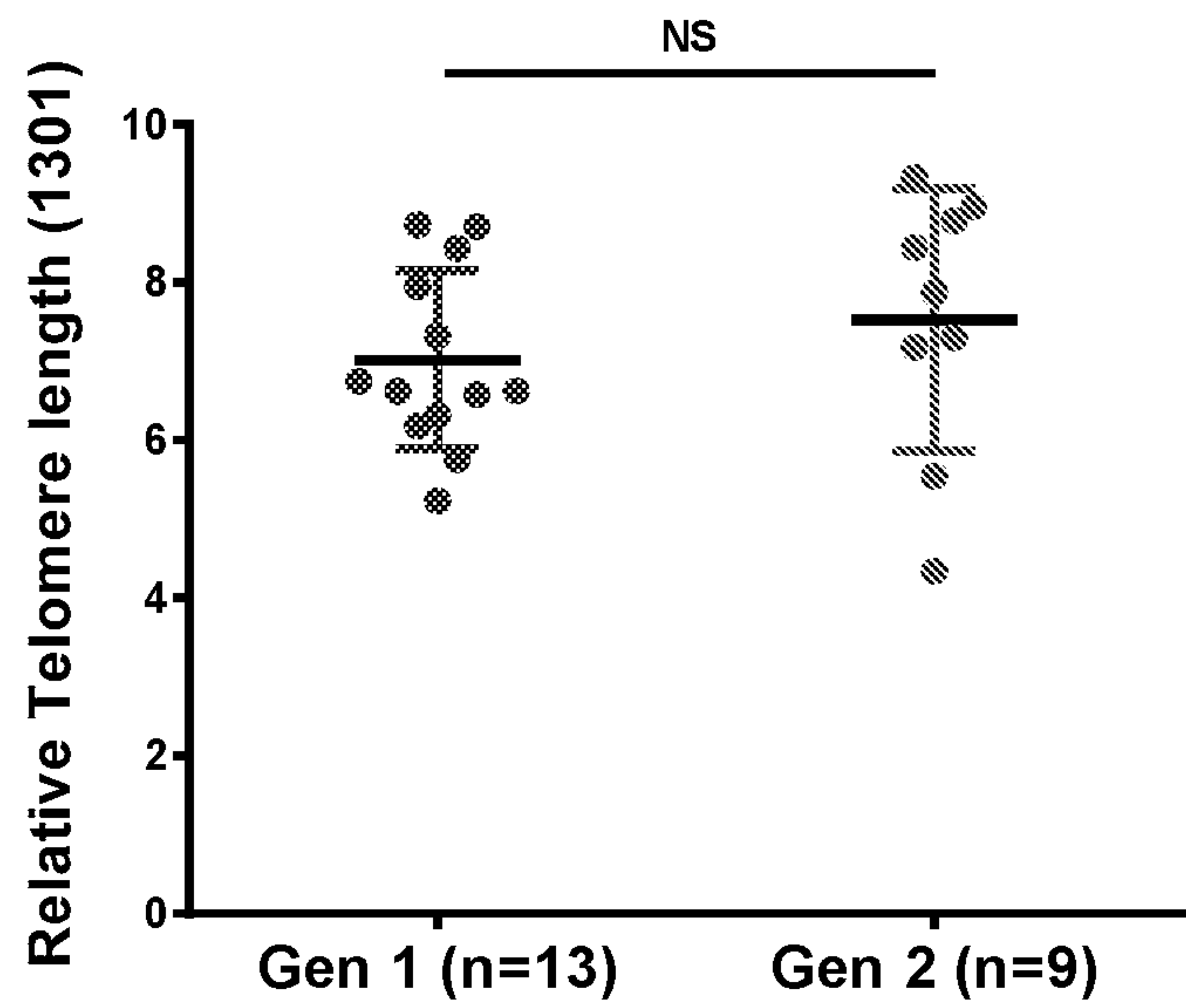


Figure 98

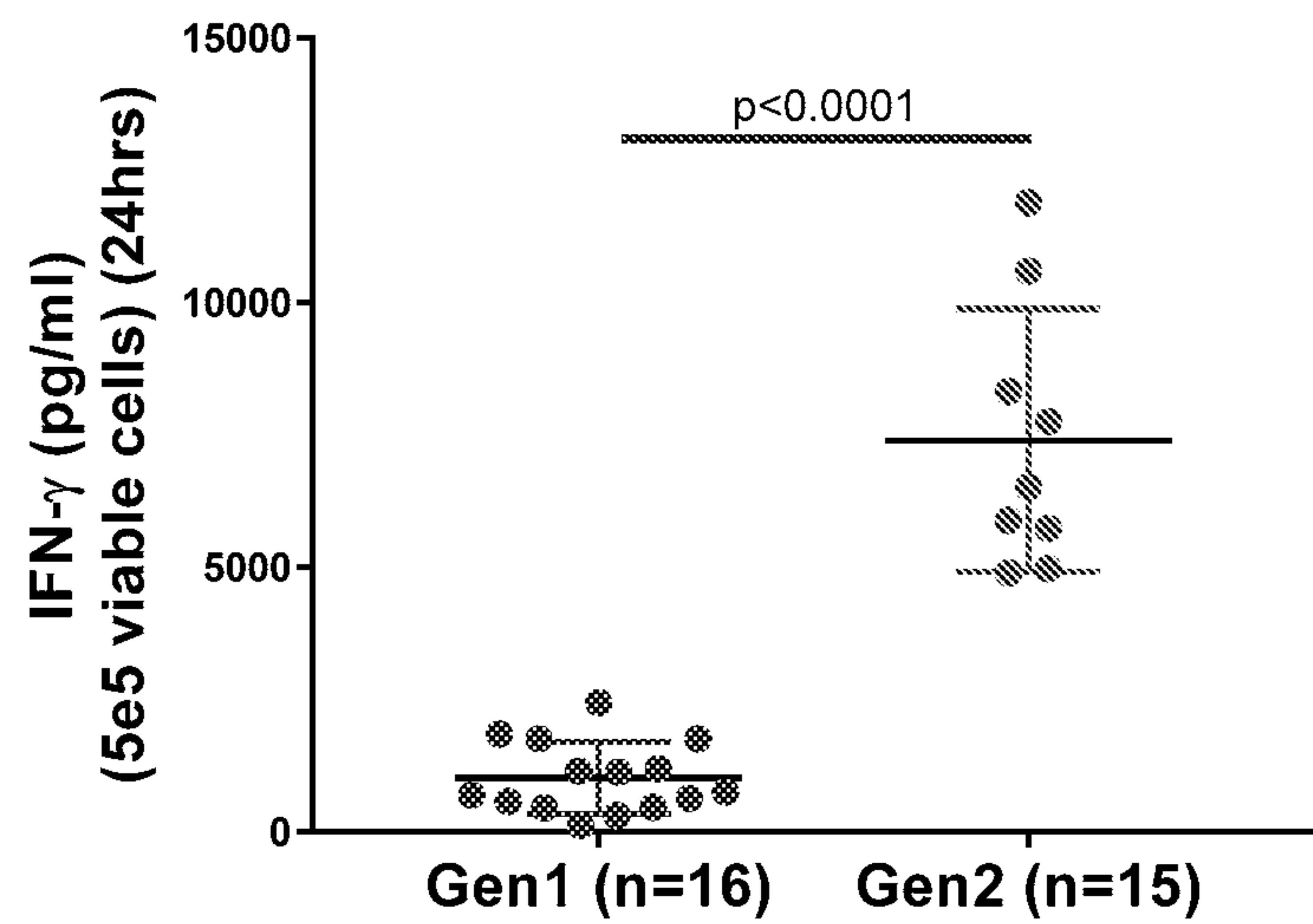


Figure 99A

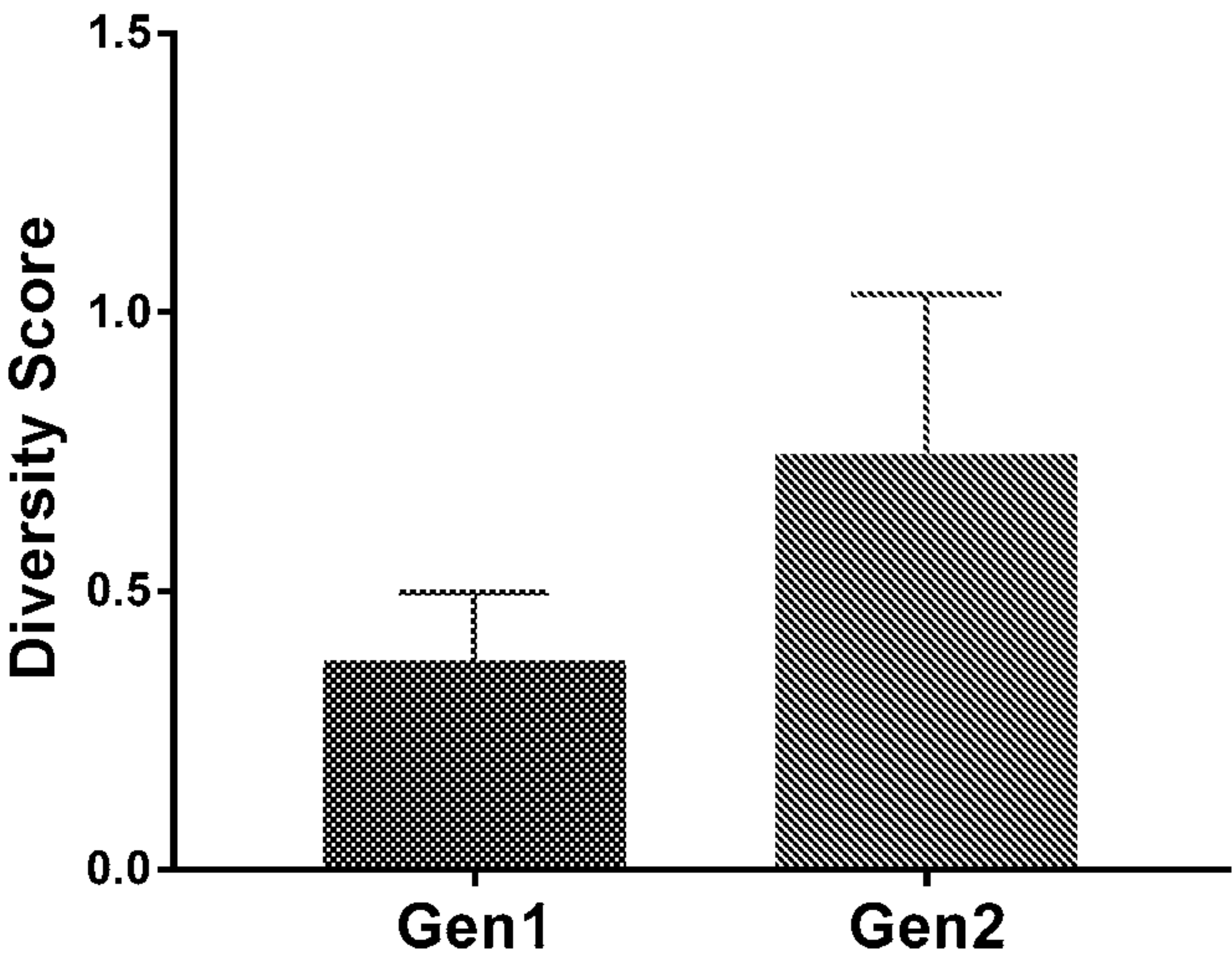


Figure 99B

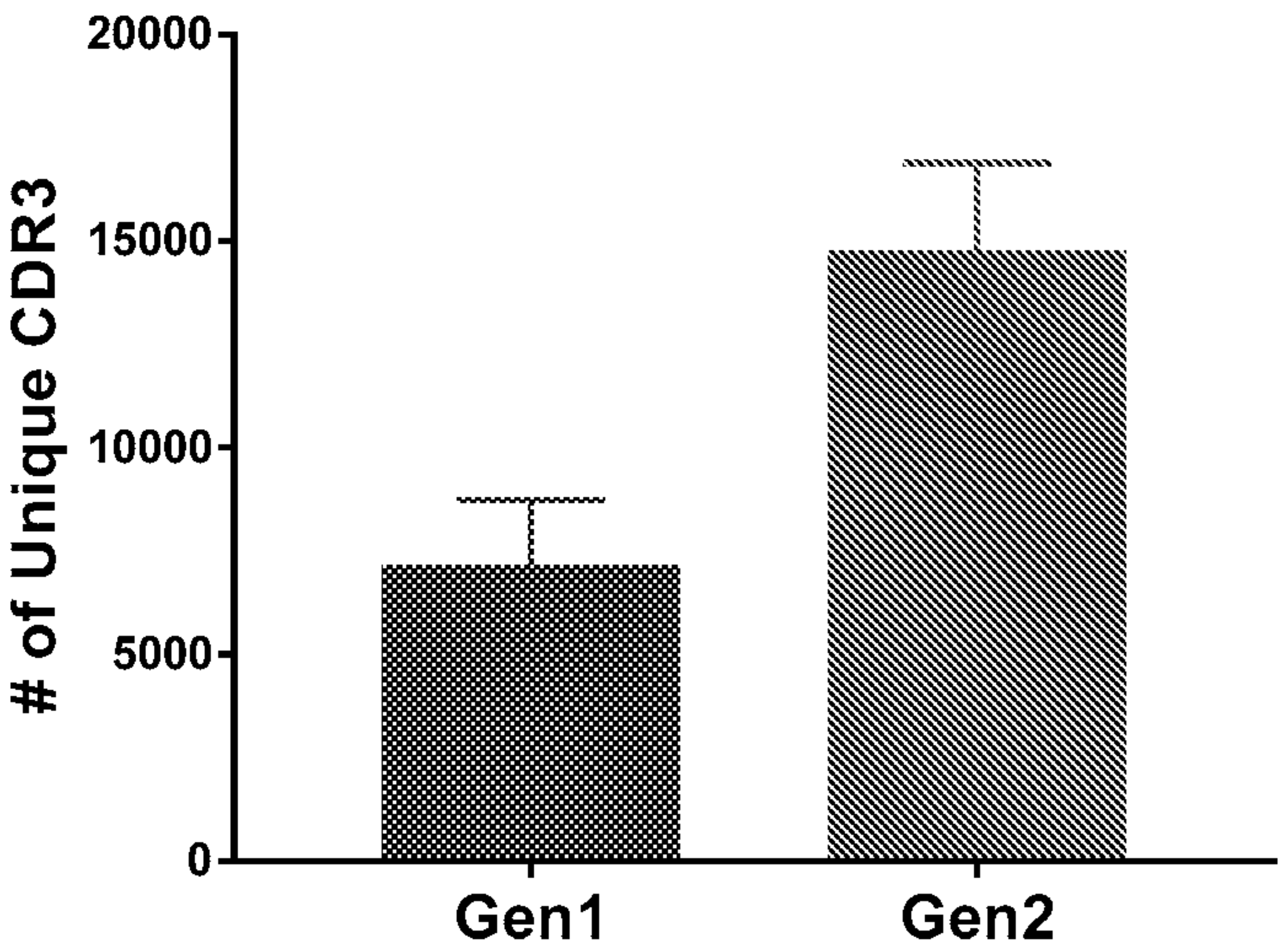


Figure 100

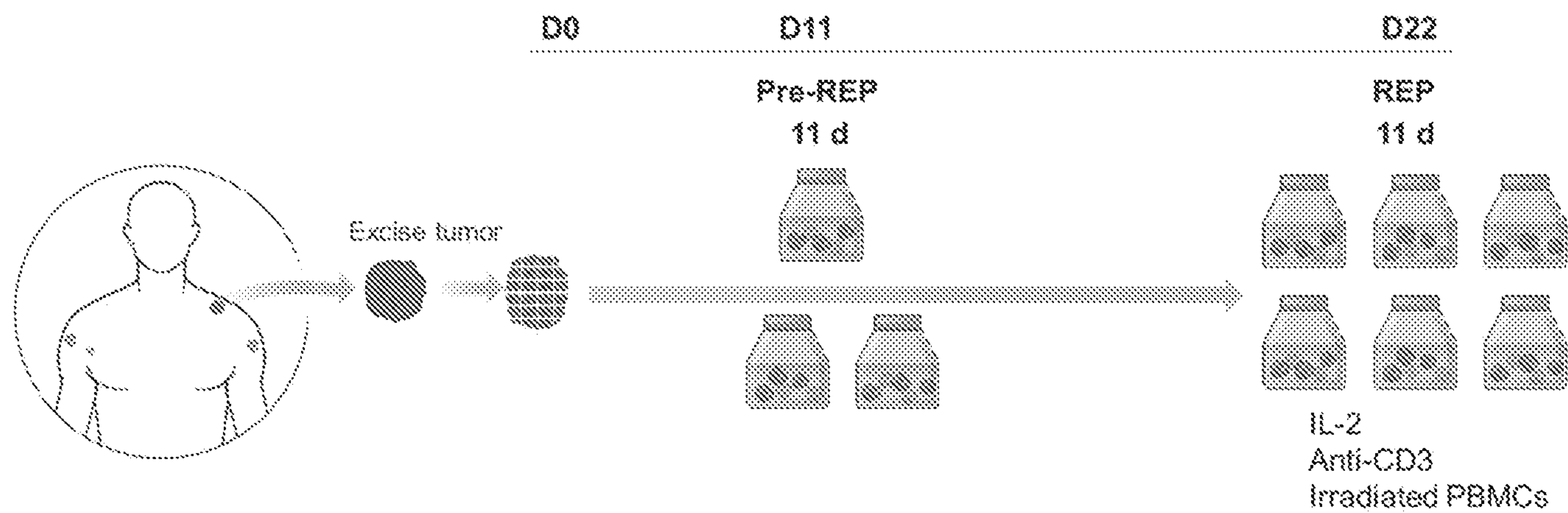


Figure 101

Tumor Histology	# of studies demonstrating >20% enhancement of growth using IL-2/IL-15/IL-21 (compared to IL-2)
Melanoma	1/5(20%)
Lung	3/8 (38%)
Colorectal	7/11 (63%)
Cervical	1/1 (100%)
Pancreatic	2/2 (100%)
Glioblastoma	1/1 (100%)
Triple Negative Breast	1/2 (50%)

