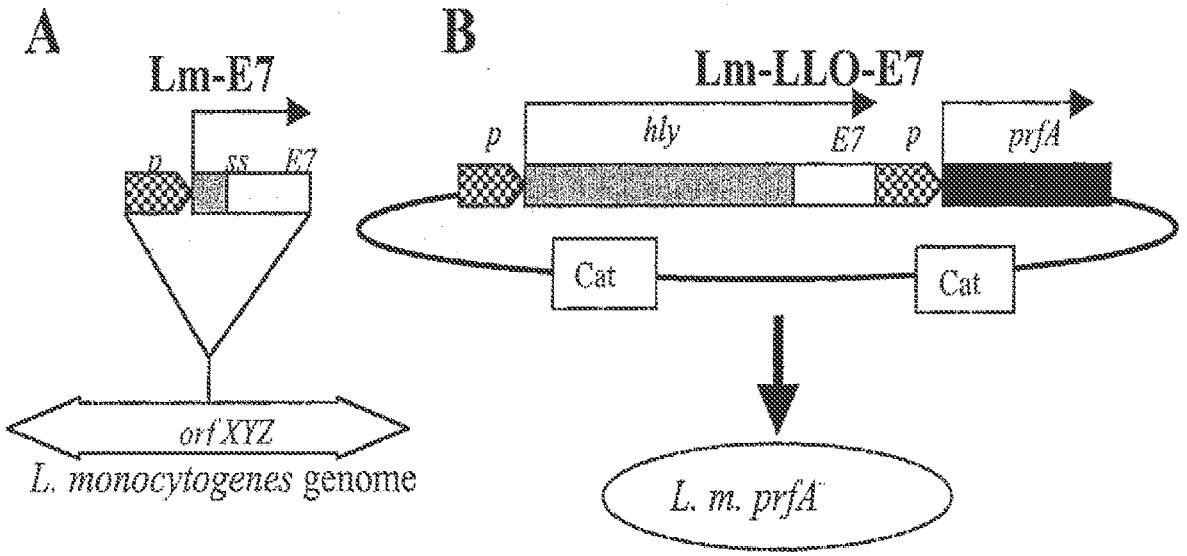


Figure 1

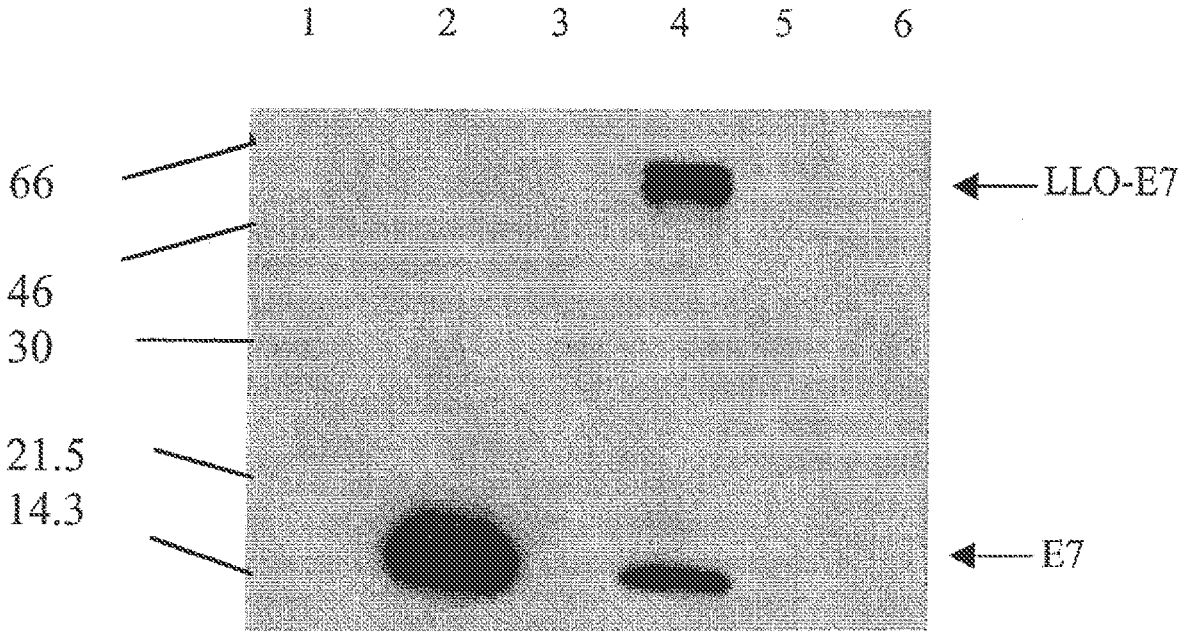


Figure 2

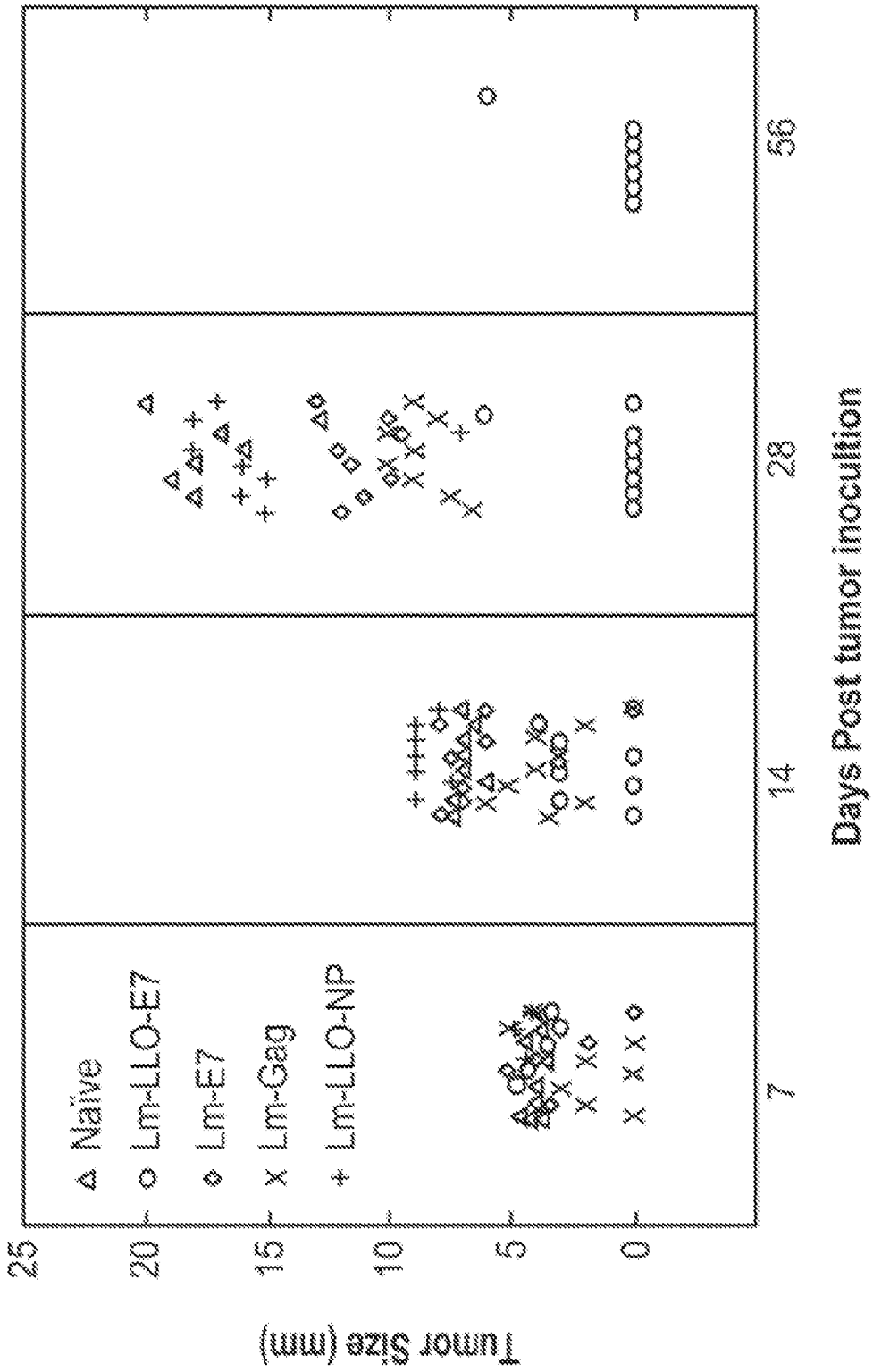

Tumor Size (mm)
25
20
15
10
5
0
Naïve
Lm-LLO-E7
Lm-E7
Lm-Gag
Lm-LLO-NP
7
14
28
56
Days Post tumor inocultion