Figure 102A

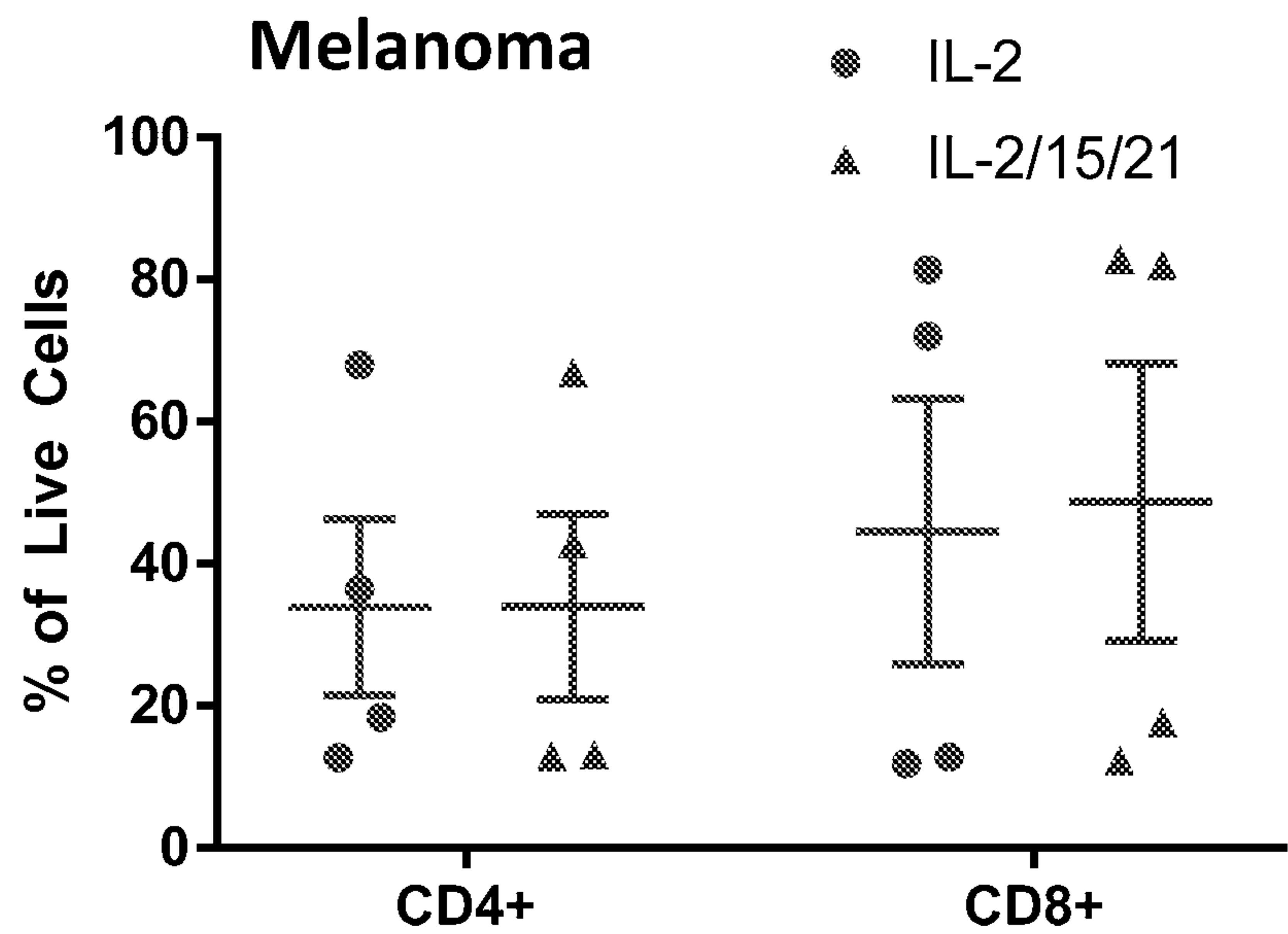


Figure 102B

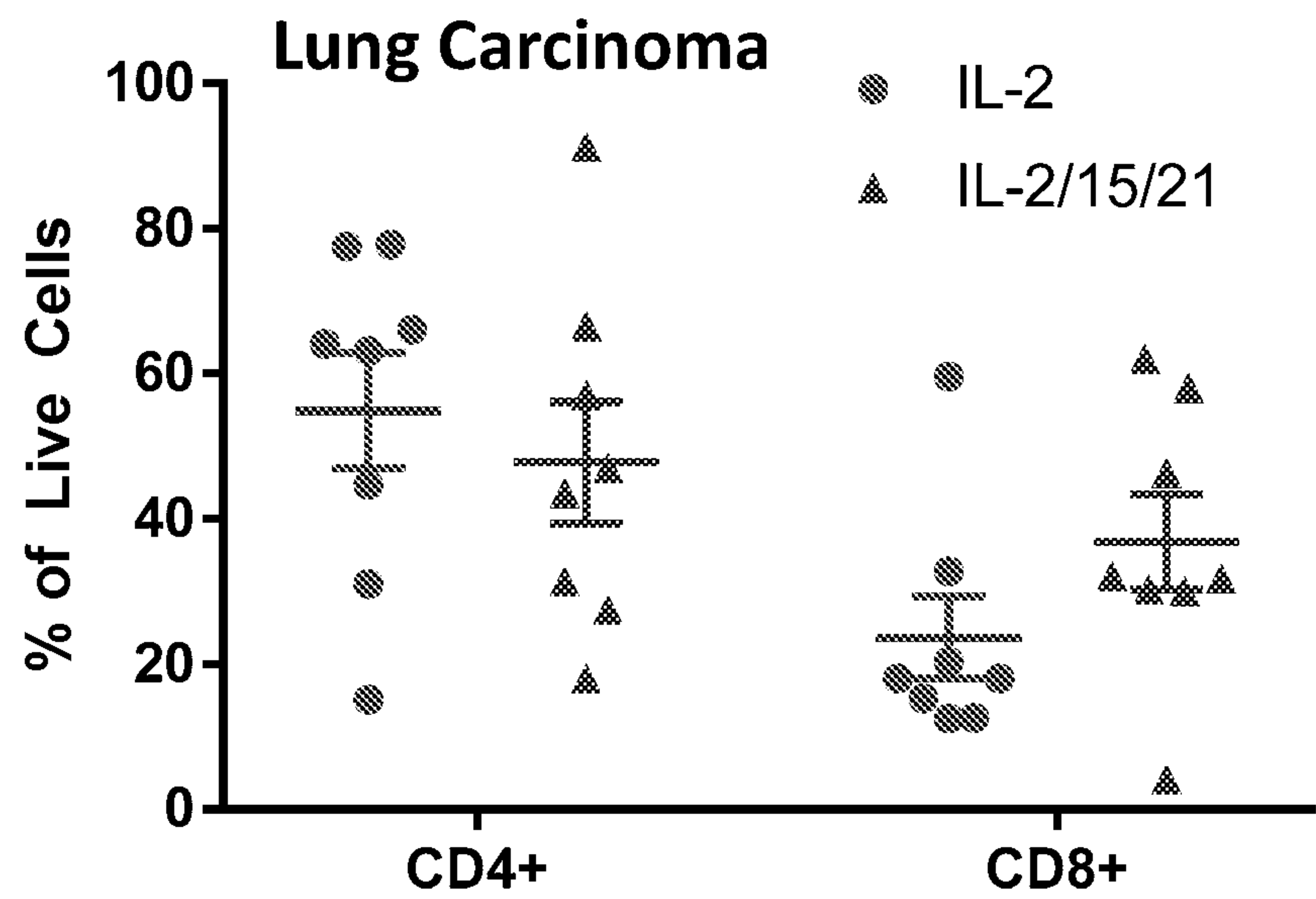


Figure 103A

Melanoma

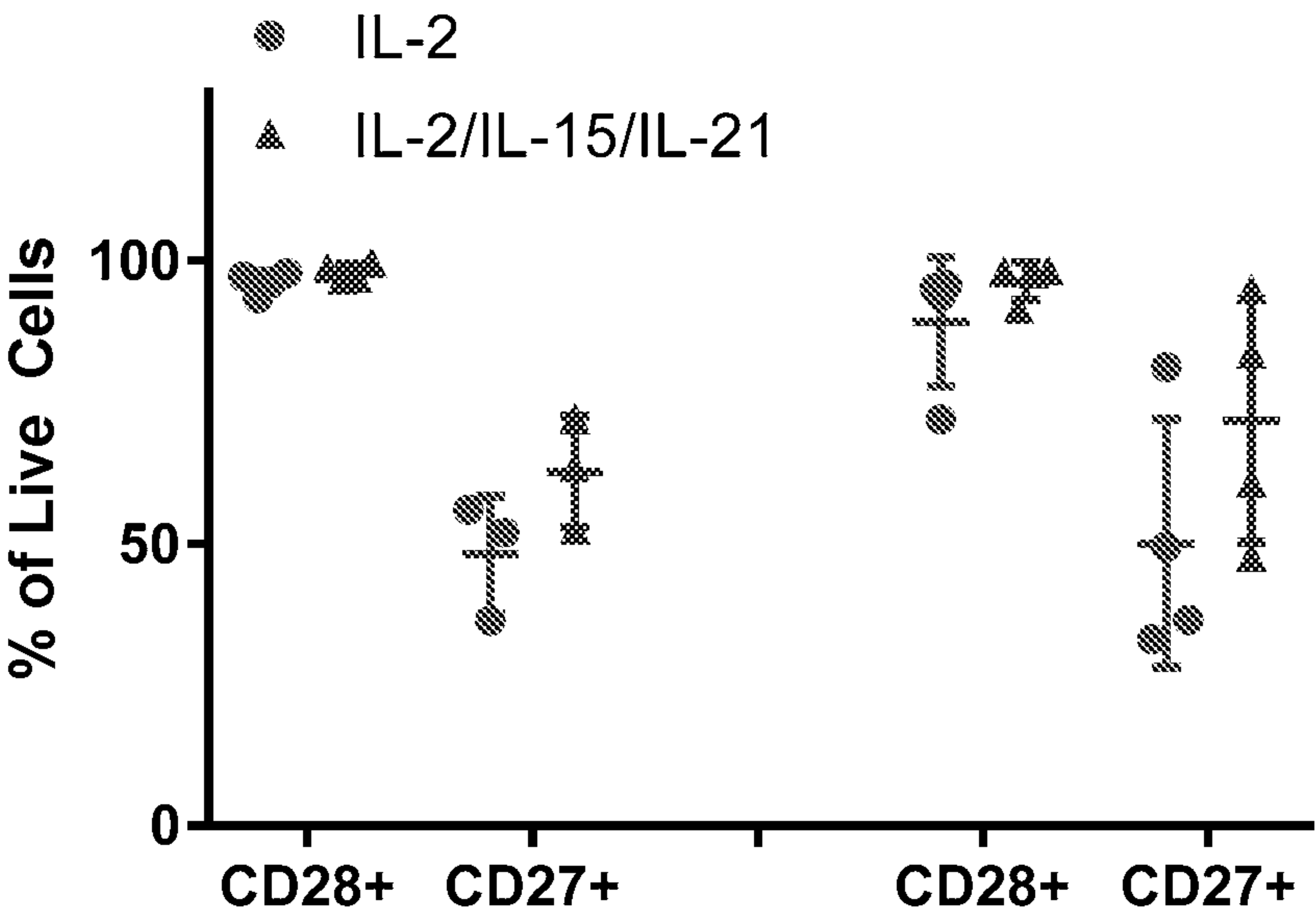


Figure 103B

Lung Carcinoma

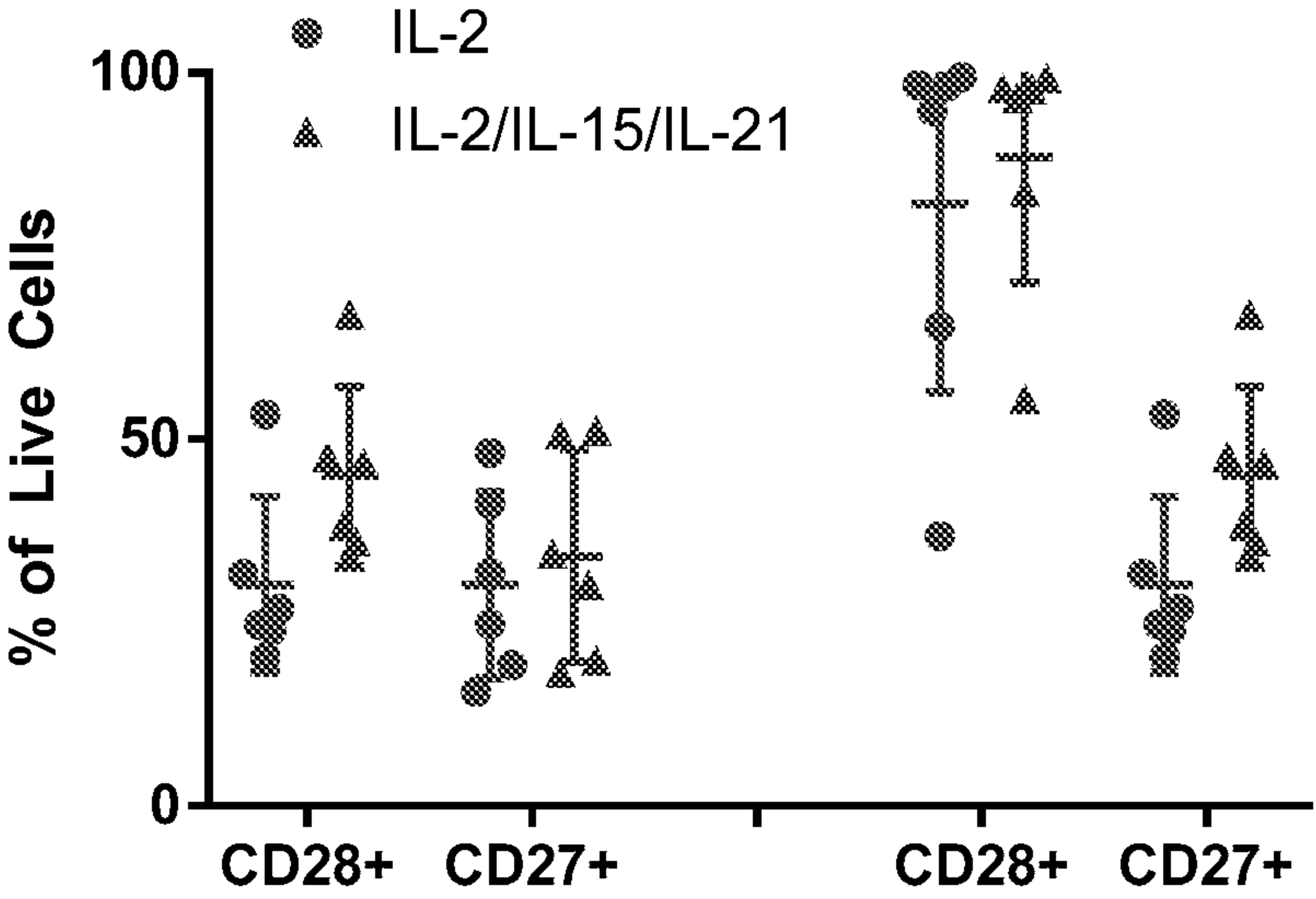


Figure 104A

Melanoma

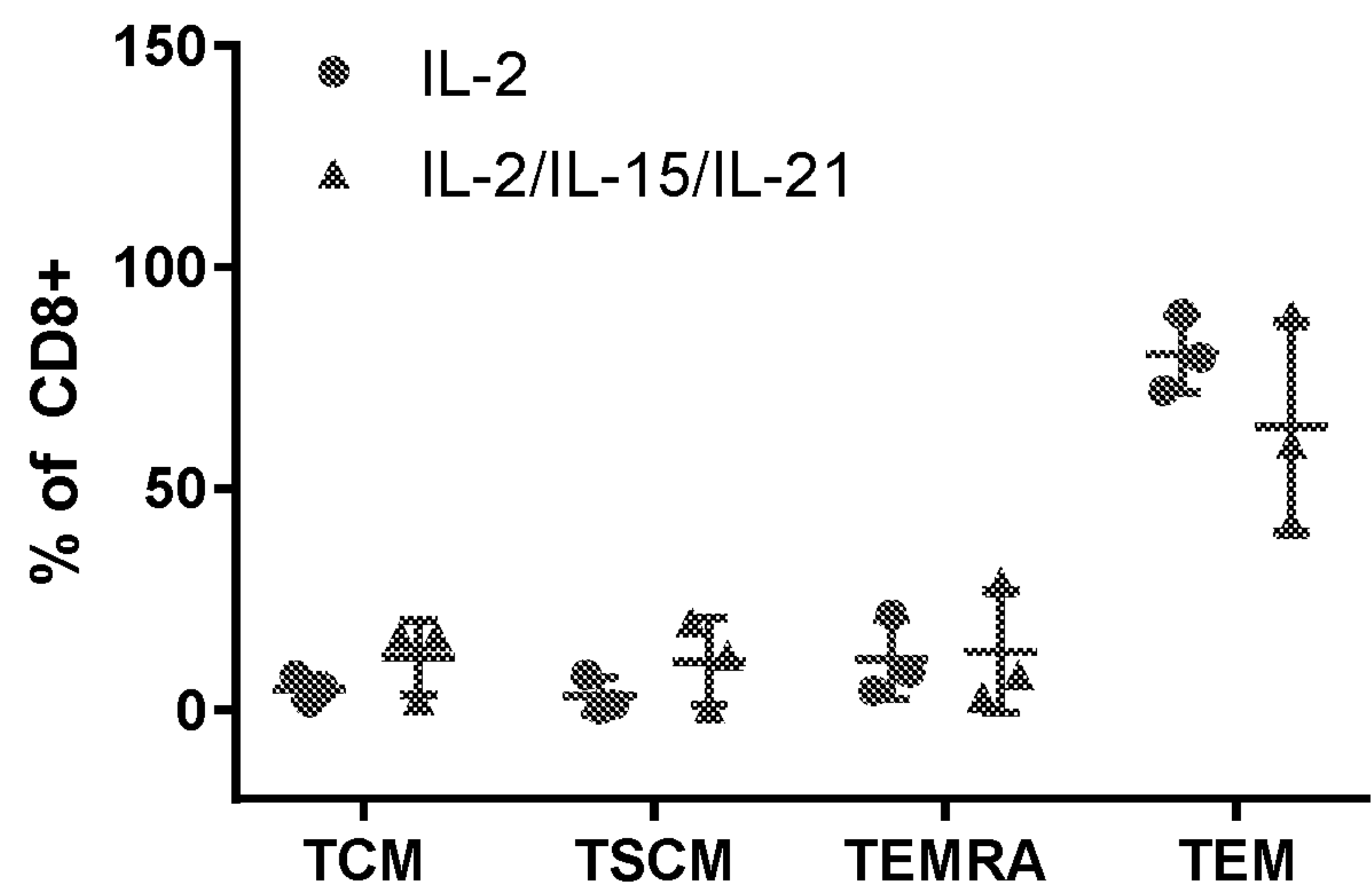


Figure 104B

Lung Carcinoma

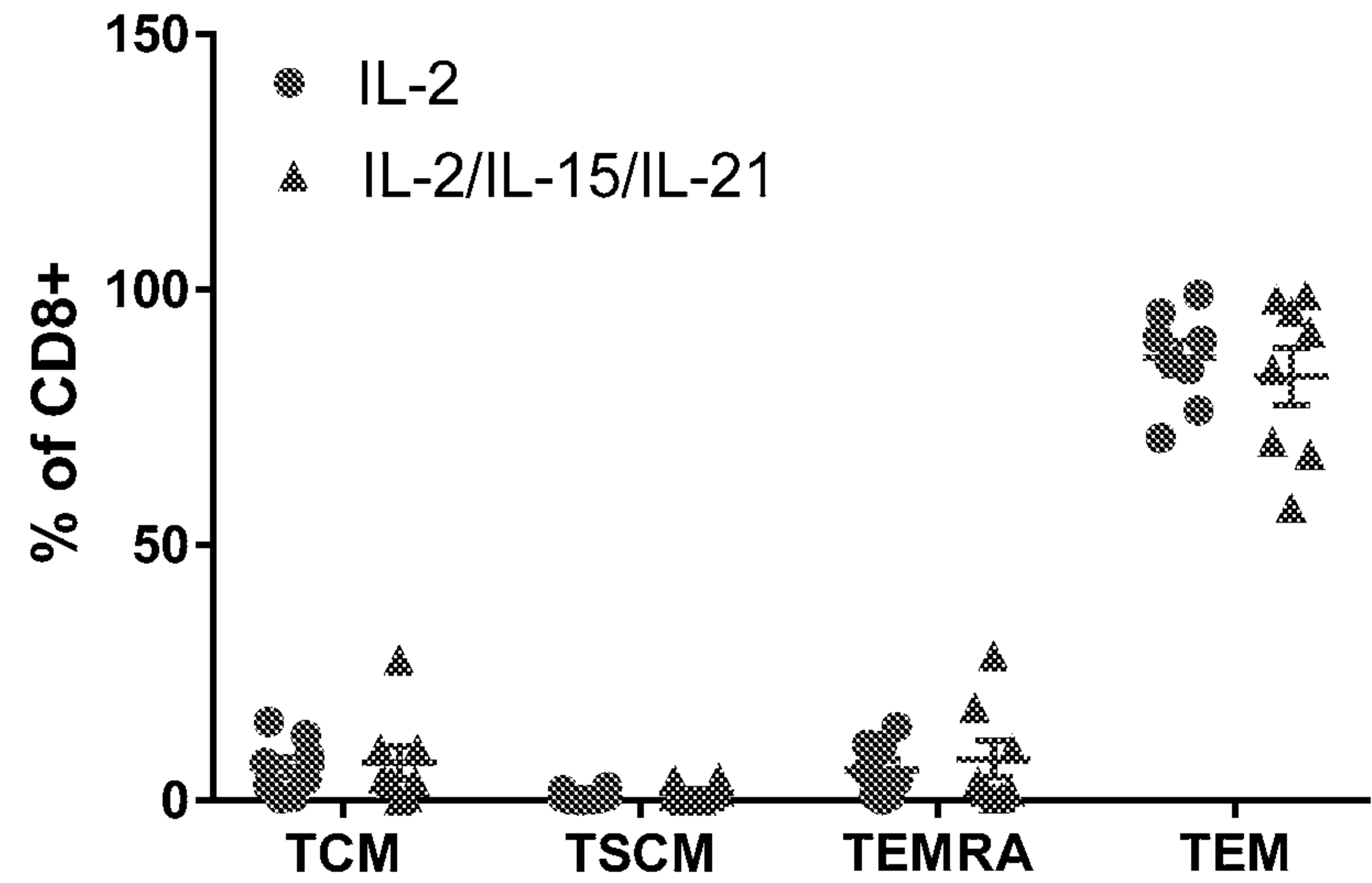


Figure 105A

Melanoma

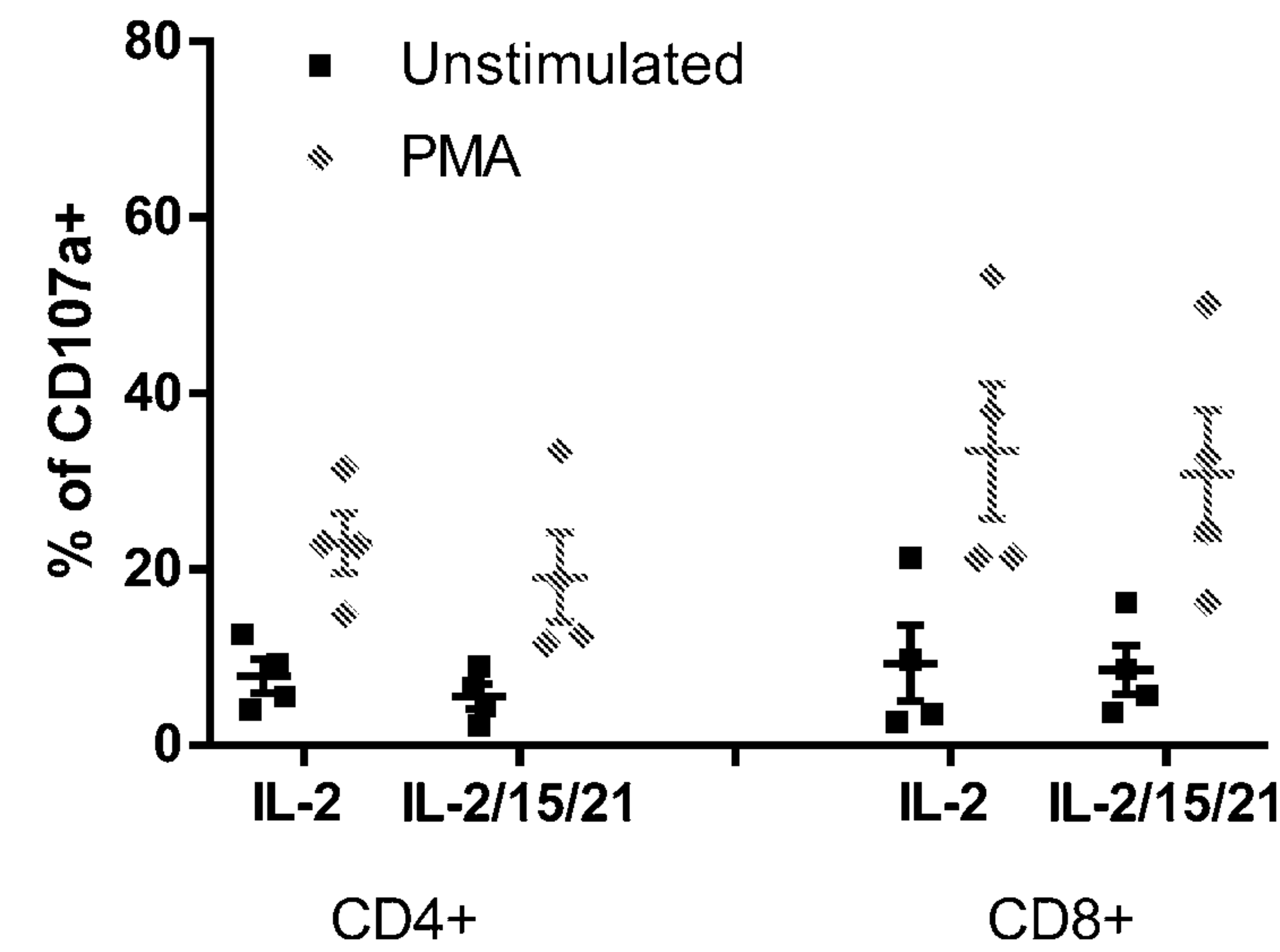


Figure 105B

Lung Carcinoma

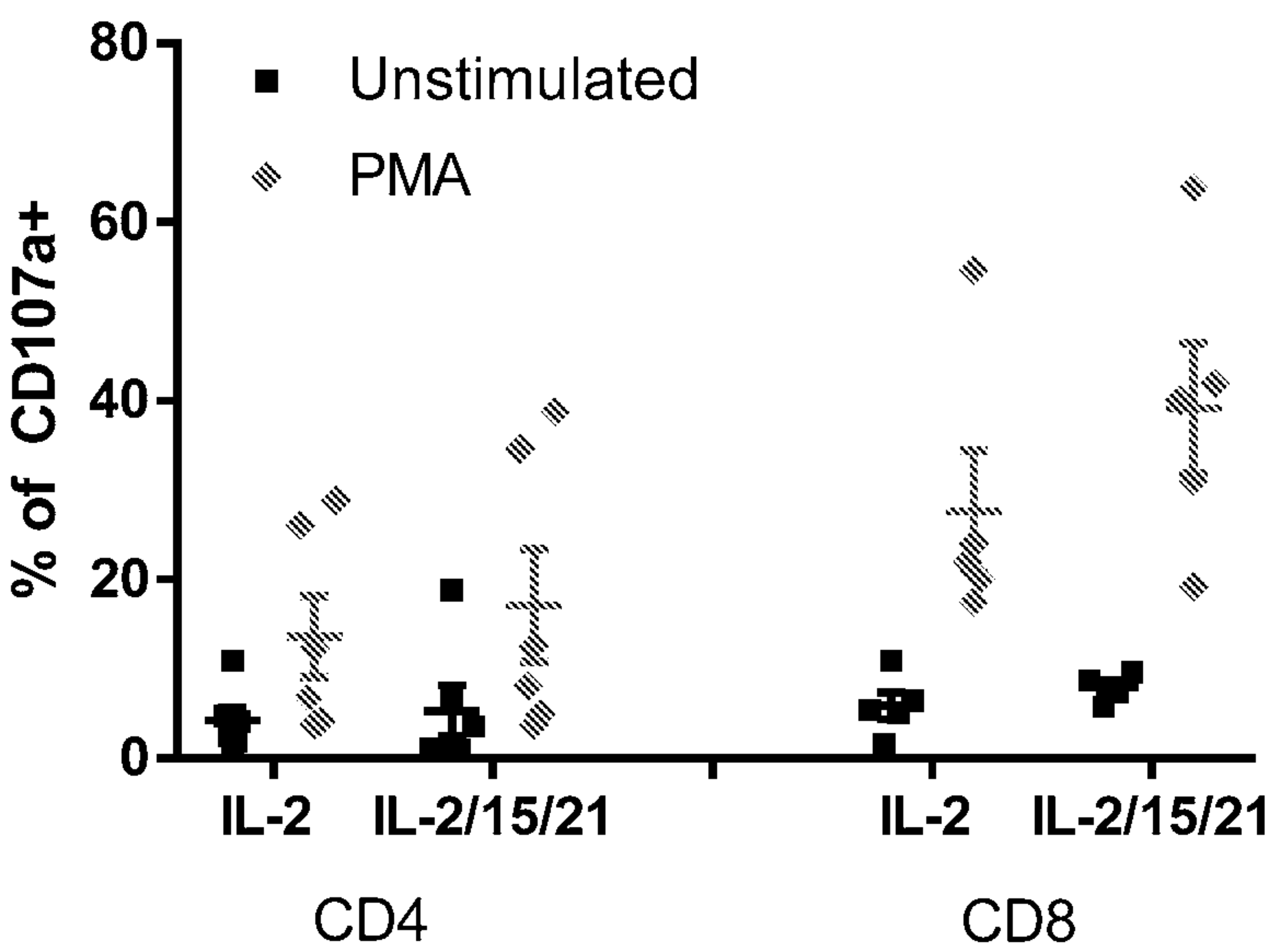


Figure 105C

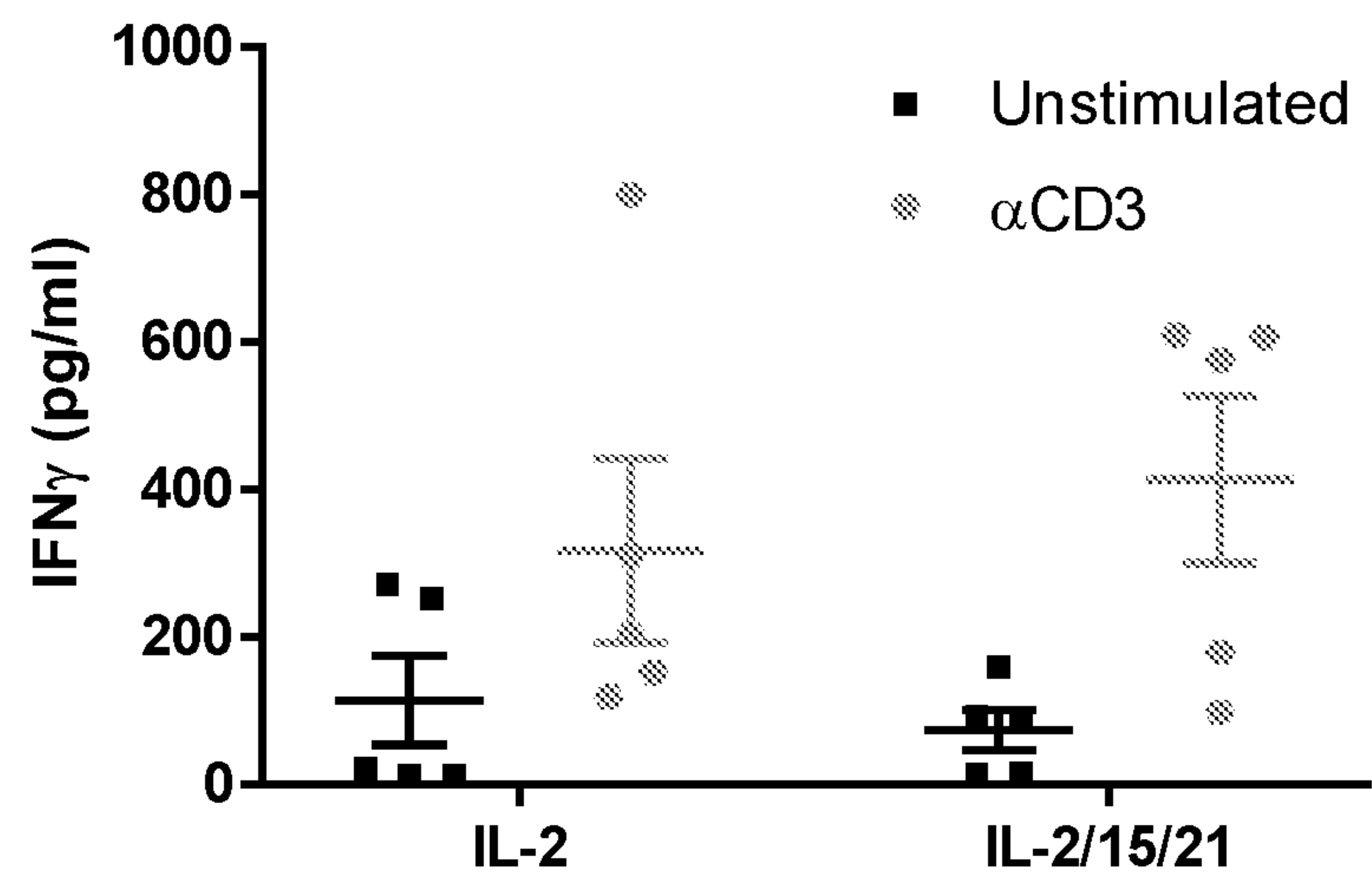