Figure 3

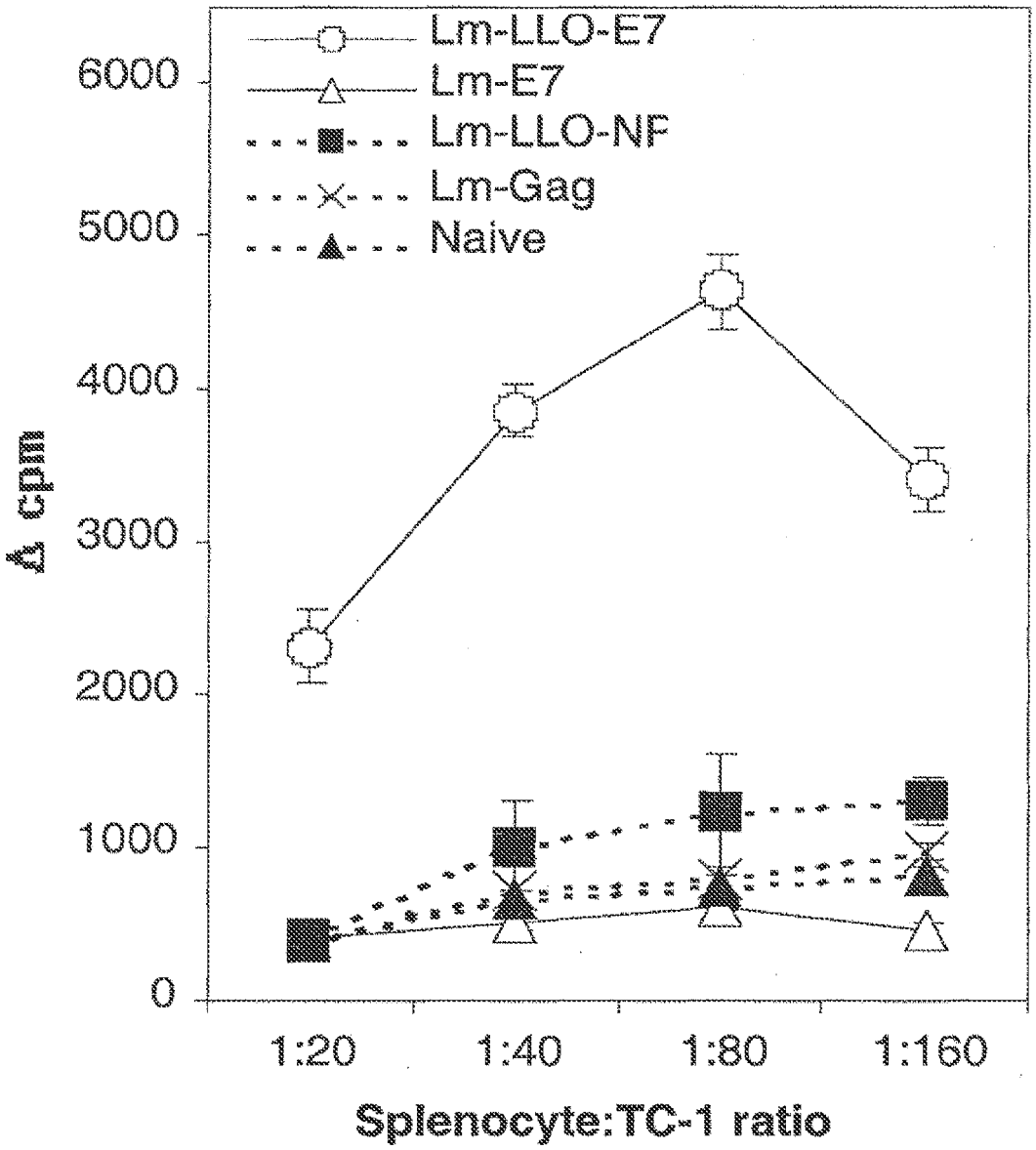

Lm-LLO-E7
Lm-E7
Lm-LLO-NF
Lm-Gag
Naive
6000
5000
4000
3000
2000
1000
0
Δ cpm
1:20
1:40
1:80
1:160
Splenocyte:TC-1 ratio

Figure 4

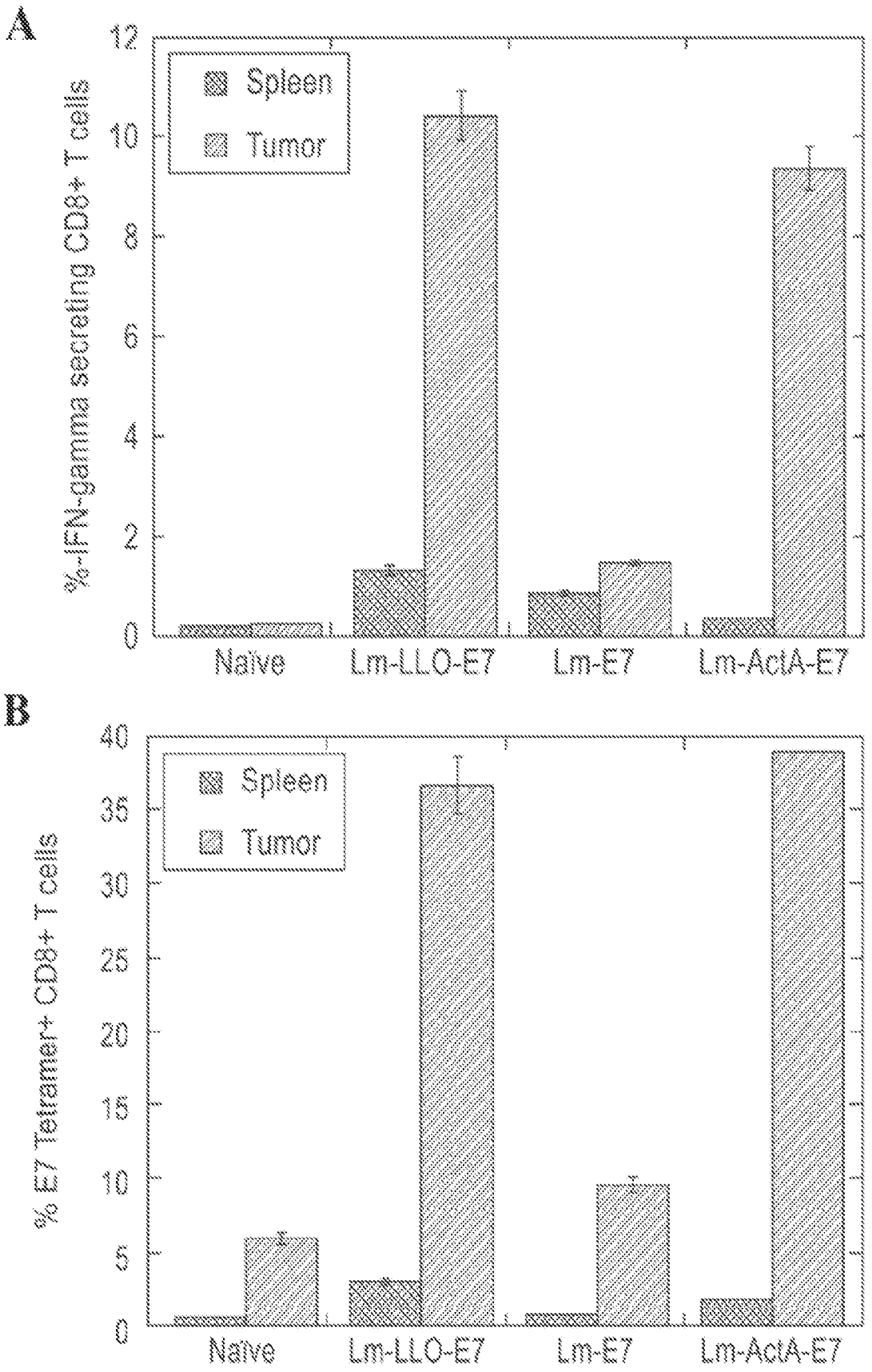

A
%-IFN-gamma secreting CD8+ T cells
0
2
4
6
8
10
12
Spleen
Tumor
Naïve
Lm-LLO-E7
Lm-E7
Lm-ActA-E7
B
% E7 Tetramer+ CD8+ T cells
0
5
10
15
20
25
30
35
40
Spleen
Tumor
Naïve
Lm-LLO-E7
Lm-E7
Lm-ActA-E7