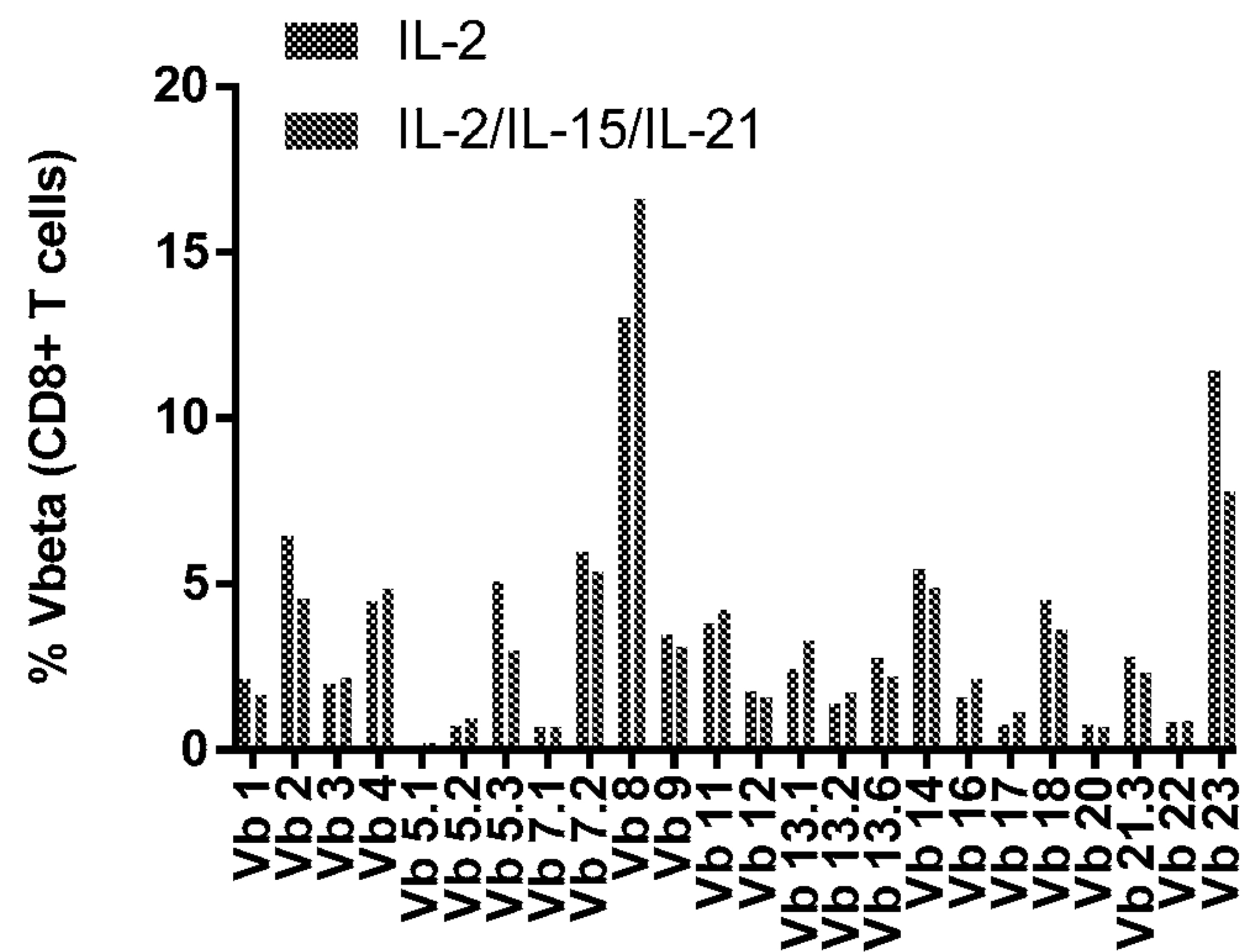
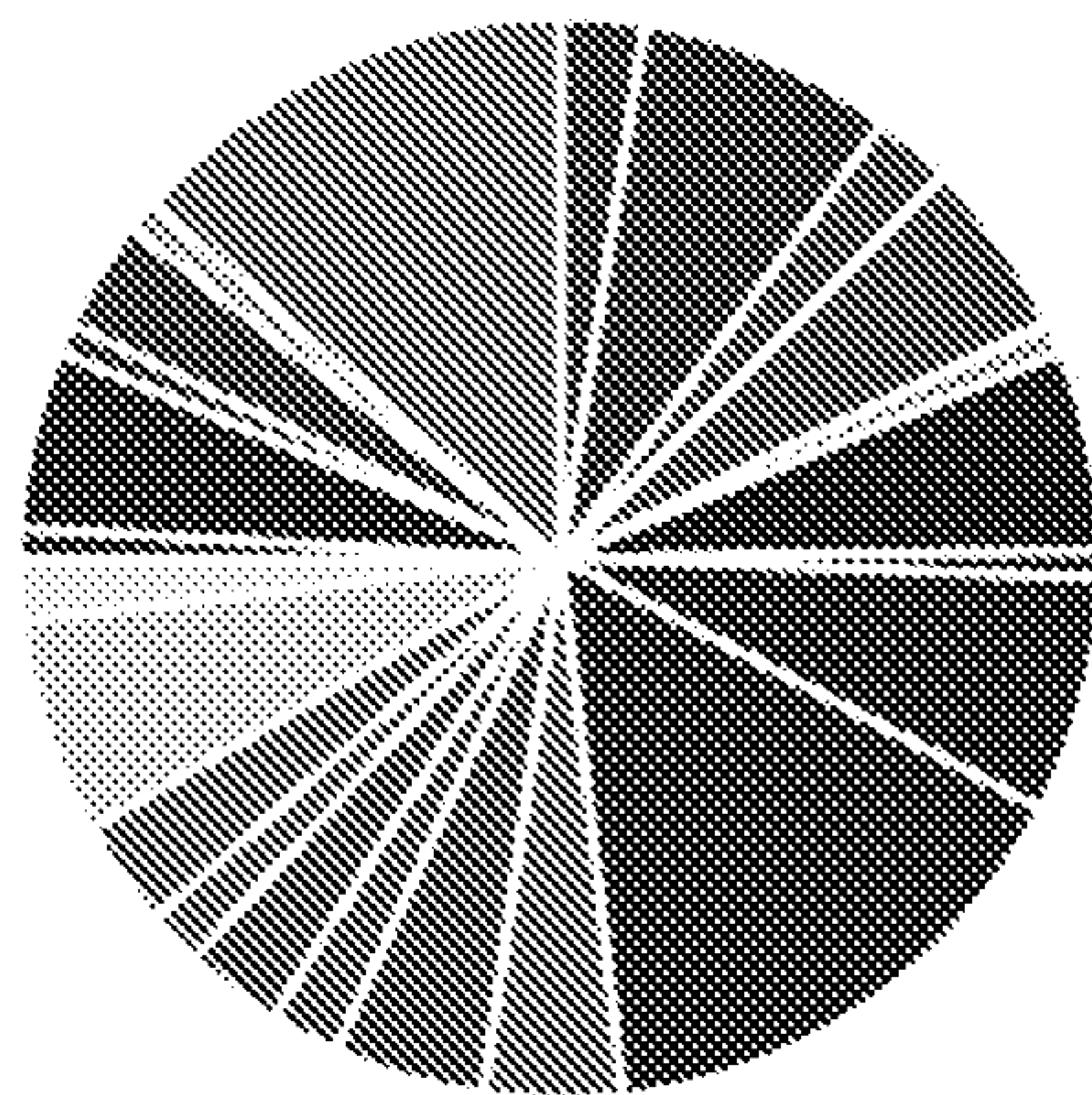


Figure 106A

Melanoma



IL-2



IL-2/IL-15/IL-21

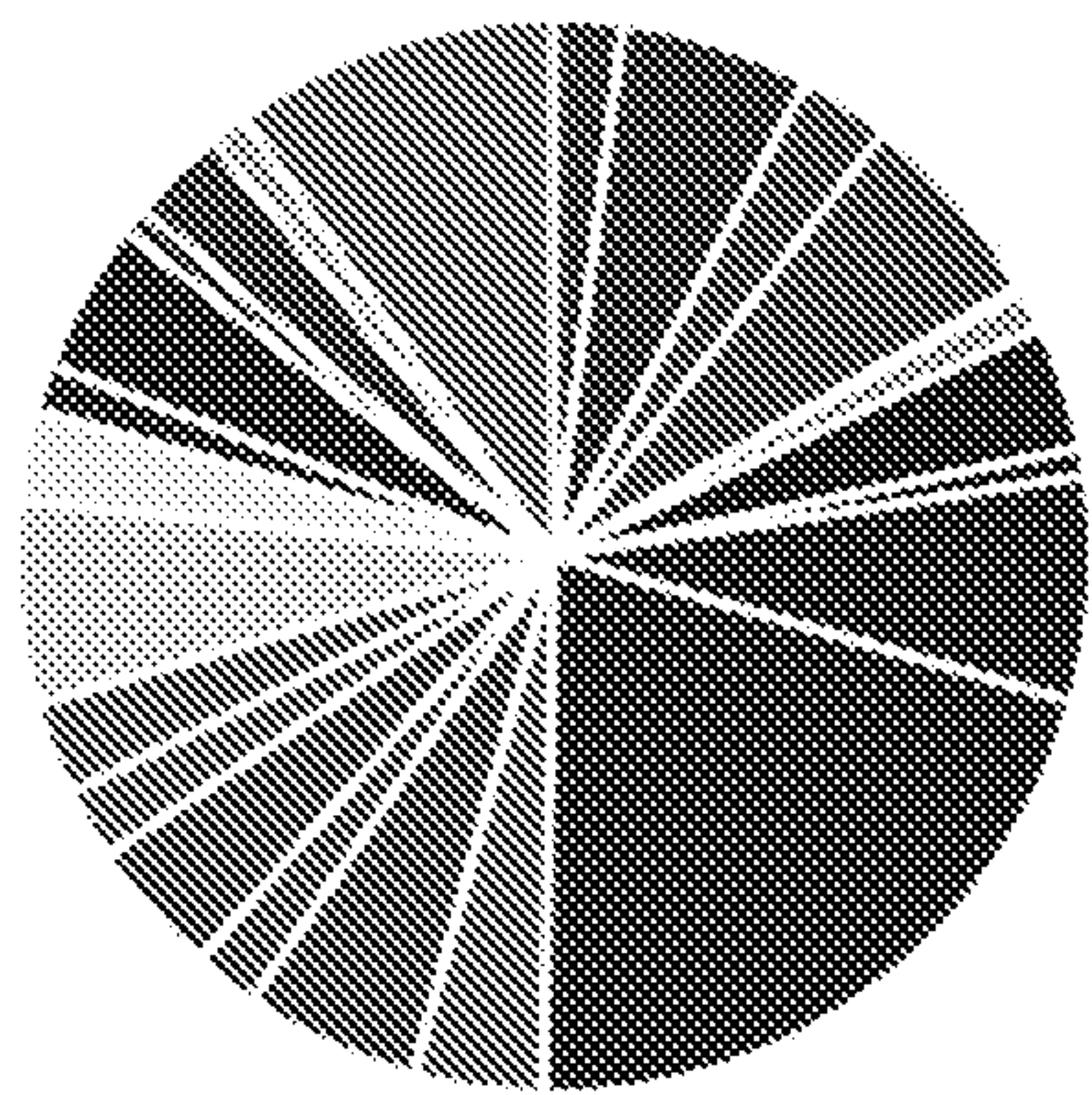
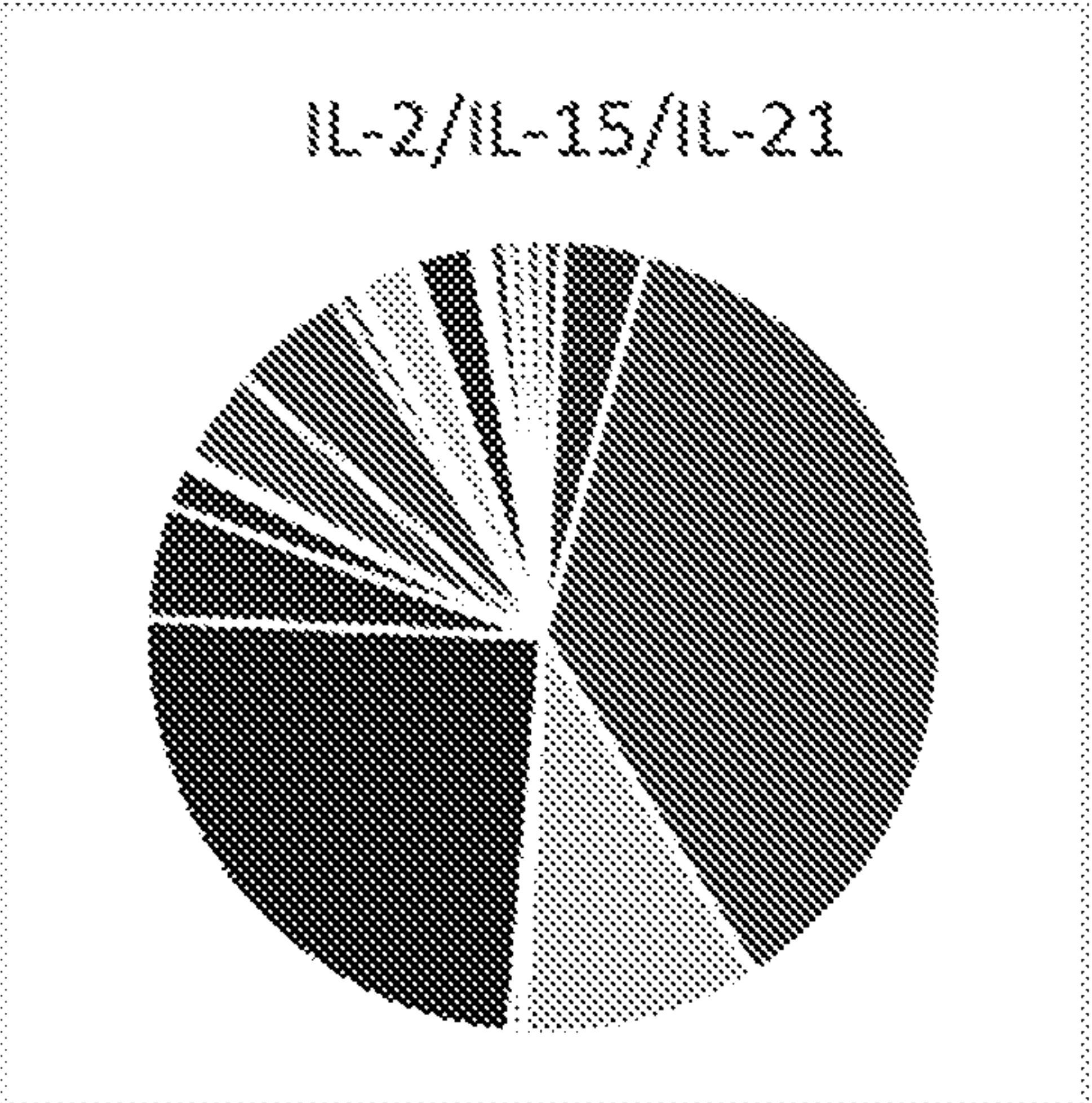
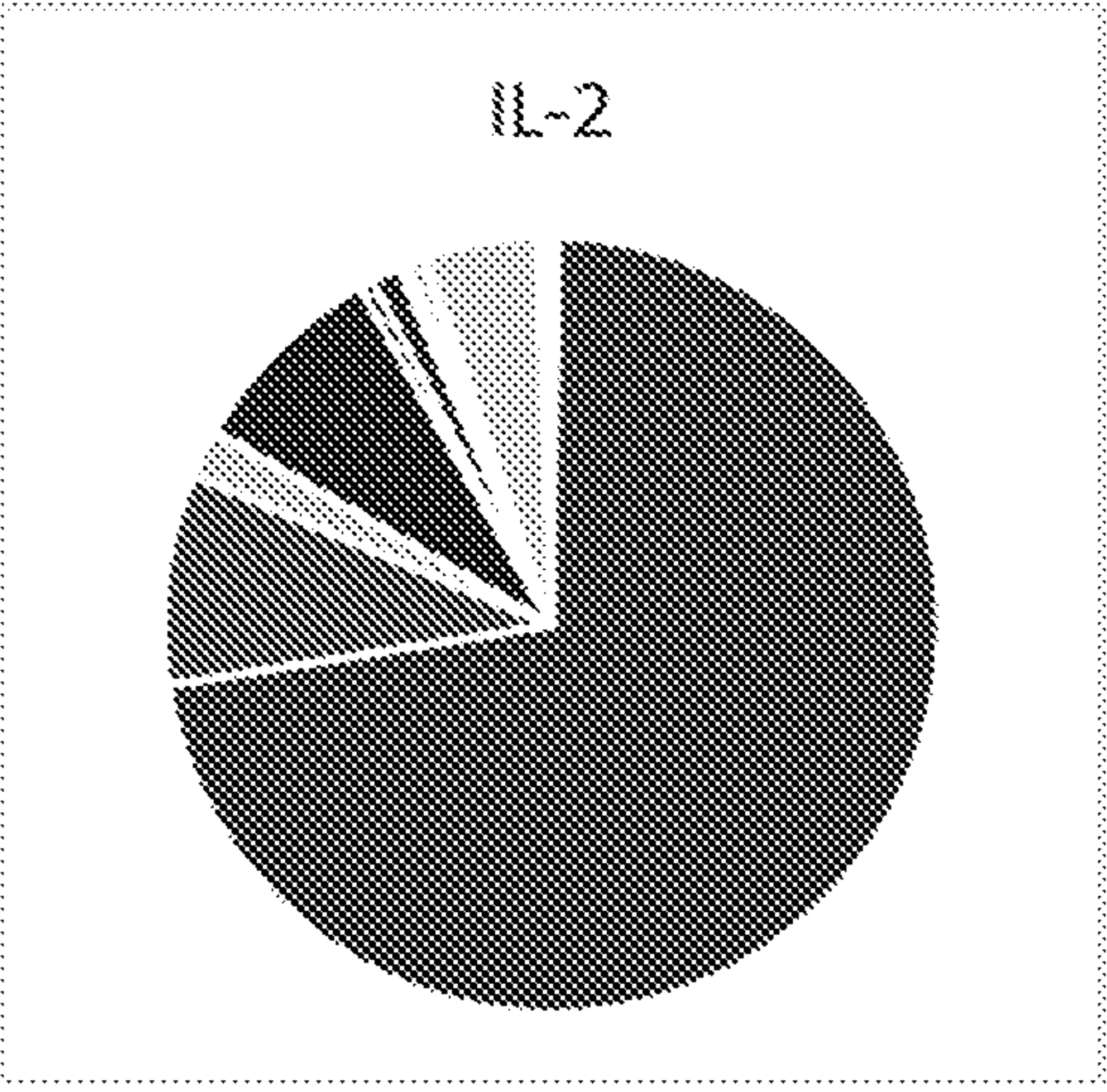
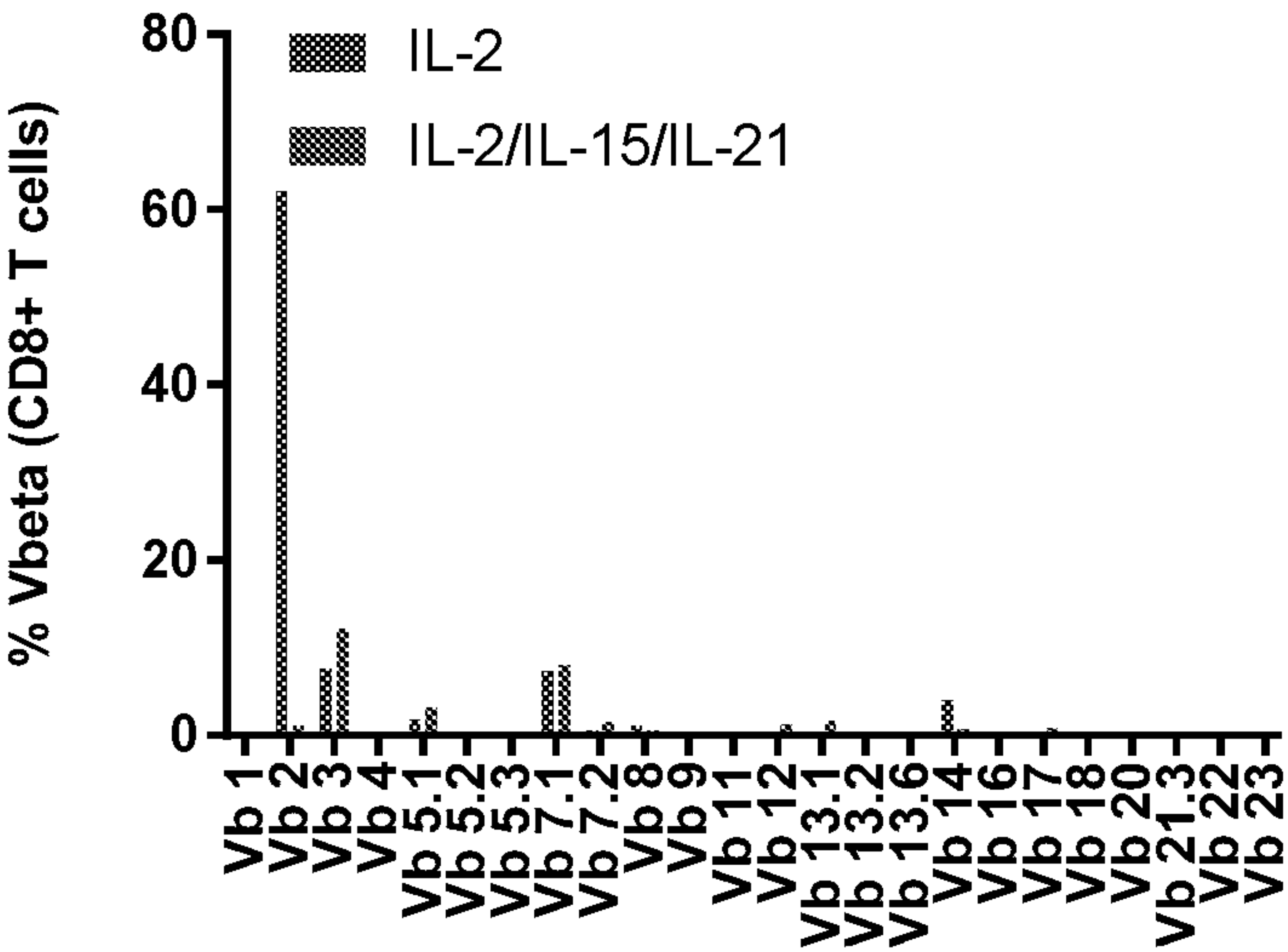