Figure 5

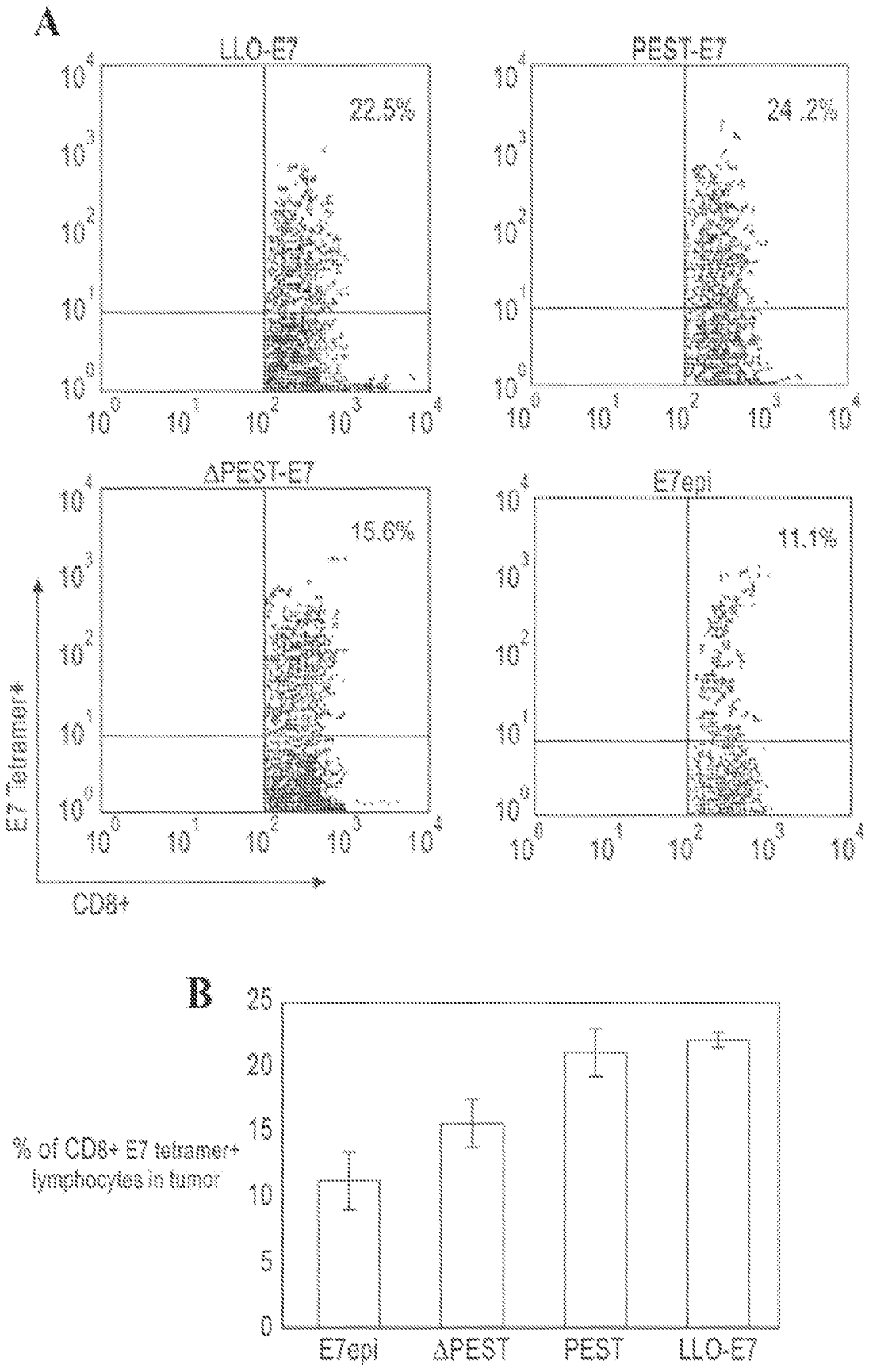

A
LLO-E7
22.5%
PEST-E7
24.2%
ΔPEST-E7
15.6%
E7epi
11.1%
E7 Tetramer+
CD8+
B
% of CD8+ E7 tetramer+ lymphocytes in tumor
25
20
15
10
5
0
E7epi
ΔPEST
PEST
LLO-E7

Figure 6

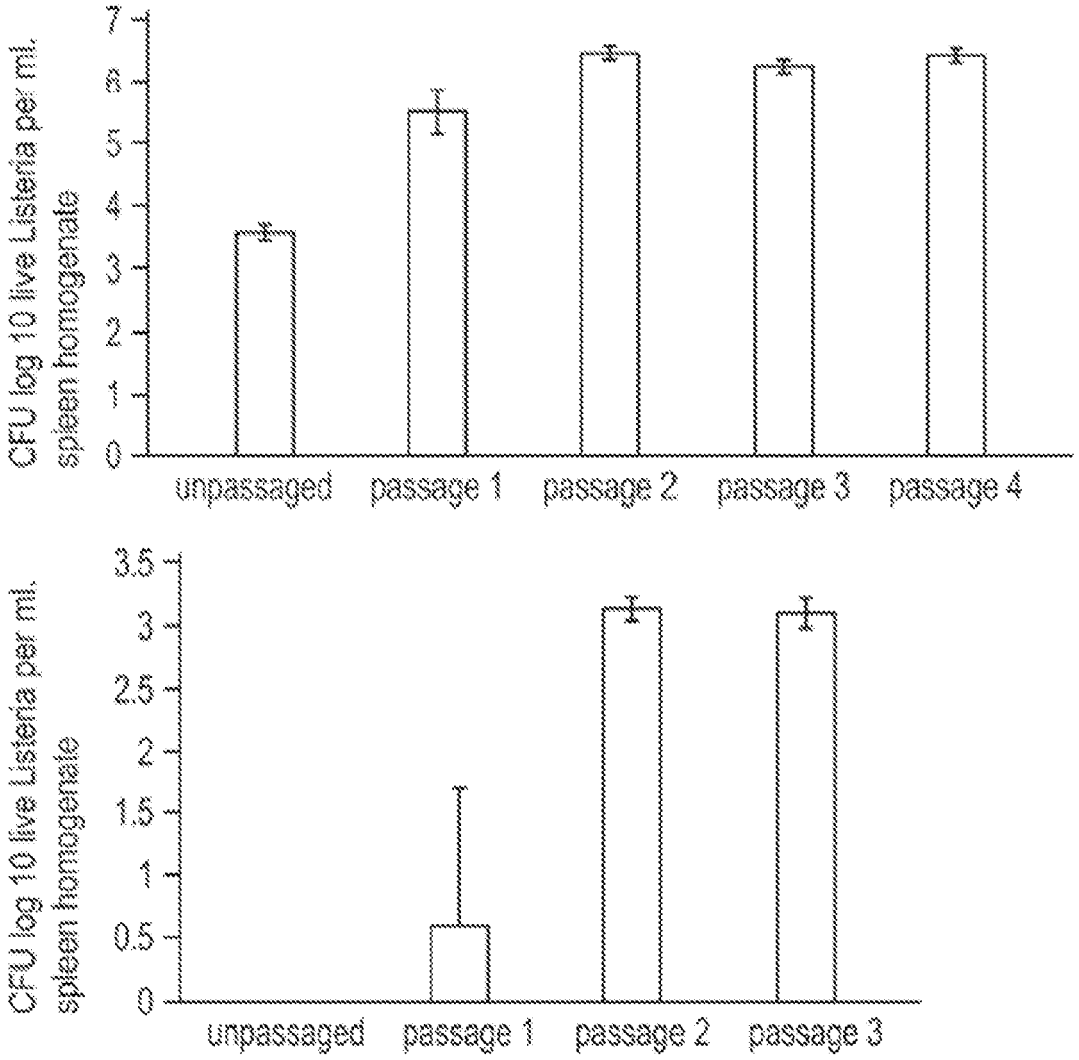

CFU log 10 live Listeria per mL spleen homogenate
0
1
2
3
4
5
6
7
unpassaged
passage 1
passage 2
passage 3
passage 4
CFU log 10 live Listeria per mL spleen homogenate
0
0.5
1
1.5
2
2.5
3
3.5
unpassaged
passage 1
passage 2
passage 3

Figure 7A

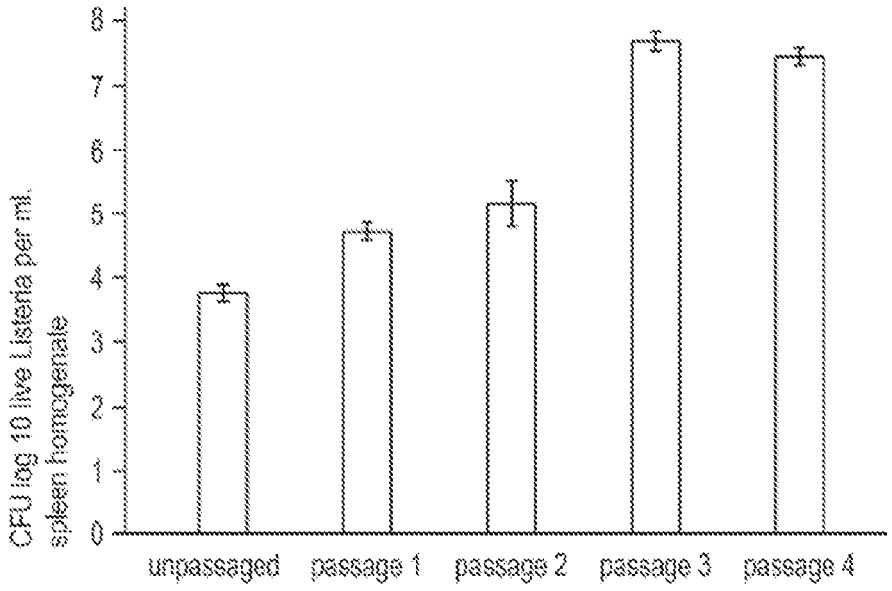

CFU log 10 live Listeria per ml. spleen homogenate
0
1
2
3
4
5
6
7
8
unpassaged
passage 1
passage 2
passage 3
passage 4

Figure 7B

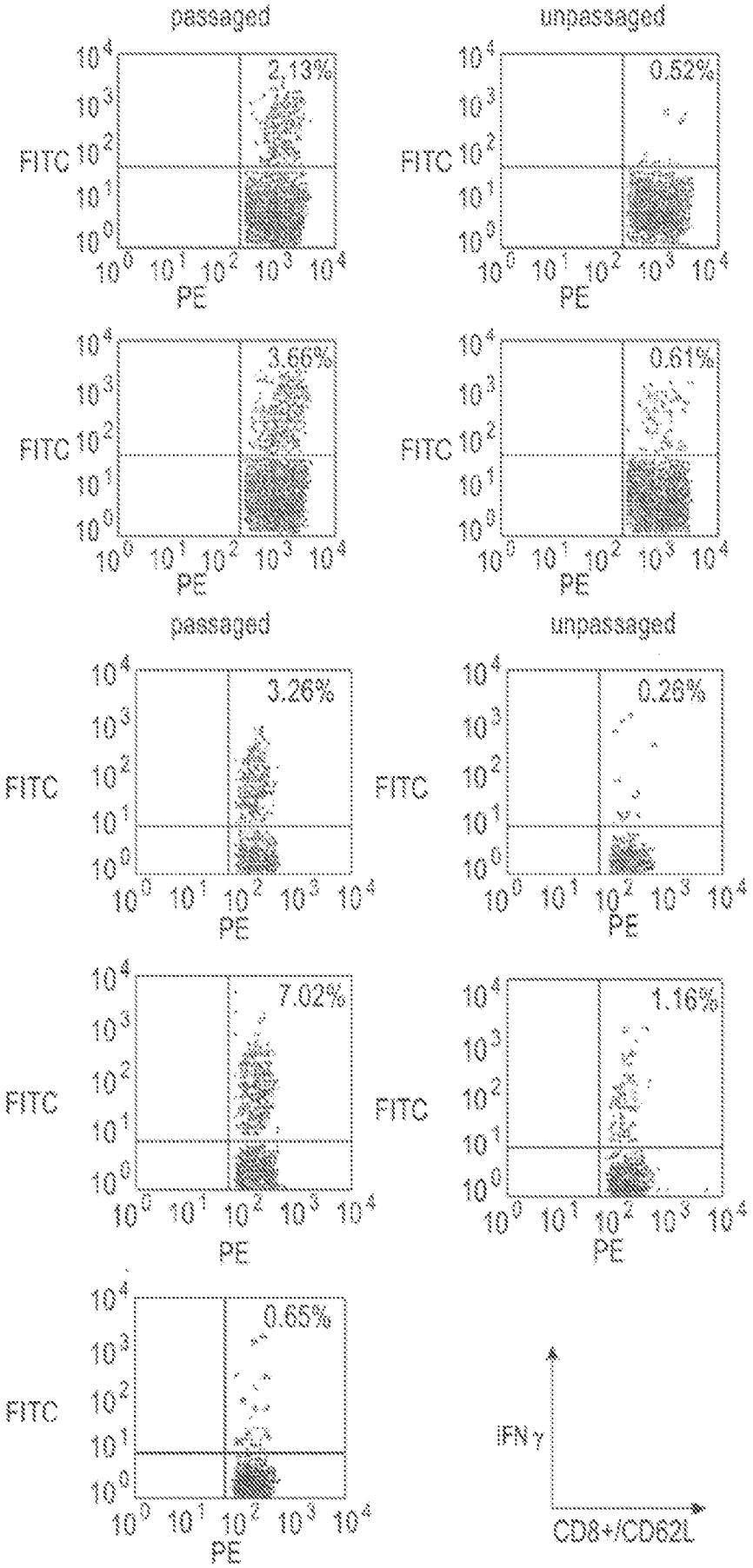
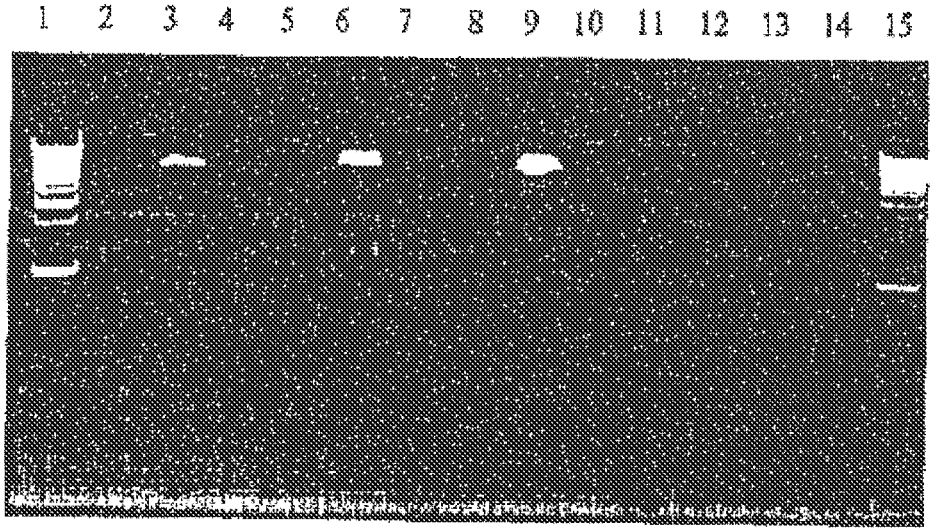

passaged
unpassaged
2.13%
0.52%
3.66%
0.61%
passaged
unpassaged
3.26%
0.26%
7.02%
1.16%
0.65%
FITC
PE
IFNγ
CD8+/CD62L

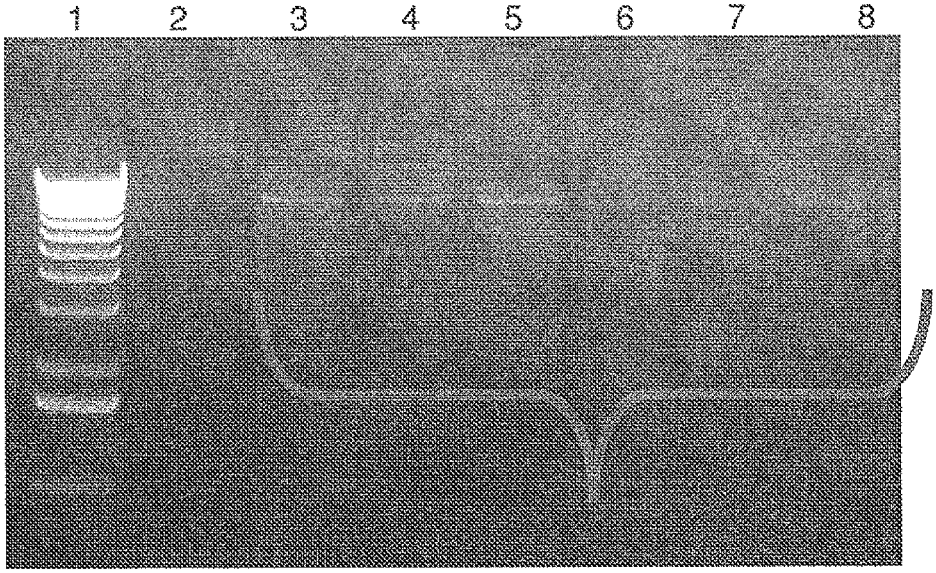
Figure 8



Lane	Sample	Lane	Sample
1	1Kb ladder	9	LB B, generation 5
2	100ng reference pGG55	10	LB A, generation 9
3	LB A, generation 5	11	LB B, generation 14
4	LB A, generation 9	12	LB B, generation 19*
5	LB A, generation 14	13	LB B, generation 24*
6	LB A, generation 19	14	LB B, generation 29*
7	LB A, generation 24	15	1Kb ladder
8	LB A, generation 29		

* Residual ethanol remaining in sample, therefore the majority of the sample did not load into the well, resulting in a less intense plasmid band

Figure 9A



Lane	Sample		
1	1Kb ladder	5	TB, generation 21
2	100ng reference pGG55	6	TB, generation 28
3	TB, generation 7	7	TB, generation 35
4	TB, generation 14	8	TB, generation 42

Figure 9B

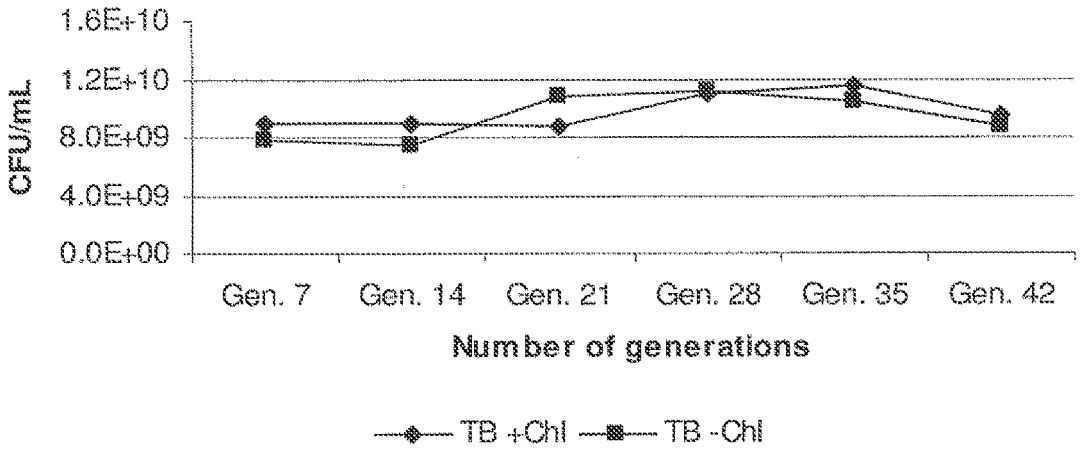

1.6E+10
1.2E+10
8.0E+09
4.0E+09
0.0E+00
CFU/mL
Gen. 7
Gen. 14
Gen. 21
Gen. 28
Gen. 35
Gen. 42
Number of generations
TB +Chl
TB -Chl