Figure 106B

Lung Carcinoma



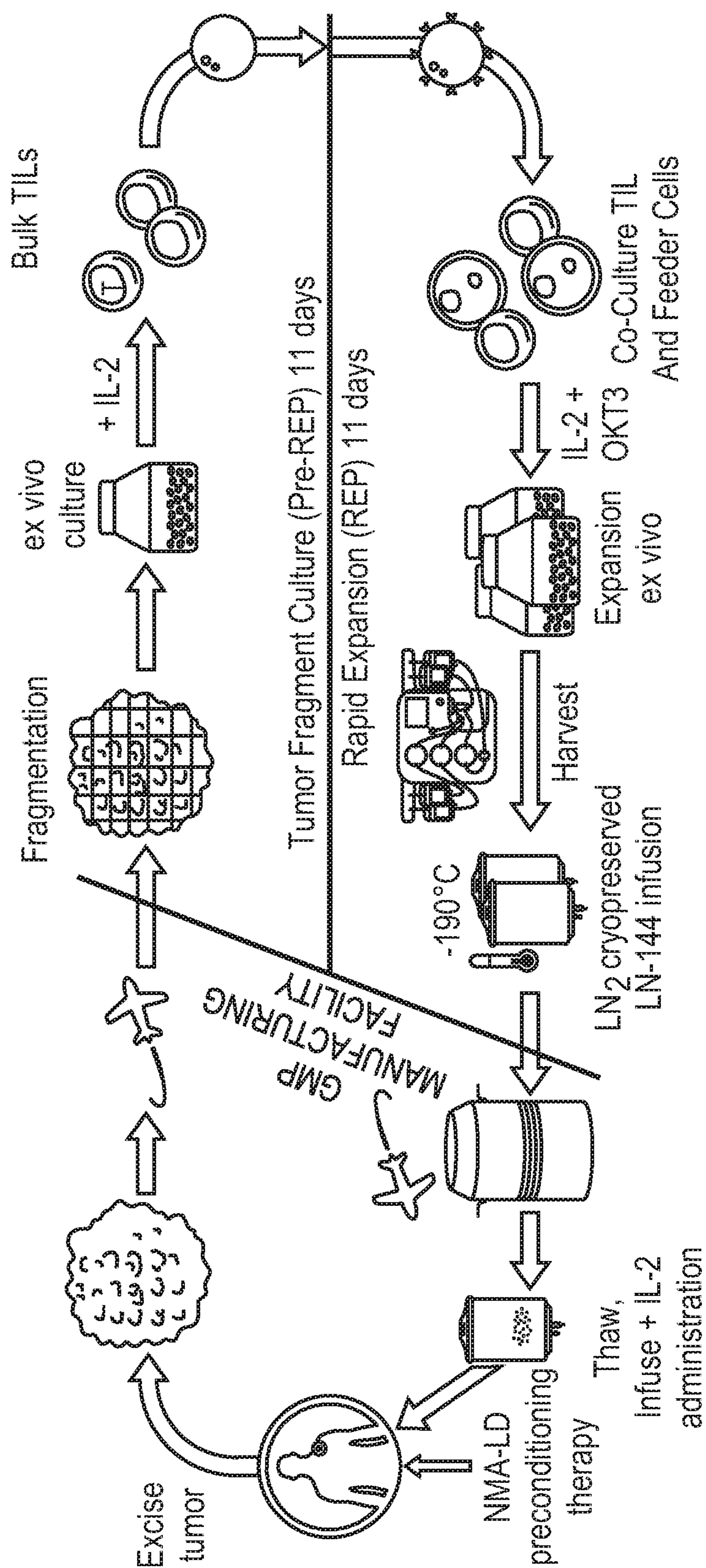
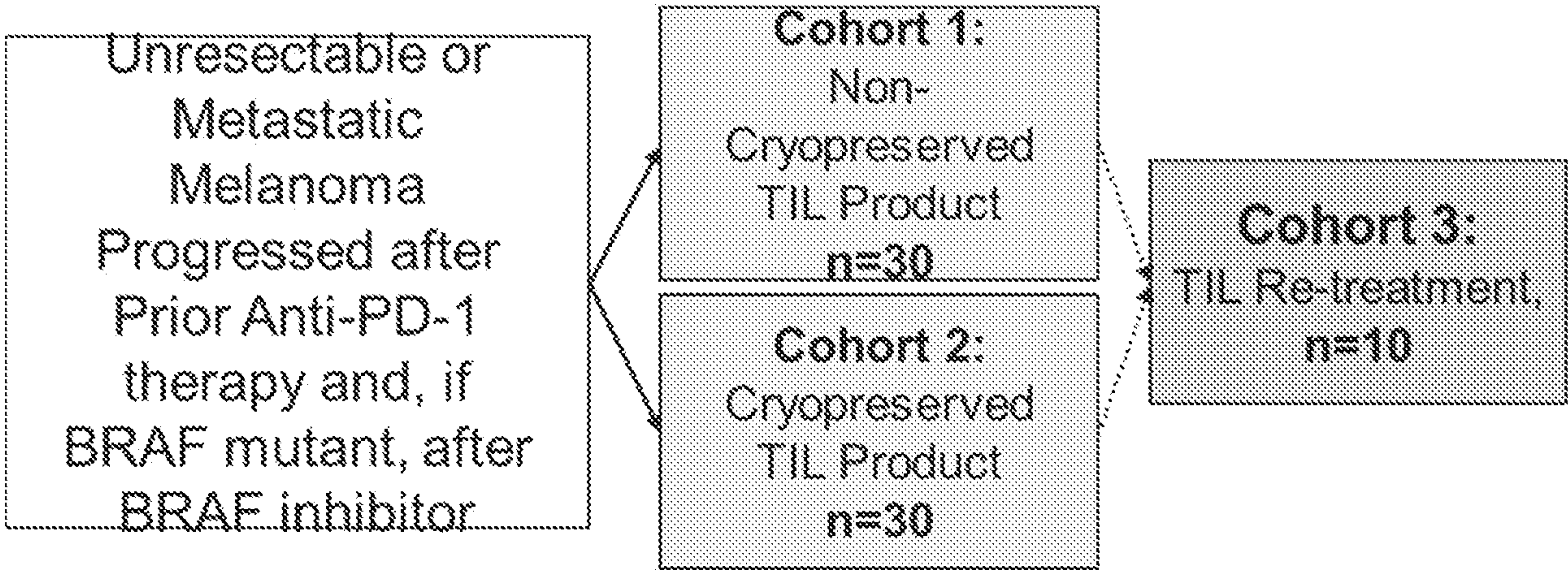


Figure 107

Figure 108



CHARACTERISTIC	Historical Cohort 1* N = 16, (%)	Cohort 2 N = 13, (%)
Gender, n (%)		
Male	7 (44)	5 (39)
Female	9 (56)	8 (62)
Age		
Median	55	54
Min, Max	41, 72	35, 66
Prior therapies, n (%)		
Mean # prior systemic therapies	3	4
Anti-CTLA-4	14 (88)	13 (100)
Anti-PD-1	21 (100)	13 (100)
Target Lesion Sum of Diameter (mm)		
Mean (SD)	104 (68)	141 (102)
Min, Max	15, 225	38, 342
CHARACTERISTIC	Historical Cohort 1* N = 16, (%)	Cohort 2 N = 13, (%)
Baseline ECOG score, n (%)		
0	9 (56)	8 (62)
1	7 (44)	5 (39)
BRAF Status, n (%)		
Mutated	9 (56)	6 (46)
Wild Type	7 (44)	7 (54)
Baseline LDH (U/L [SD])		
1-2 times ULN	7 (44)	7 (54)
Min, Max	1 (6)	2 (15)
Number of Target & Non-Target Lesions (at Base Line)		
>3	12(75)	10(77)
Mean	5.6	5.5

Figure 109

PREFERRED TERM	Historical Cohort 1 (N = 16)			Cohort 2 (N = 13)		
	Any Grade n (%)	Grade 3/4 n (%)	Grade 5 n (%)	Any Grade n (%)	Grade 3/4 n (%)	Grade 5 n (%)
Number of patients reporting at least one Treatment-Emergent AE	14 (87.5)	14 (87.5)	0	12 (85.7)	11 (78.6)	0
Nausea	14 (87.5)	0	0	7 (53.8)	0	0
Platelet count decreased	12 (75.0)	12 (75.0)	0	7 (53.8)	6 (46.2)	0
Anaemia	11 (68.8)	8 (50.0)	0	8 (61.5)	7 (53.8)	0
Neutrophil count decreased	11 (68.8)	11 (68.8)	0	6 (46.2)	6 (46.2)	0
Febril neutropenia	10 (62.5)	10 (62.5)	0	7 (53.8)	6 (46.2)	0
White blood count decreased	10 (62.5)	10 (62.5)	0	6 (46.2)	6 (46.2)	0
Chills	9 (56.3)	0	0	6 (46.2)	1 (7.7)	0
Diarrhoea	8 (50.0)	1 (6.3)	0	4 (30.8)	0	0
Fatigue	7 (43.8)	0	0	7 (53.8)	0	0
Vomiting	7 (43.8)	0	0	2 (15.4)	0	0
Constipation	6 (37.5)	0	0	3 (23.1)	0	0
Decreased appetite	5 (31.3)	0	0	4 (30.8)	0	0
Headache	5 (31.3)	0	0	3 (23.1)	0	0
Hypocalcaemia	5 (31.3)	0	0	1 (7.7)	0	0
Hypokalaemia	5 (31.3)	0	0	3 (23.1)	0	0
Hypophosphataemia	5 (31.3)	5 (31.3)	0	4 (23.1)	1 (7.7)	0
Hypotension	5 (31.3)	2 (12.5)	0	3 (23.1)	3 (7.7)	0
Lymphocyte count decreased	5 (31.3)	5 (31.3)	0	3 (23.1)	3 (23.1)	0
Nasal Congestion	5 (31.3)	0	0	0	0	0
Pyrexia	5 (31.3)	0	0	9 (69.2)	1 (7.7)	0
Cough	4 (25.0)	0	0	4 (30.8)	0	0
Oedema peripheral	4 (25.0)	0	0	4 (30.8)	0	0
Pruritus	4 (25.0)	0	0	4 (30.8)	0	0

Notes: Adverse events are coded by MedDRA version 18.1.

Patients with multiple events for a given preferred term are counted only once using the maximum grade under each preferred term.

Events are sorted by decreasing frequency of preferred term under SOC per any grade.

Treatment-Emergent Adverse Events refer to all AEs starting on or after the first dose date of pre-treatment chemotherapy(Fludarabine and Cyclophosphamide) up to the last dose of IL2 + 30 days.

Figure 110

Figure 111

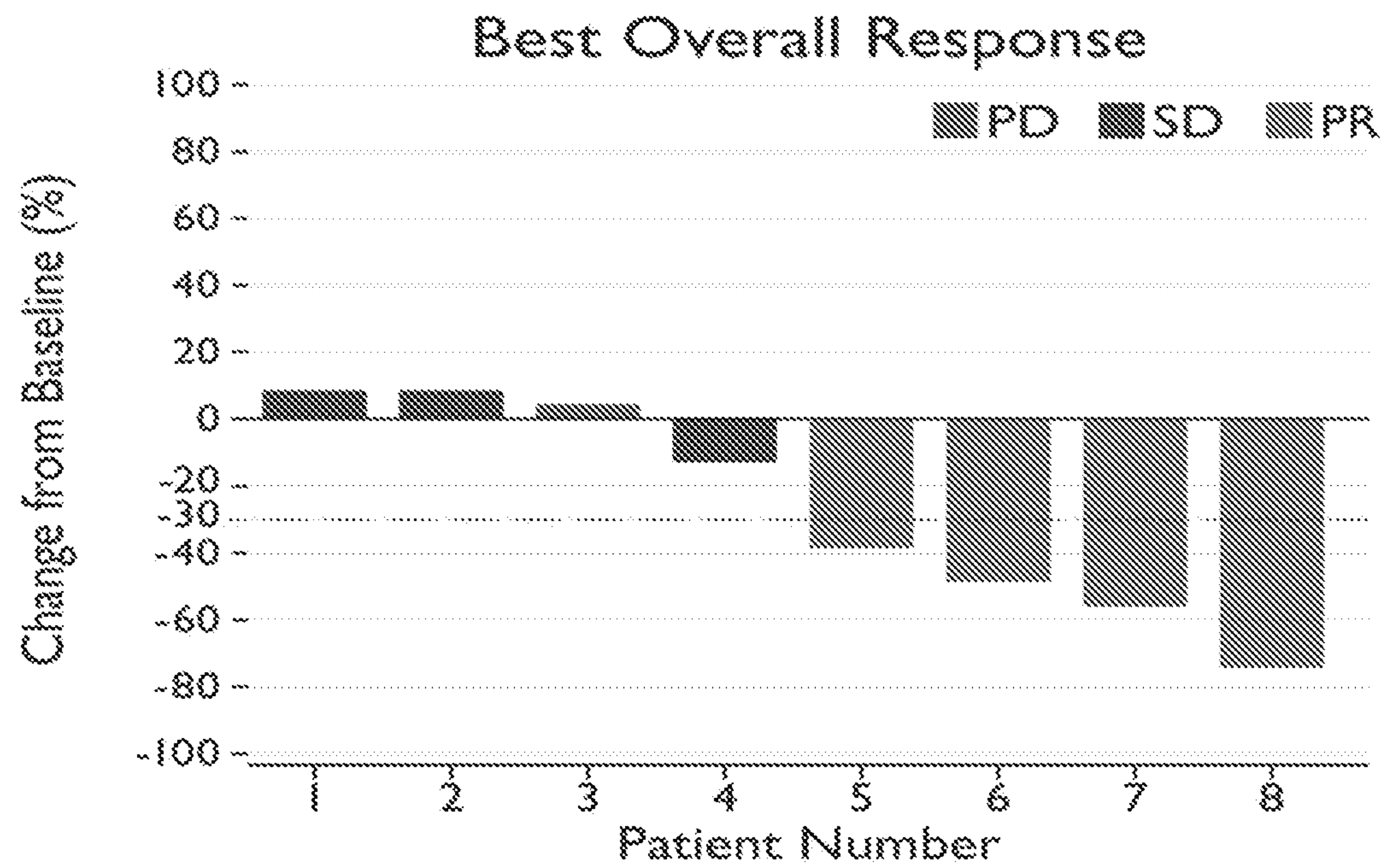
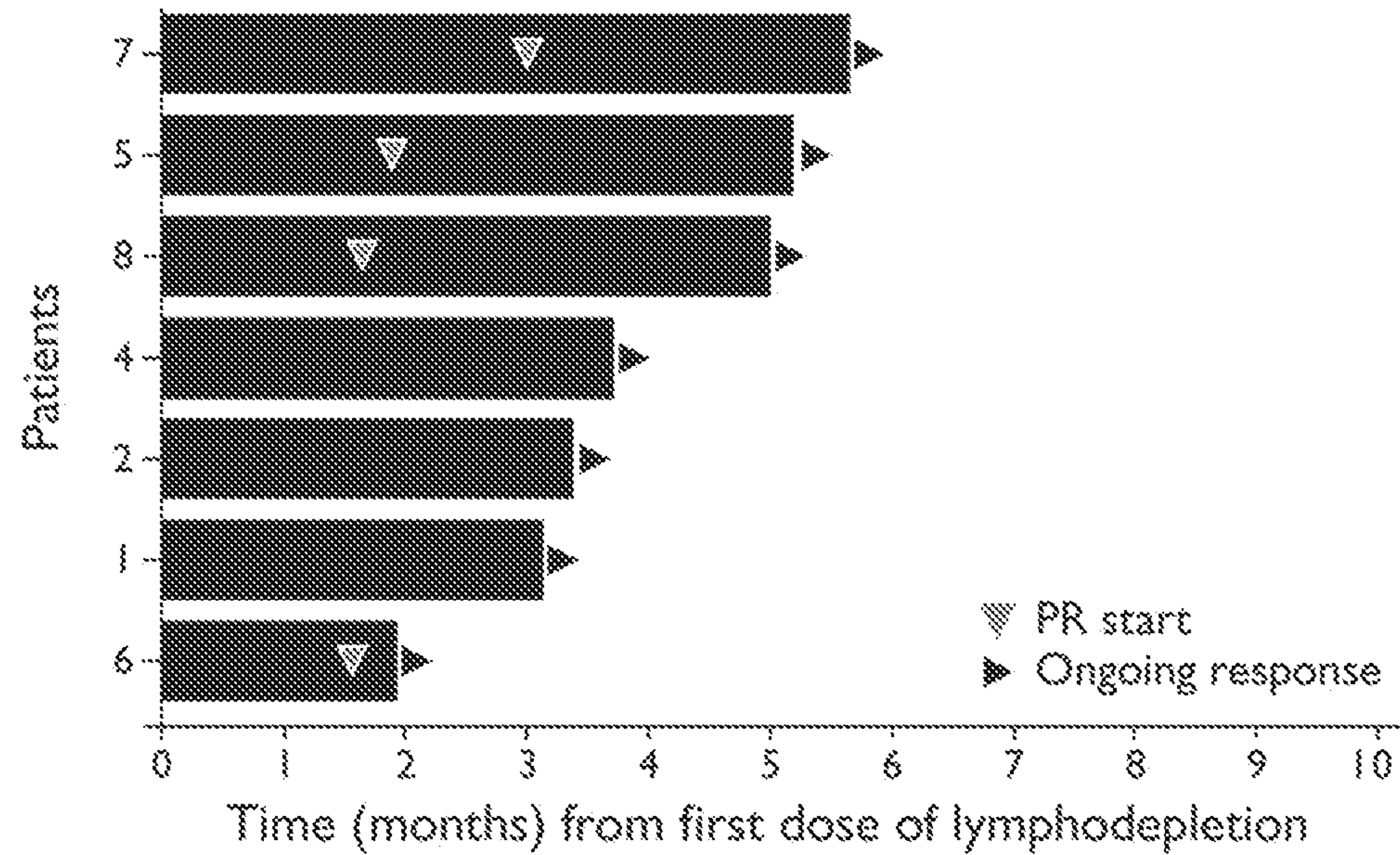
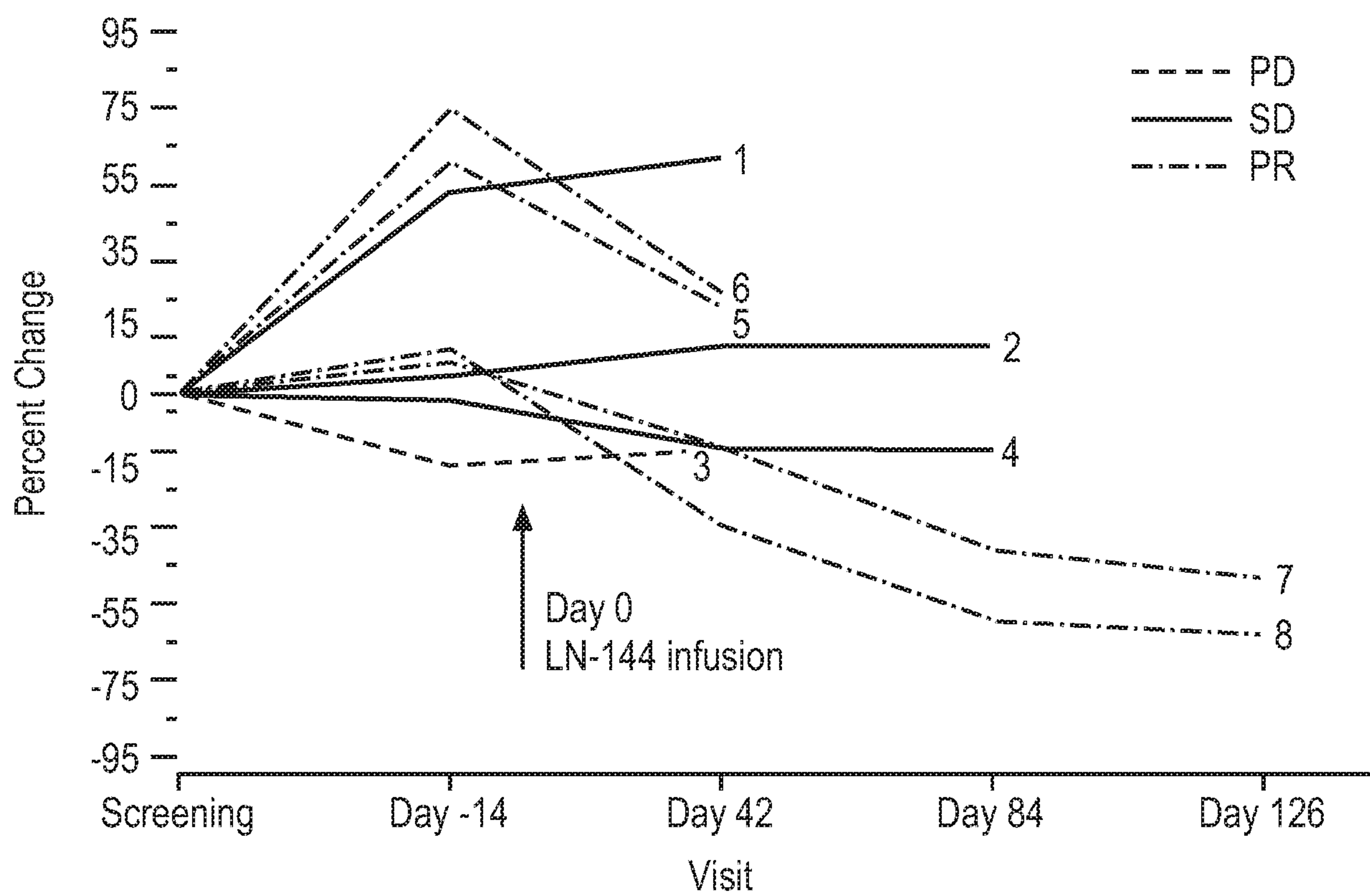


Figure 112



*Figure 113*

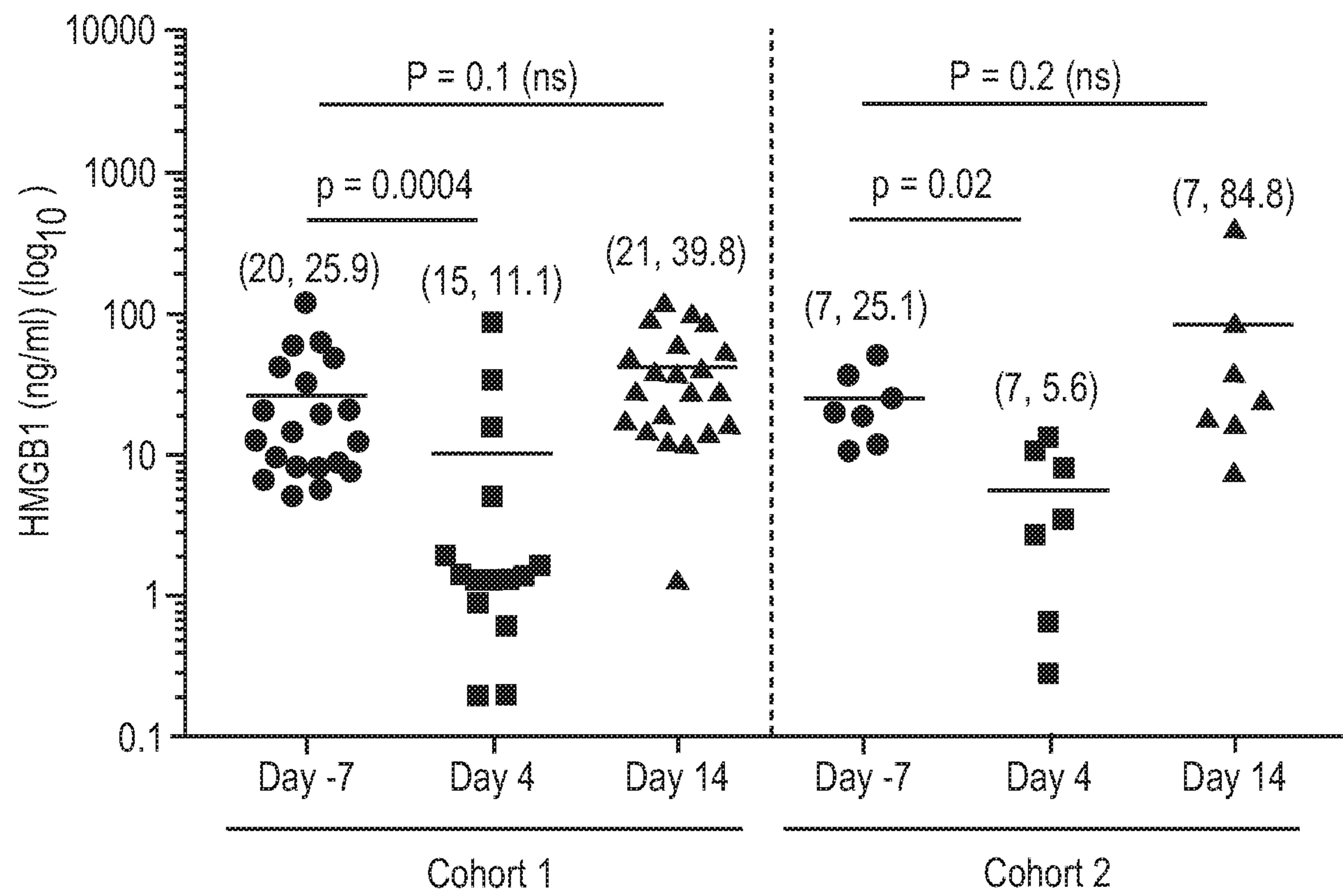
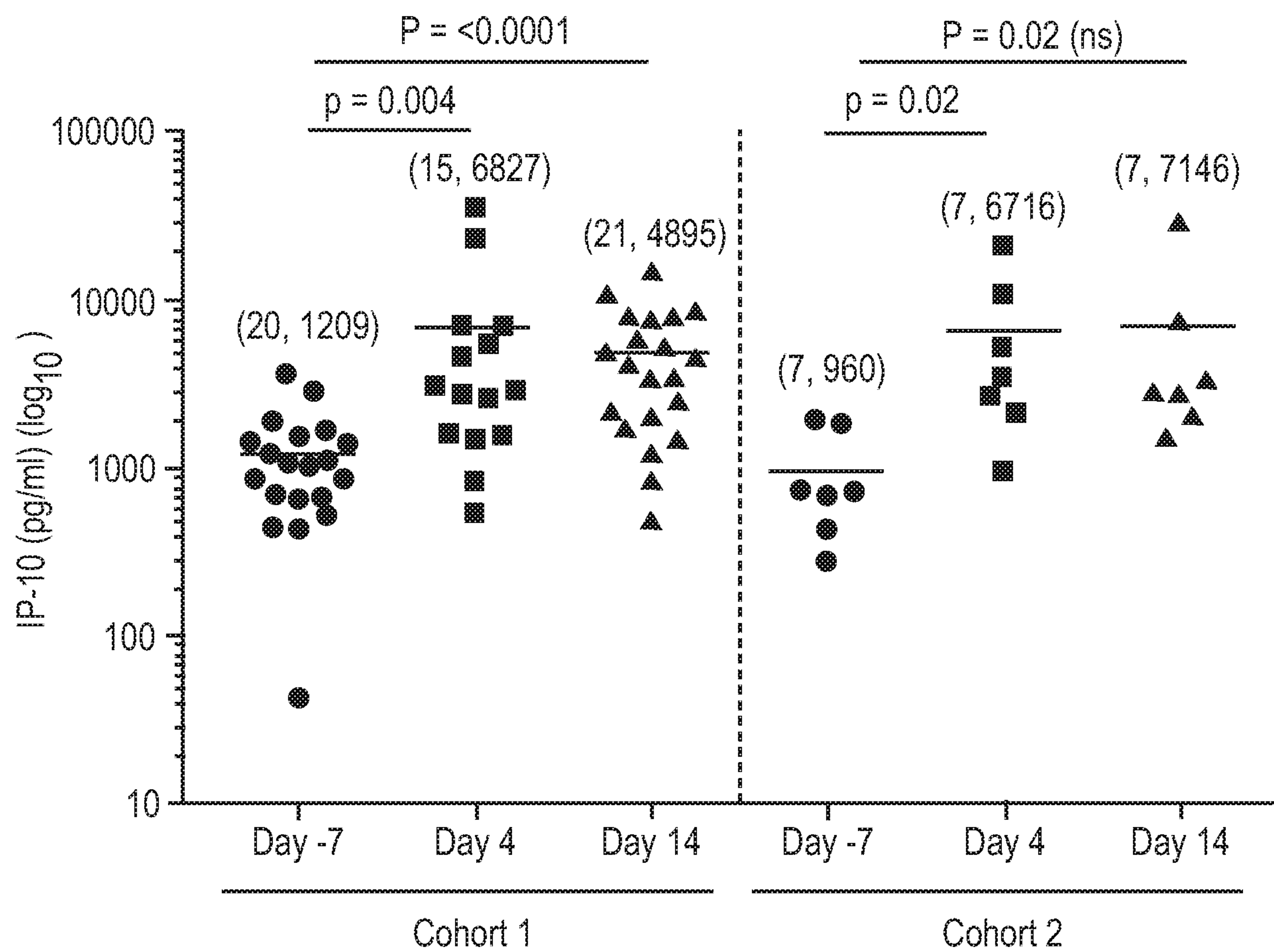