Figure 9C

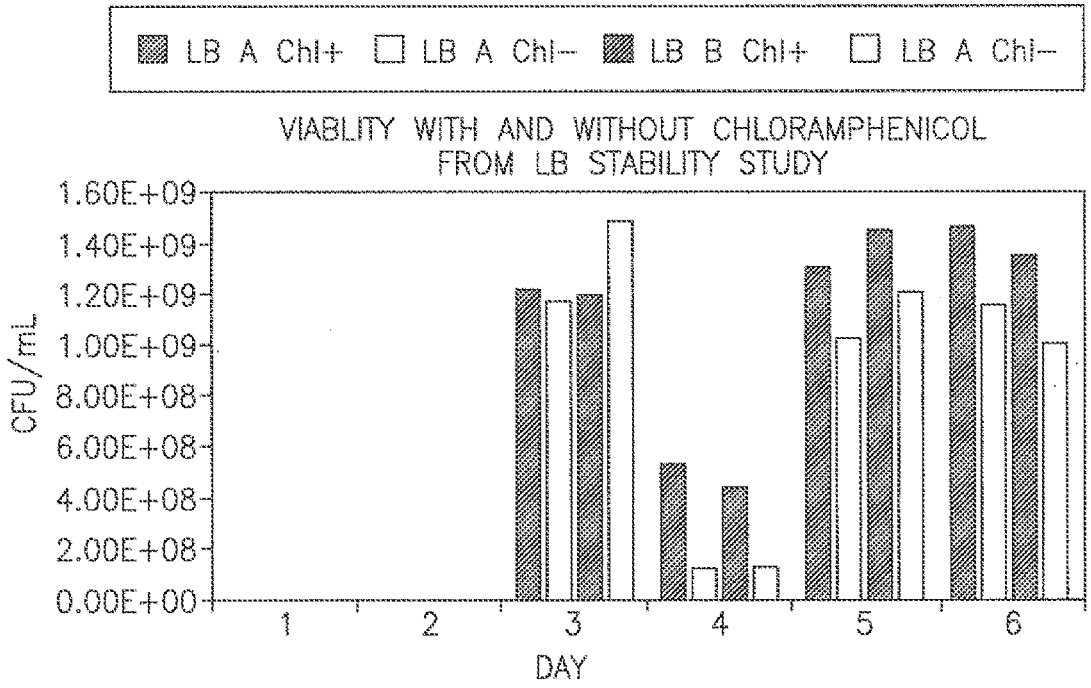


Figure 10

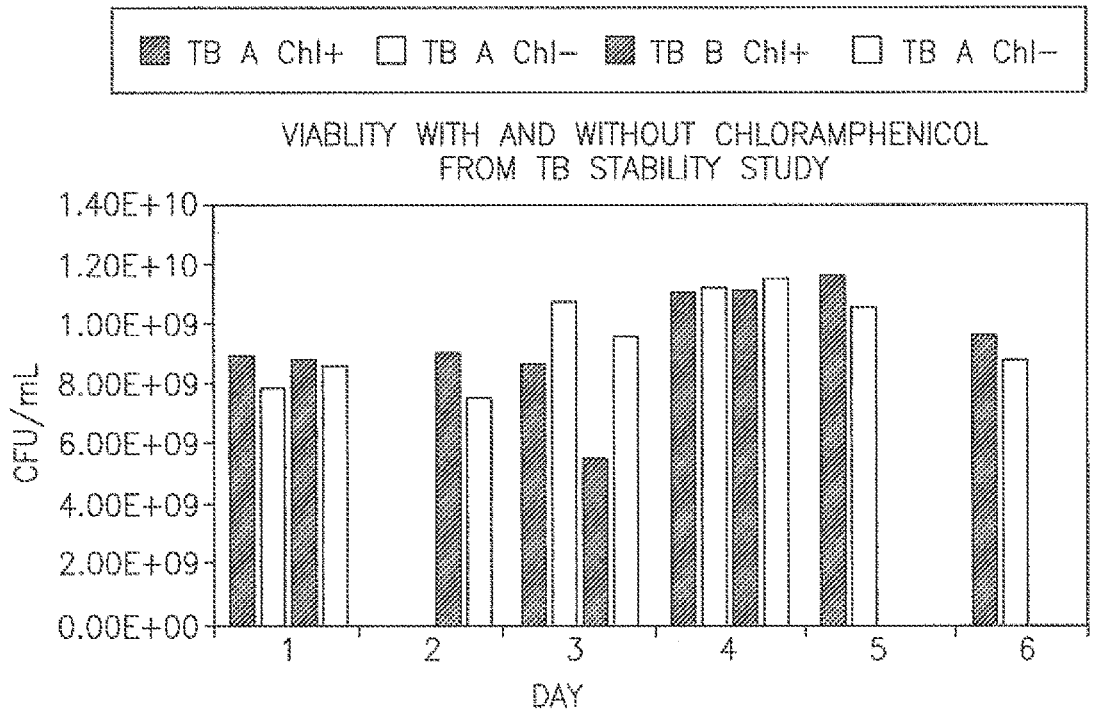
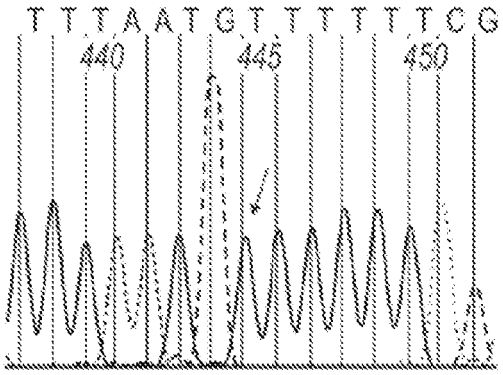
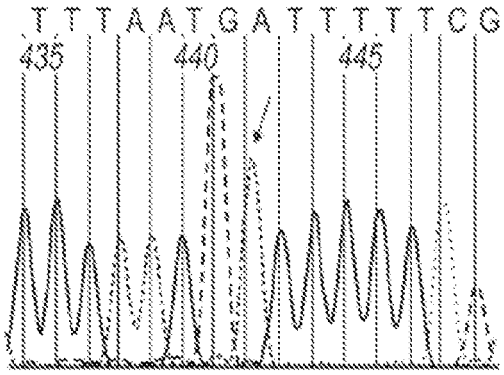


Figure 11

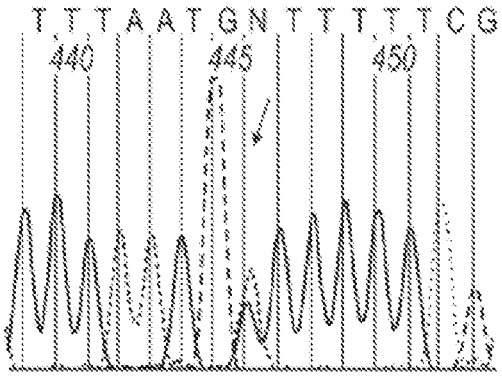
pGG55 D133V only (1:0)



pGG55 WT only (0:1)

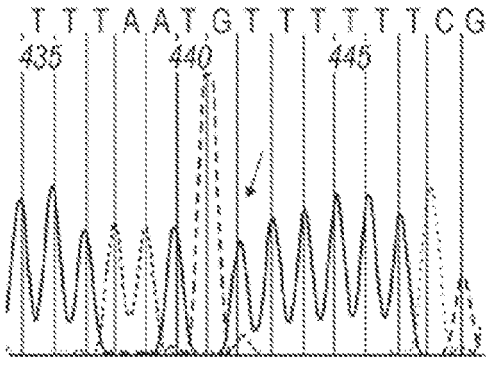


pGG55 D133V + pGG55 WT (1:1)



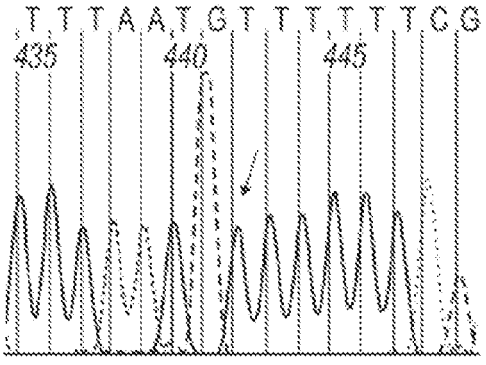
Two peaks are clearly visible and indicated by the arrow when plasmids are mixed in equimolar amounts.

pGG55 D133V + pGG55 WT (10:1)



1 in 10 is the maximum limit of detection and the peak from the wild-type sequence is still clearly detectable.

pGG55 D133V + pGG55 WT (100:1)



The peak from the wild-type sequence has disappeared completely when the wild-type prfA plasmid is diluted 1 to 100 or more.

Figure 12

ADV451 —>

Lovaxin_C_pGG55 CCAAACCCTACAAAAACAAGTTTCATACAGCCTAGCTAAATTTAATGTTT
Reference_104033_prfA CCAAACCCTACAAAAACAAGTTTCATACAGCCTAGCTAAATTTAATGATT

ADV452 —>

Lovaxin_C_pGG55 TTTCGATTAACGGGAAGCTTGGCTCTATTTGCGGTCAACTTTTAATCCTG
Reference_104033_prfA TTTCGATTAACGGGAAGCTTGGCTCTATTTGCGGTCAACTTTTAATCCTG

Lovaxin_C_pGG55 ACCTATGTGTATGGTAAAGAAACTCCTGATGGCATCAAGATTACACTGGA
Reference_104033_prfA ACCTATGTGTATGGTAAAGAAACTCCTGATGGCATCAAGATTACACTGGA

Lovaxin_C_pGG55 TAATTTAACAATGCAGGAGTTAGGATATTCAAGTGGCATCGCACATAGCT
Reference_104033_prfA TAATTTAACAATGCAGGAGTTAGGATATTCAAGTGGCATCGCACATAGCT

Lovaxin_C_pGG55 CAGCTGTTAGCAGAATTATTTCCAAATTAAAGCAAGAGAAAGTTATCGTG
Reference_104033_prfA CAGCTGTTAGCAGAATTATTTCCAAATTAAAGCAAGAGAAAGTTATCGTG

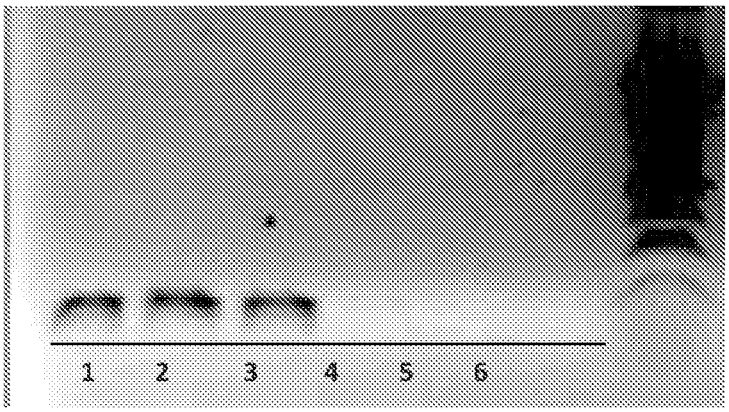
Lovaxin_C_pGG55 TATAAAAATTCATGCTTTTATGTACAAAATCGTGATTATCTCAAAGATA
Reference_104033_prfA TATAAAAATTCATGCTTTTATGTACAAAATCTTGATTATCTCAAAAGATA

Lovaxin_C_pGG55 TGCCCCTAAATTAGATGAATGGTTTTATTTAGCATGTCCTGCTACTTGGG
Reference_104033_prfA TGCCCCTAAATTAGATGAATGGTTTTATTTAGCATGTCCTGCTACTTGGG

←ADV453

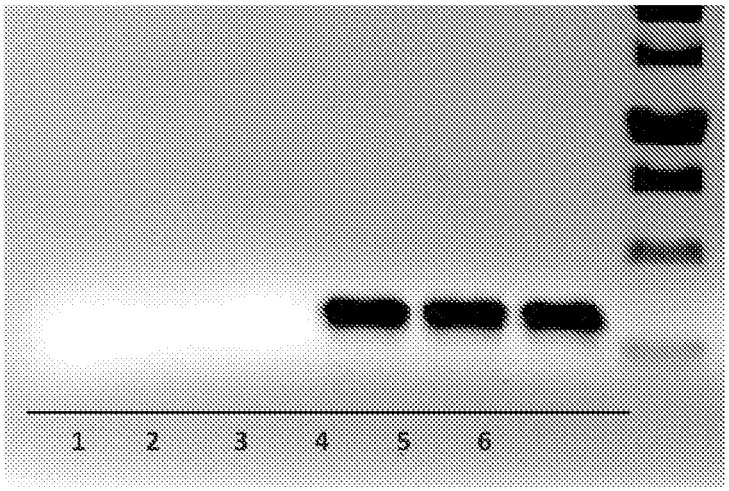
Lovaxin_C_pGG55 GAAAATTAAATTAA (SEQ ID NO: 31)
Reference_104033_prfA GAAAATTAAATTAA (SEQ ID NO: 32)

Figure 13



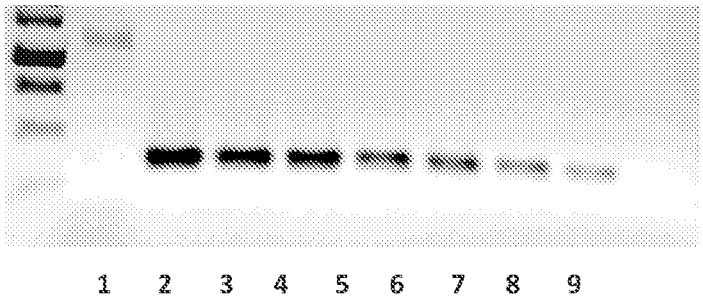
1. 5 ng of pGG55 D133V;
2. 1 ng of pGG55 D133V;
3. 0.2 ng of pGG55 D133V;
4. 5 ng of pGG55 wild-type;
5. 1 ng of pGG55 wild-type;
6. 0.2 ng of pGG55 wild-type;

Figure 14



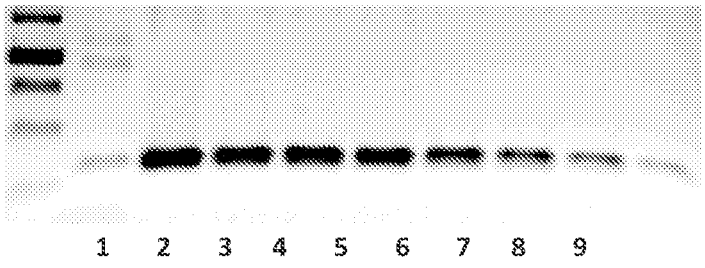
1) 5 ng of pGG55 D133V;
2) 1 ng of pGG55 D133V;
3) 0.2 ng of pGG55 D133V;
4) 5 ng of pGG55 wild-type;
5) 1 ng of pGG55 wild-type;
6) 0.2 ng of pGG55 wild-type;

Figure 15



1. 1 ng of pGG55 D133V
2. 1 ng of pGG55 wild-type
3. 100 pg of pGG55 wild-type (10^{-1})
4. 10 pg of pGG55 wild-type (10^{-2})
5. 1 pg of pGG55 wild-type (10^{-3})
6. 100 fg of pGG55 wild-type (10^{-4})
7. 10 fg of pGG55 wild-type (10^{-5})
8. 1 fg of pGG55 wild-type (10^{-6})

Figure 16



1. 5 ng of pGG55 D133V
2. 5 ng of pGG55 wild-type
3. 500 pg of pGG55 wild-type (10^{-1})
4. 50 pg of pGG55 wild-type (10^{-2})
5. 5 pg of pGG55 wild-type (10^{-3})
6. 500 fg of pGG55 wild-type (10^{-4})
7. 50 fg of pGG55 wild-type (10^{-5})
8. 5 fg of pGG55 wild-type (10^{-6})