Figure 114

*Figure 115*

CHARACTERISTIC	Cohort 2 N = 17, (%)
Gender, n (%)	
Male	8 (47)
Female	9 (53)
Age	
Median	54
Min, Max	35, 66
Prior therapies, n (%)	
Mean # prior systemic therapies	3.6
Anti-CTLA-4	15 (88)
Anti-PD-1	16 (94)
Target Lesion Sum of Diameter (mm)	
Mean (SD)	140 (93)
Min, Max	38, 342
CHARACTERISTIC	Cohort 2 N = 17, (%)
Baseline ECOG, n (%)	
0	11 (65)
1	6 (35)
BRAF Status, n (%)	
Mutated	5 (29)
Wild Type	9 (53)
Unknown	3 (18)
Baseline LDH (U/L [SD])	
1-2 times ULN	8 (47)
> 2 times ULN	2 (12)
Number of Target & Non-Target Lesions (at Base Line)	
> 3	12 (71)
Mean	5.9

Cohort 2 has:
3.6 median prior therapies
High tumor burden at baseline as reflected by 140 mm sum of diameters for target lesions

Figure 116

PREFERRED TERM	Cohort 2 (N = 17)		
	Any Grade n (%)	Grade 3/4 n (%)	Grade 5 n (%)
Number of patients reporting at least one Treatment-Emergent AE	16 (94.1)	16 (94.1)	0
Pyrexia	13 (76.5)	1 (5.9)	0
Anaemia	11 (64.7)	10 (58.8)	0
Neutrophil count decreased	10 (58.8)	10 (58.8)	0
Platelet count decreased	10 (58.8)	8 (47.1)	0
Febrile neutropenia	10 (58.8)	8 (47.1)	0
Fatigue	10 (58.8)	0	0
Chills	9 (52.9)	1 (5.9)	0
Nausea	9 (52.9)	0	0
White blood cell count decreased	8 (47.1)	8 (47.1)	0
Lymphocyte count decreased	6 (35.3)	6 (35.3)	0
Diarroea	6 (35.3)	0	0
Decreased appetite	6 (35.3)	0	0

Notes: Patients with multiple events for a given preferred term are counted only once using the maximum grade under each preferred term. Treatment-Emergent Adverse Events refer to all AEs starting on or after the first dose date of pre-treatment chemotherapy (Fludarabine and Cyclophosphamide) up to the last dose of IL-2 + 30 days.

Figure 117

Figure 118

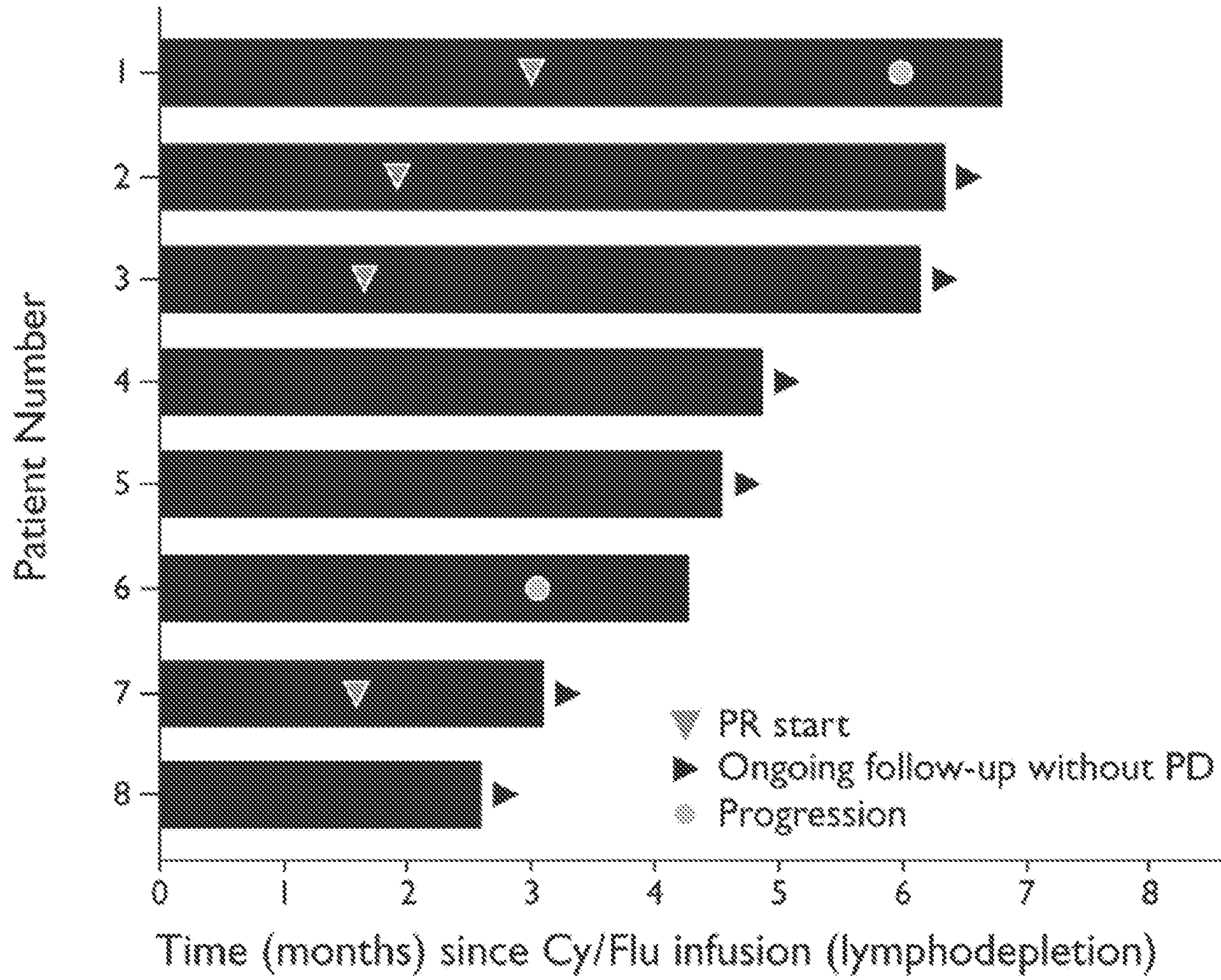


Figure 119

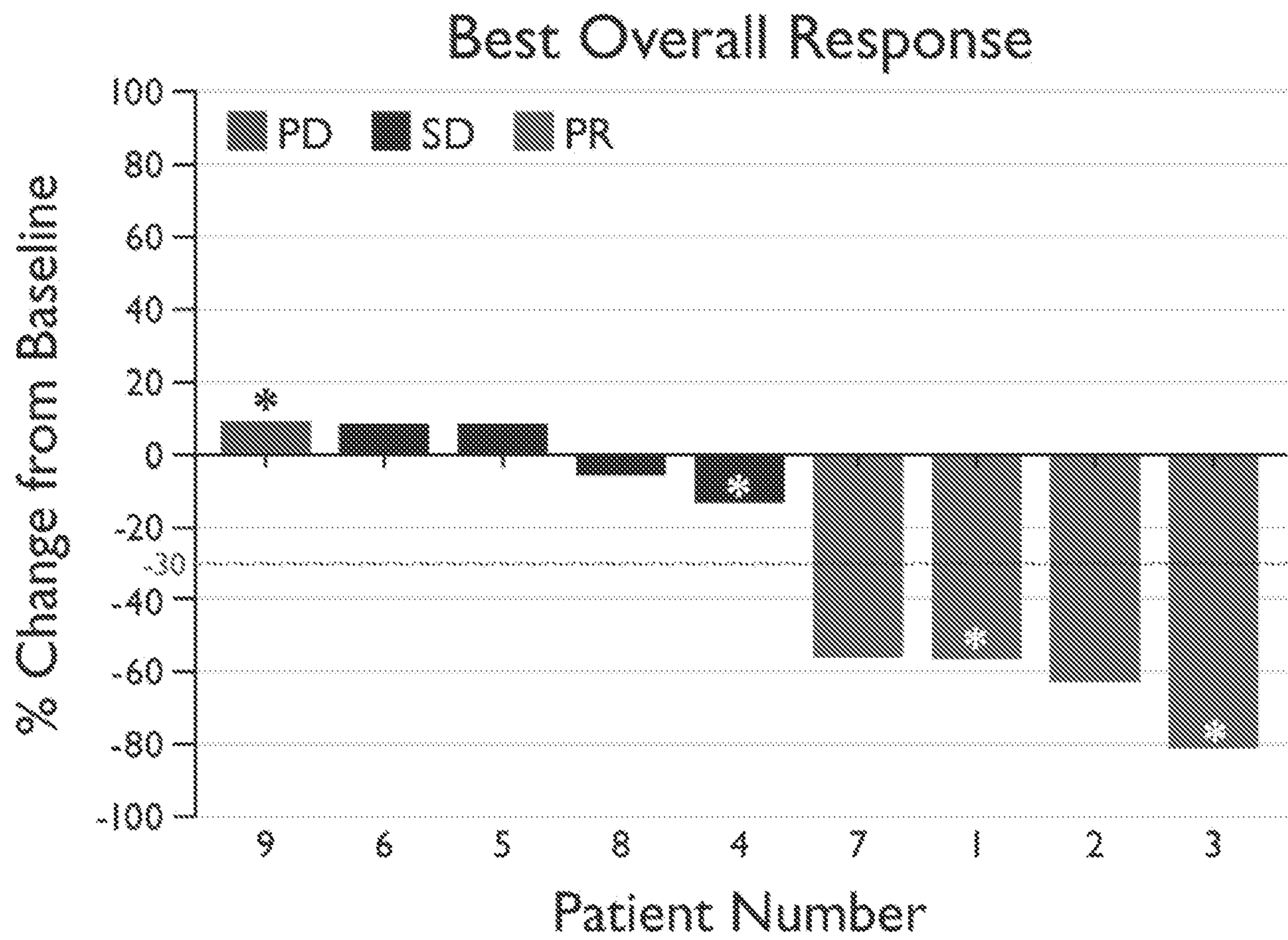
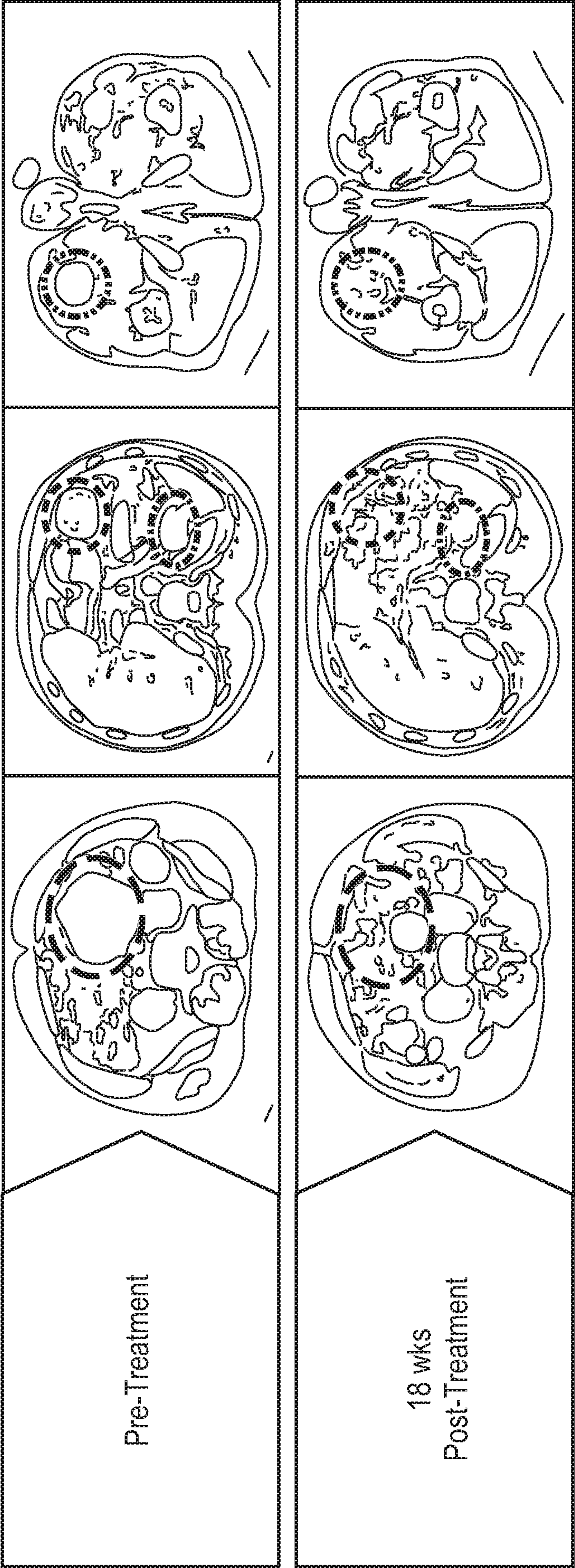


Figure 120

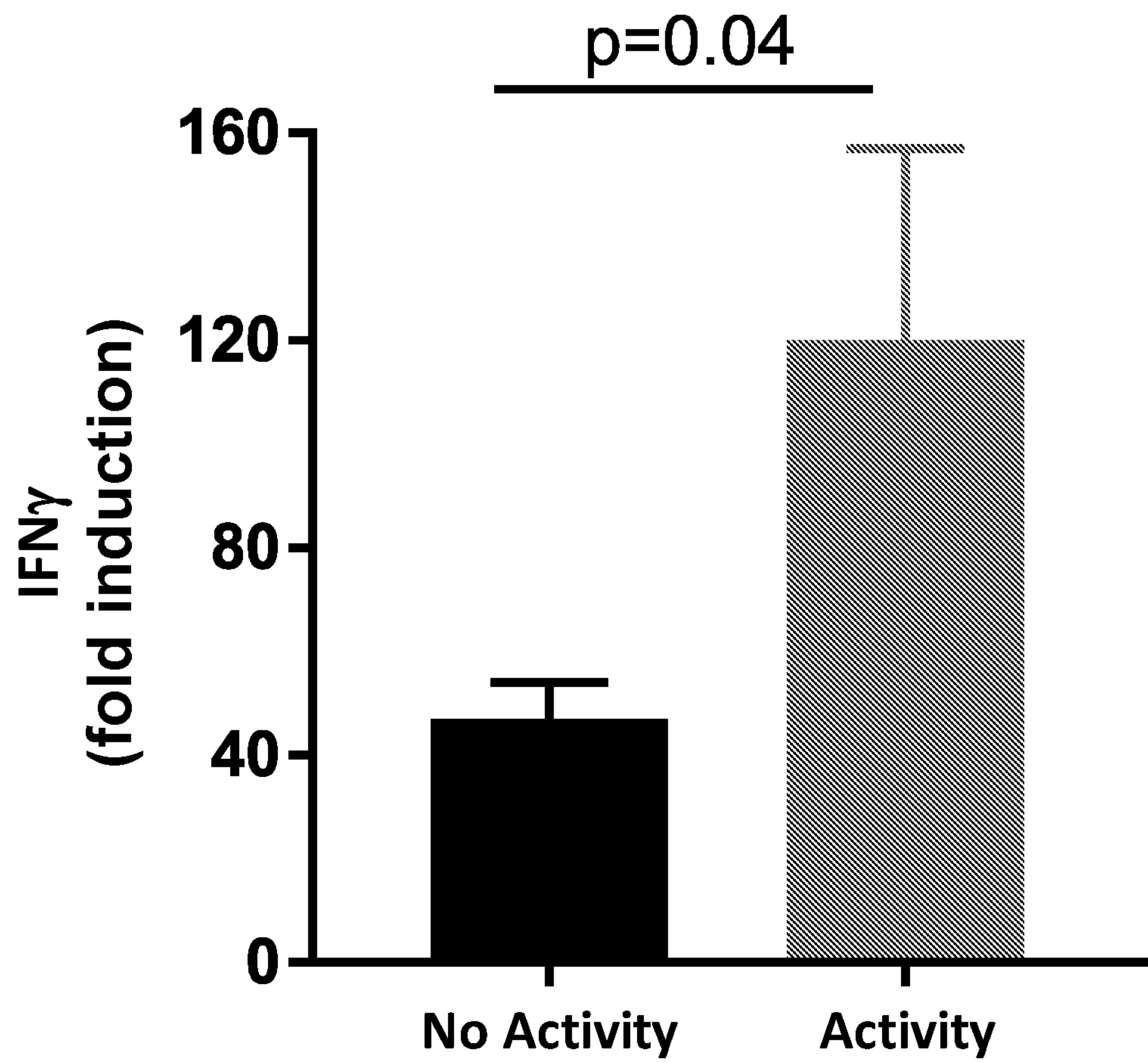
RESPONSE	PATIENTS, N=10 n (%)
Objective Response Rate	4 (40%)
Disease Control Rate	8 (80%)
Partial Response	4 (40%)
Stable Disease	4 (40%)
Progressive Disease	1 (10%)
Non-Evaluable*	1 (10%)