Figure 17

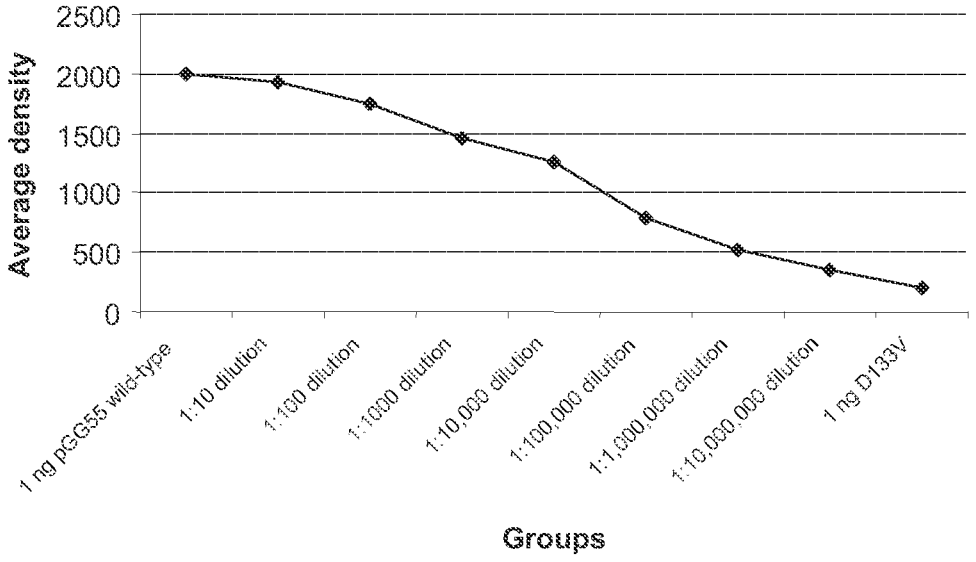


Figure 18

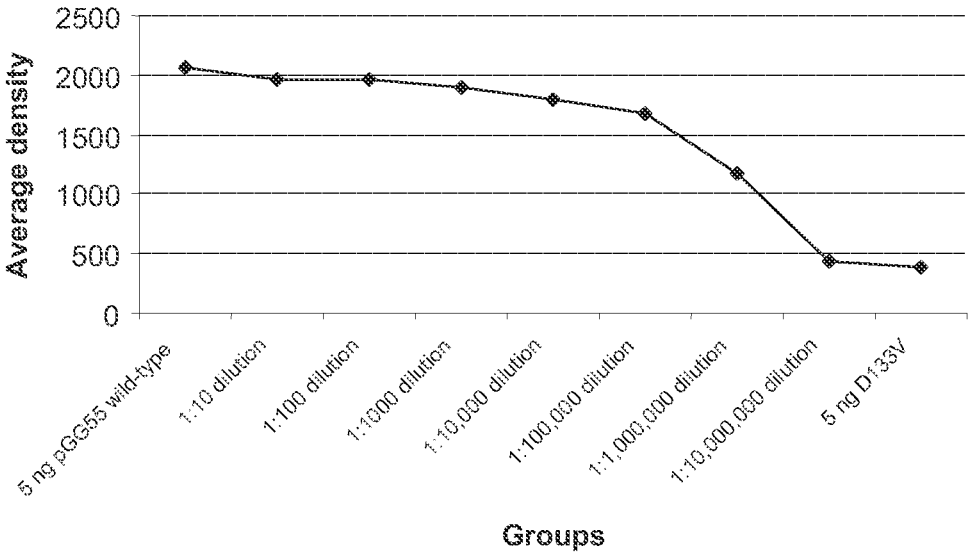


Figure 19

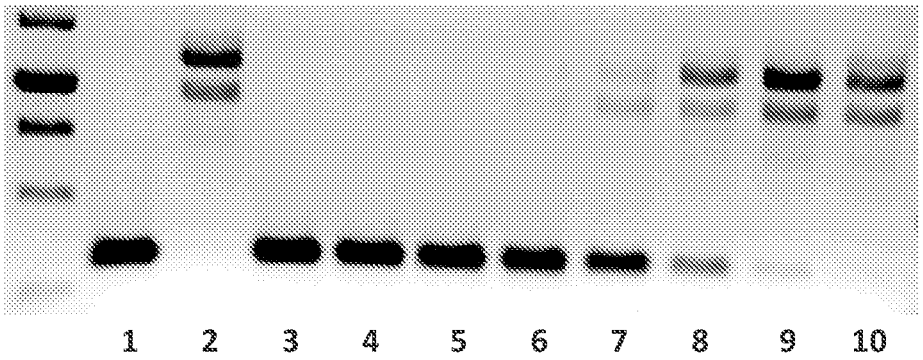


Figure 20

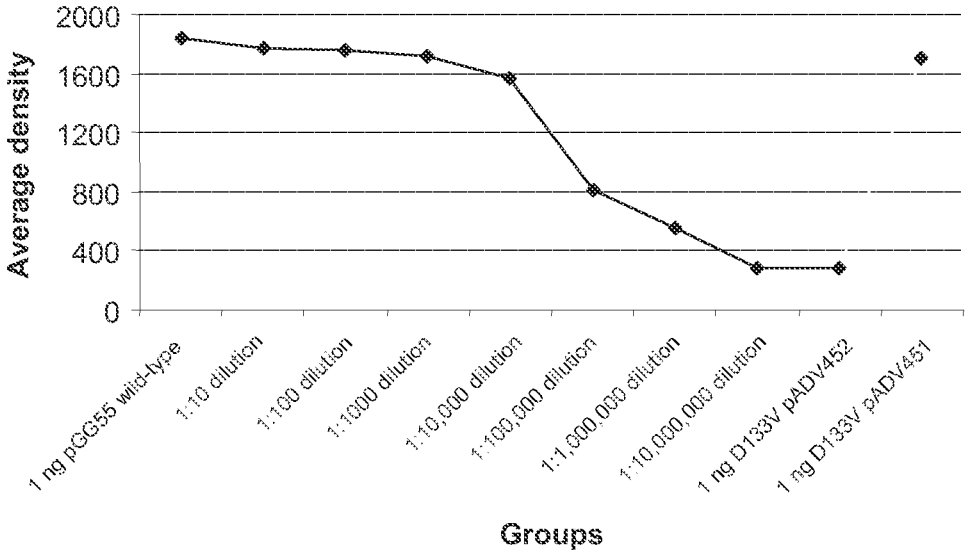
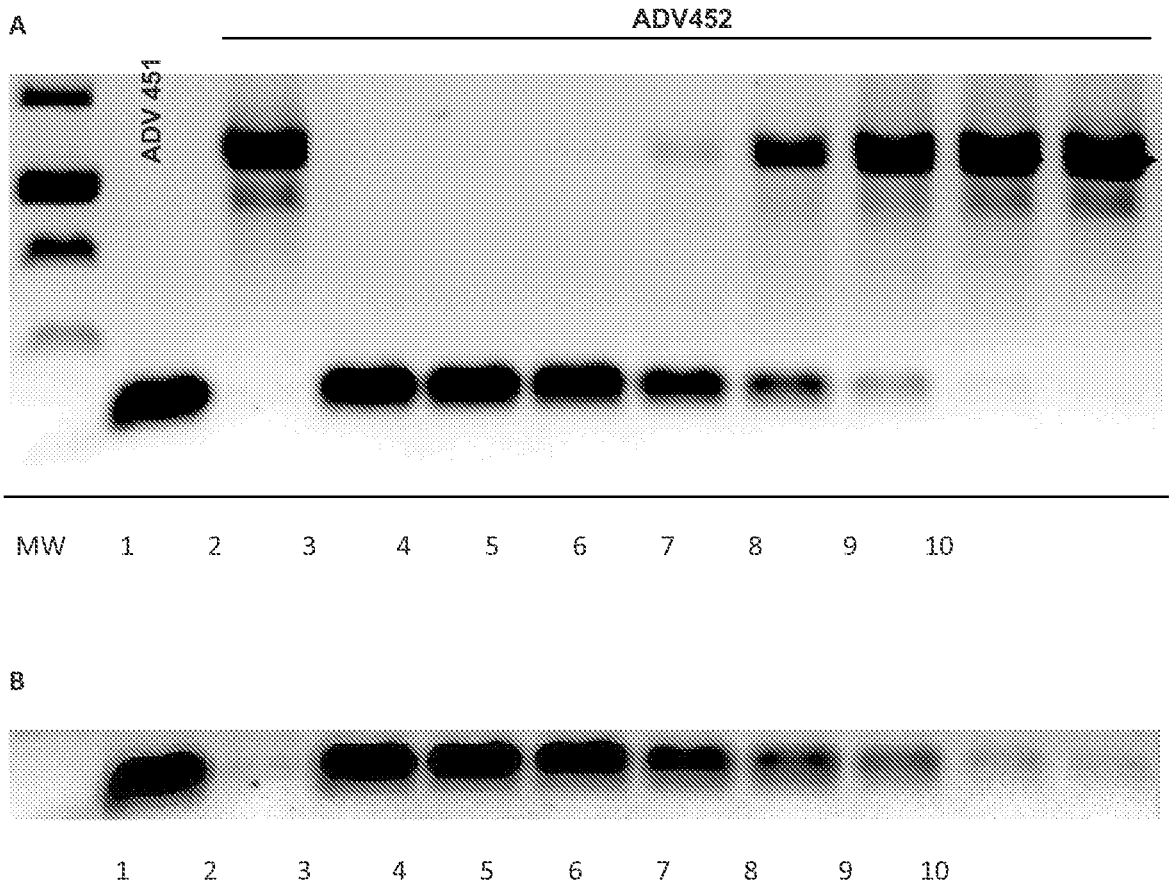

2000
1600
1200
800
400
0
Average density
1 ng pGG55 wild-type
1:10 dilution
1:100 dilution
1:1000 dilution
1:10,000 dilution
1:100,000 dilution
1:1,000,000 dilution
1:10,000,000 dilution
1 ng D133V pADV452
1 ng D133V pADV451
Groups