○ TL1: Lt low. quad. abdom. - BL: 8.8 cm / 18 wk: 3.7 cm ○ TL3: Lt renal - BL: 4.1 cm / 18 wk: 2.1 cm
○ TL2: Lt upper. quad. abdom. - BL: 5.2 cm / 18 wk: 0 cm ○ TL5: Rt femoral LN - 4 cm (short axis) / 18 wk: 2.3 cm

Figure 121

Figure 122



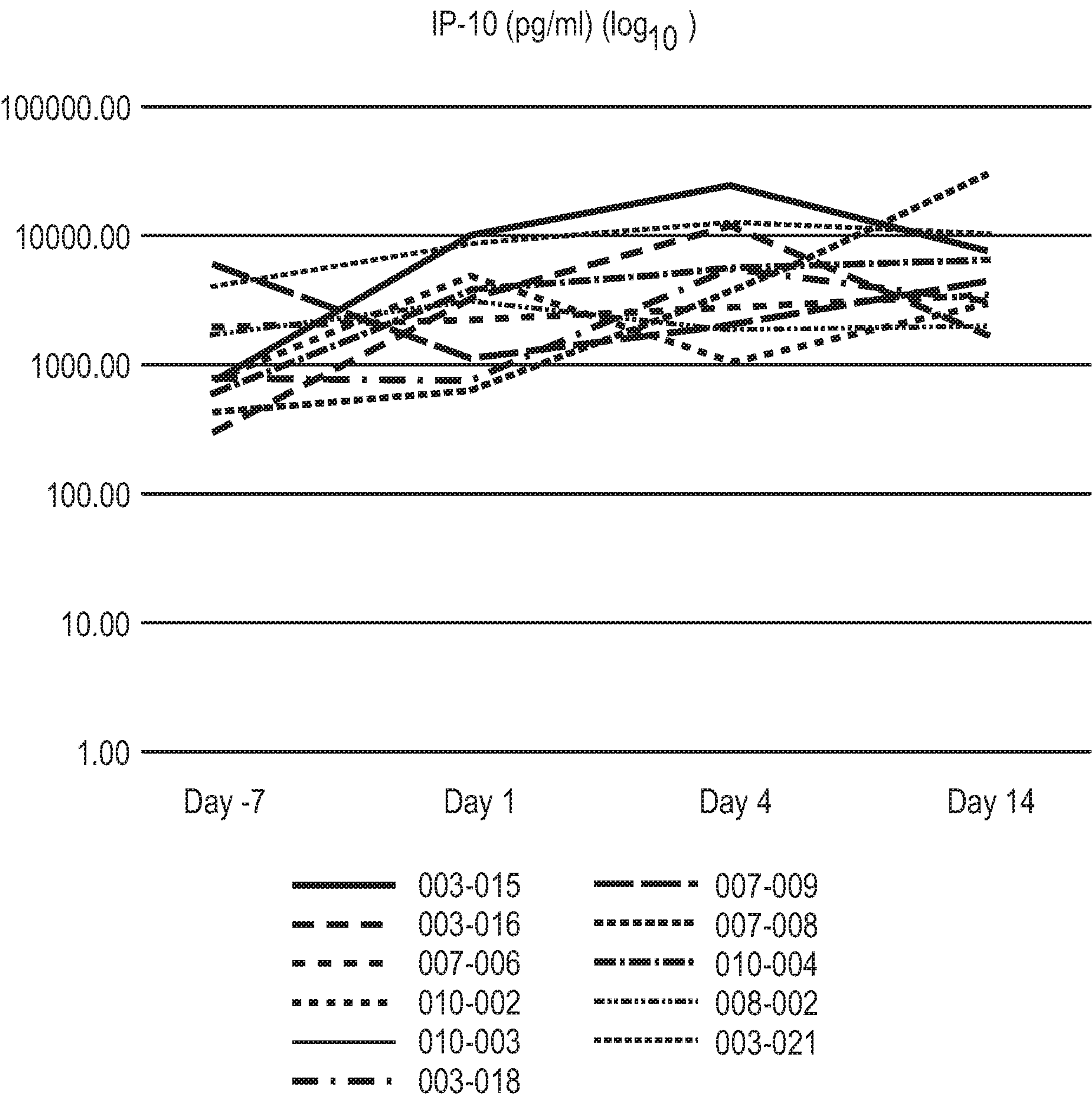


Figure 123

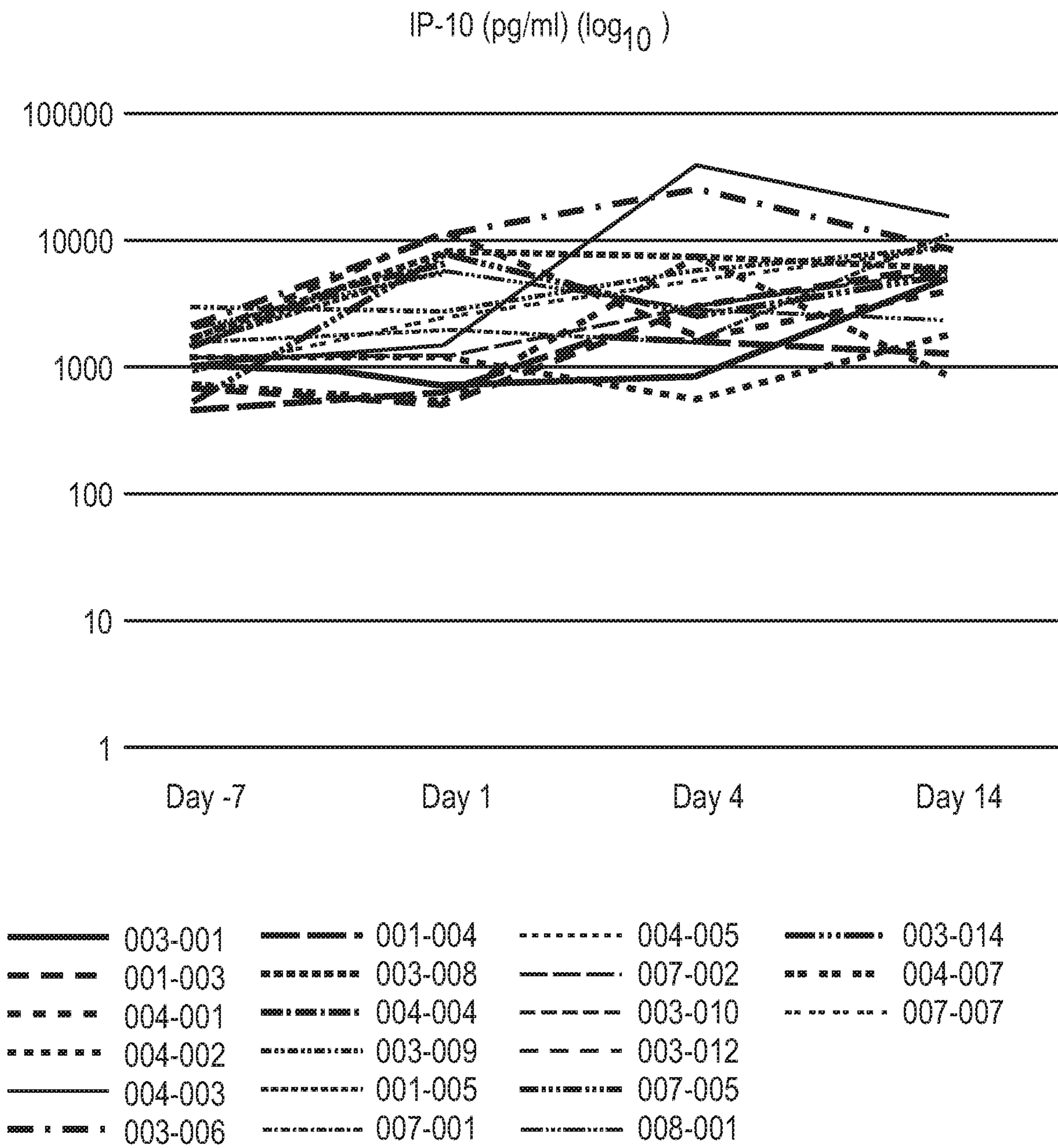


Figure 124

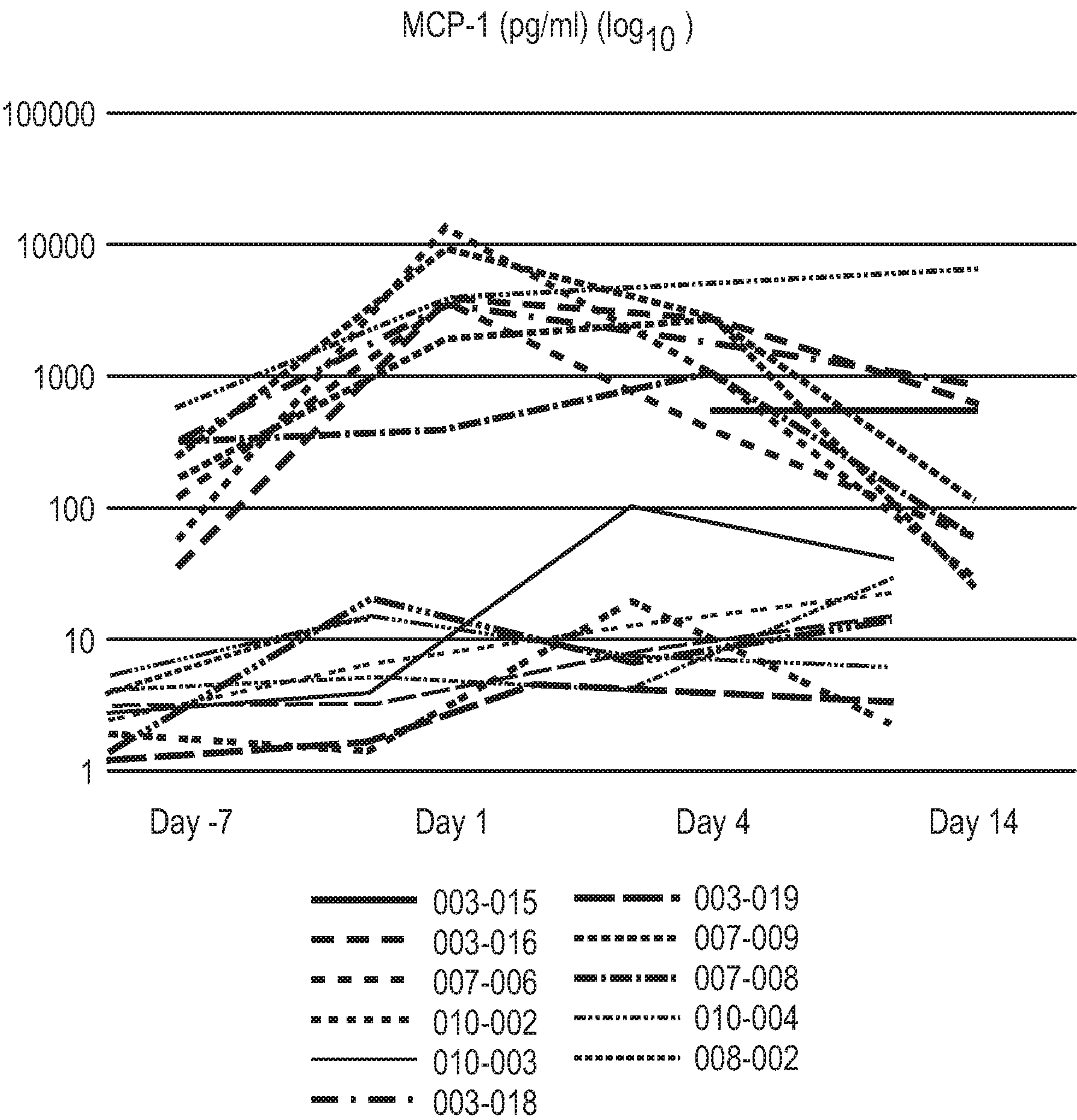


Figure 125

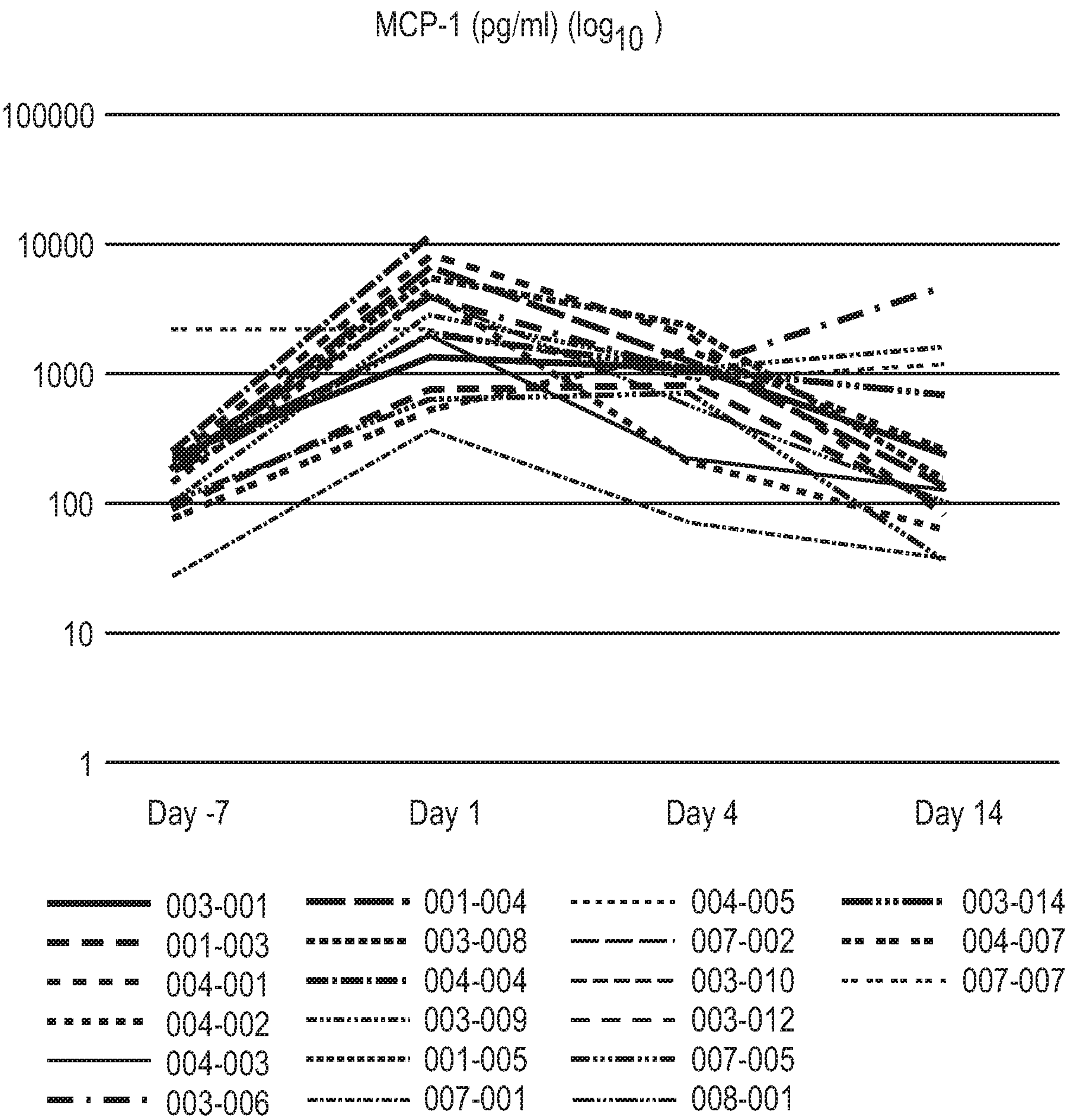


Figure 126

Cervical Carcinoma (C-145-04)								
Pt No	INFUSION	# CELLS INFUSED	RESPONSE DAY 42	RESPONSE DAY 84	RESPONSE DAY 126	RESPONSE AT 6 MONTHS	RESPONSE AT 9 MONTHS	BOR
1	9-Aug-17	32.6 bil	PR	PR	-	-	-	-
2	19-Sep-17	41.4 bil	SD (needs confirmation)			-	-	-
HNSCC (C-145-03)								
Pt No	INFUSION	# CELLS INFUSED	RESPONSE DAY 28	RESPONSE DAY 56	RESPONSE DAY 84	RESPONSE AT 4 MONTHS	RESPONSE AT 6 MONTHS	BOR
1	31-May-17	21 bil	SD	PD	Discon.	-	-	SD
2	20-Jun-17	21 bil	PR	SD	SD	Passed away.	-	SD
3	1-Aug-17	30 bil	PR	PR	PR	PD	-	PR
4	14-Sep-17	65 bil	PR	PR	-	-	-	PR
5	03-Nov-17	10 bil	-	-	-	-	-	-
6	07-Nov-17	37 bil	-	-	-	-	-	-
7	08-Nov-17	21.5 bil	-	-	-	-	-	-

Figure 127