Figure 21



1) 1 ng of pGG55 D133V only

2) 1 ng of pGG55 D133V only

3) 1 ng of pGG55 D133V + 1 ng of pGG55 wild-type prfA

4) 1 ng of pGG55 D133V + 100 pg of pGG55 wild-type prfA

6) 1 ng of pGG55 D133V + 1 pg of pGG55 wild-type prfA

7) 1 ng of pGG55 D133V + 100 fg of pGG55 wild-type prfA

8) 1 ng of pGG55 D133V + 10 fg of pGG55 wild-type prfA

9) 1 ng of pGG55 D133V + 1 fg of pGG55 wild-type prfA

Figure 22

Trial Scheme

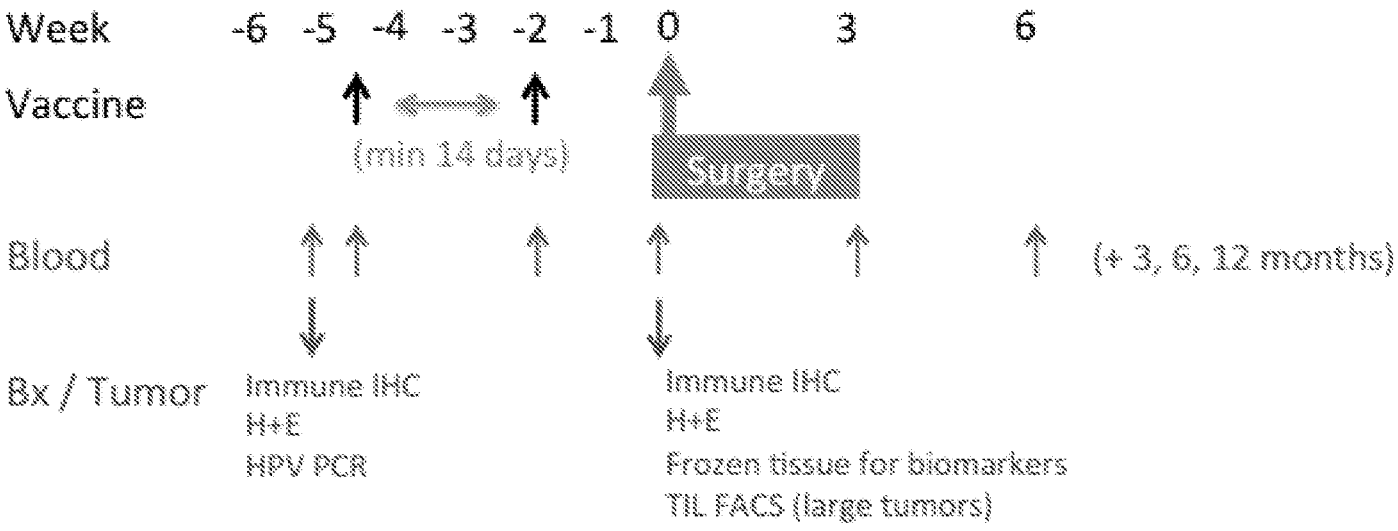


FIGURE 23

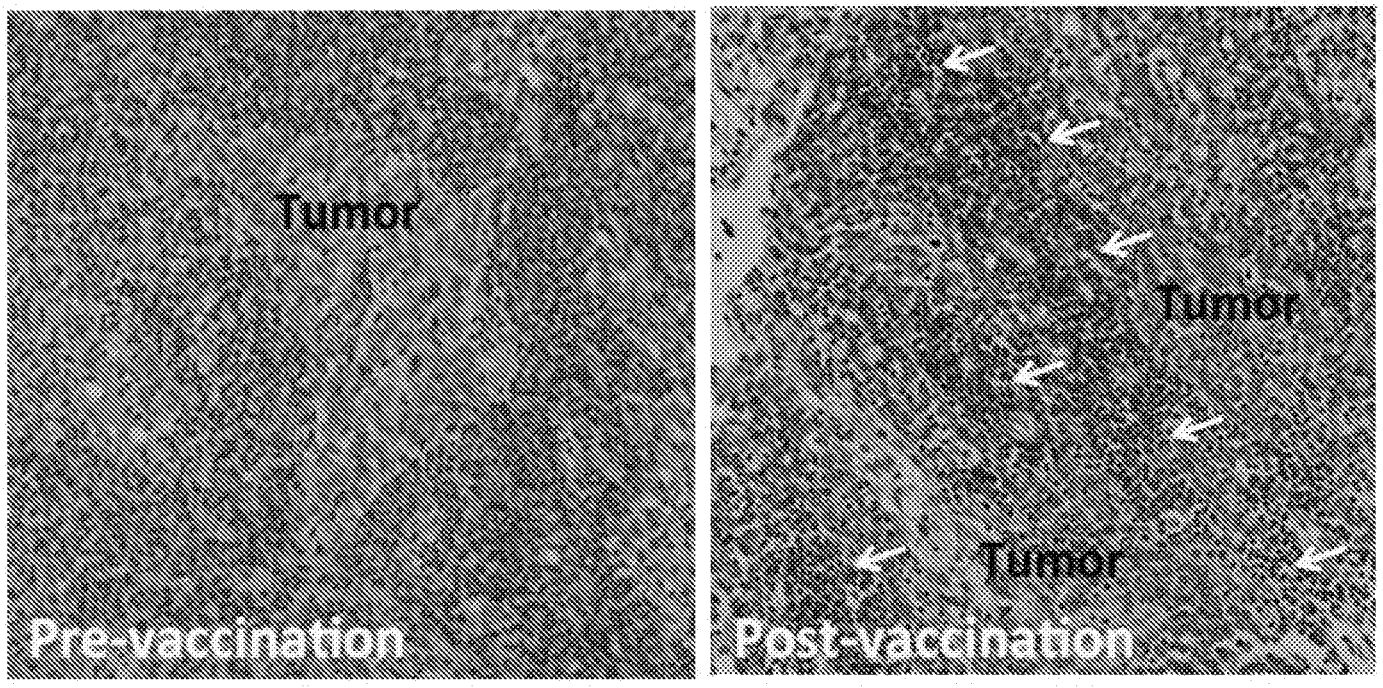


FIGURE 24

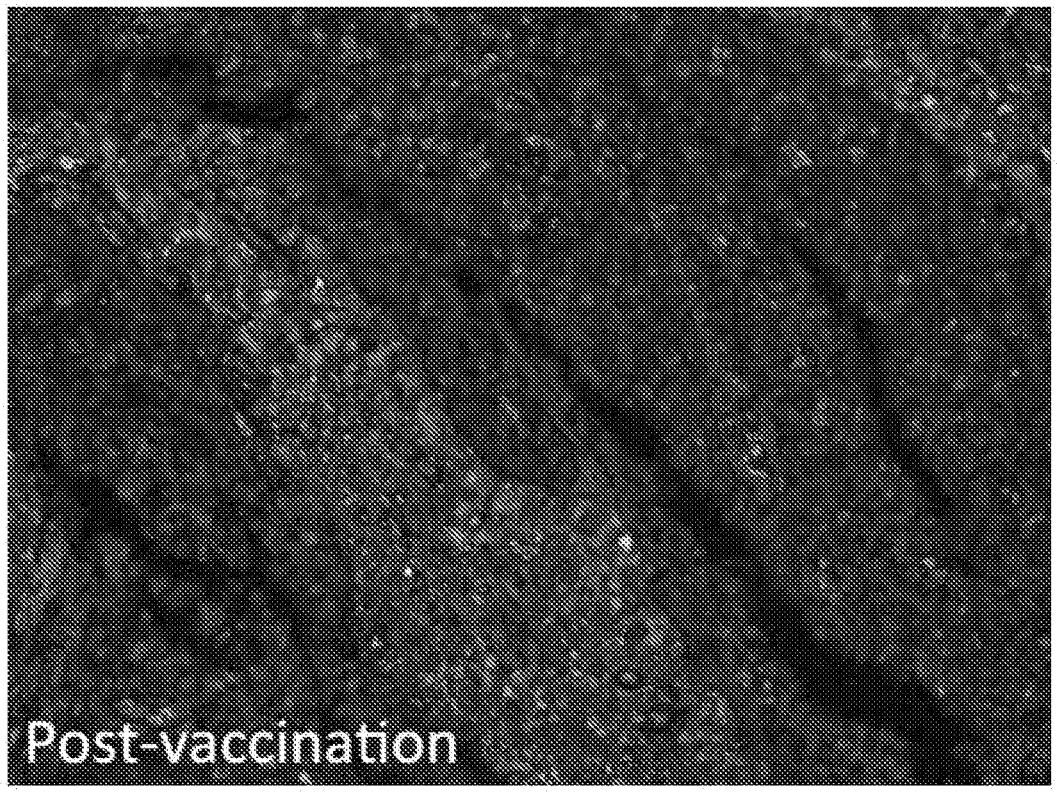


FIGURE 25

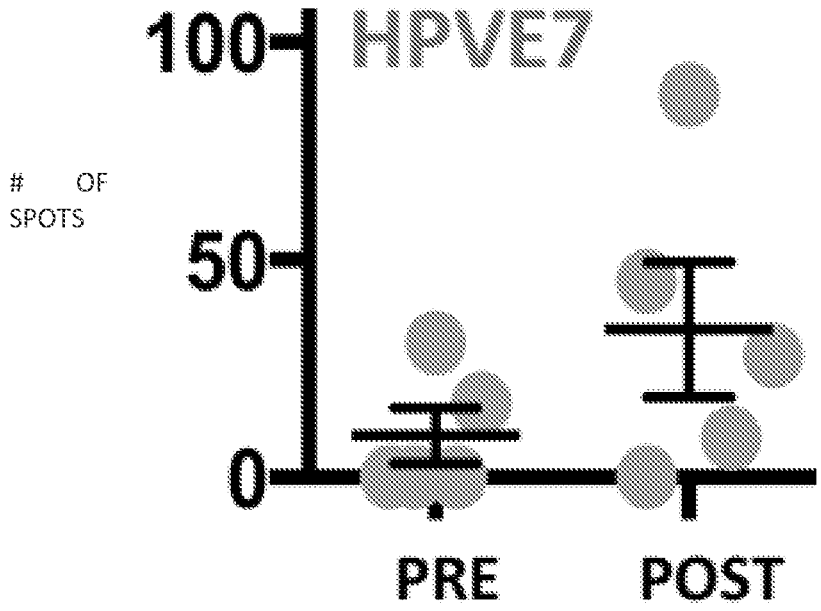


FIGURE 26

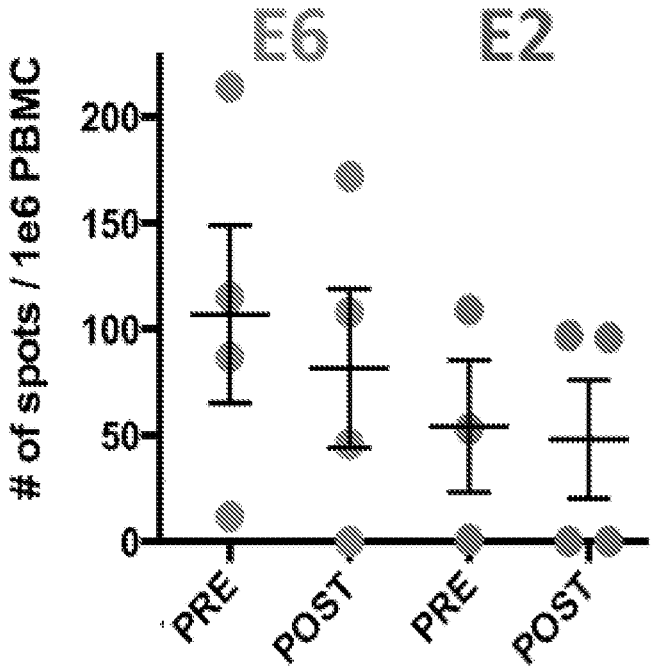


FIGURE 27

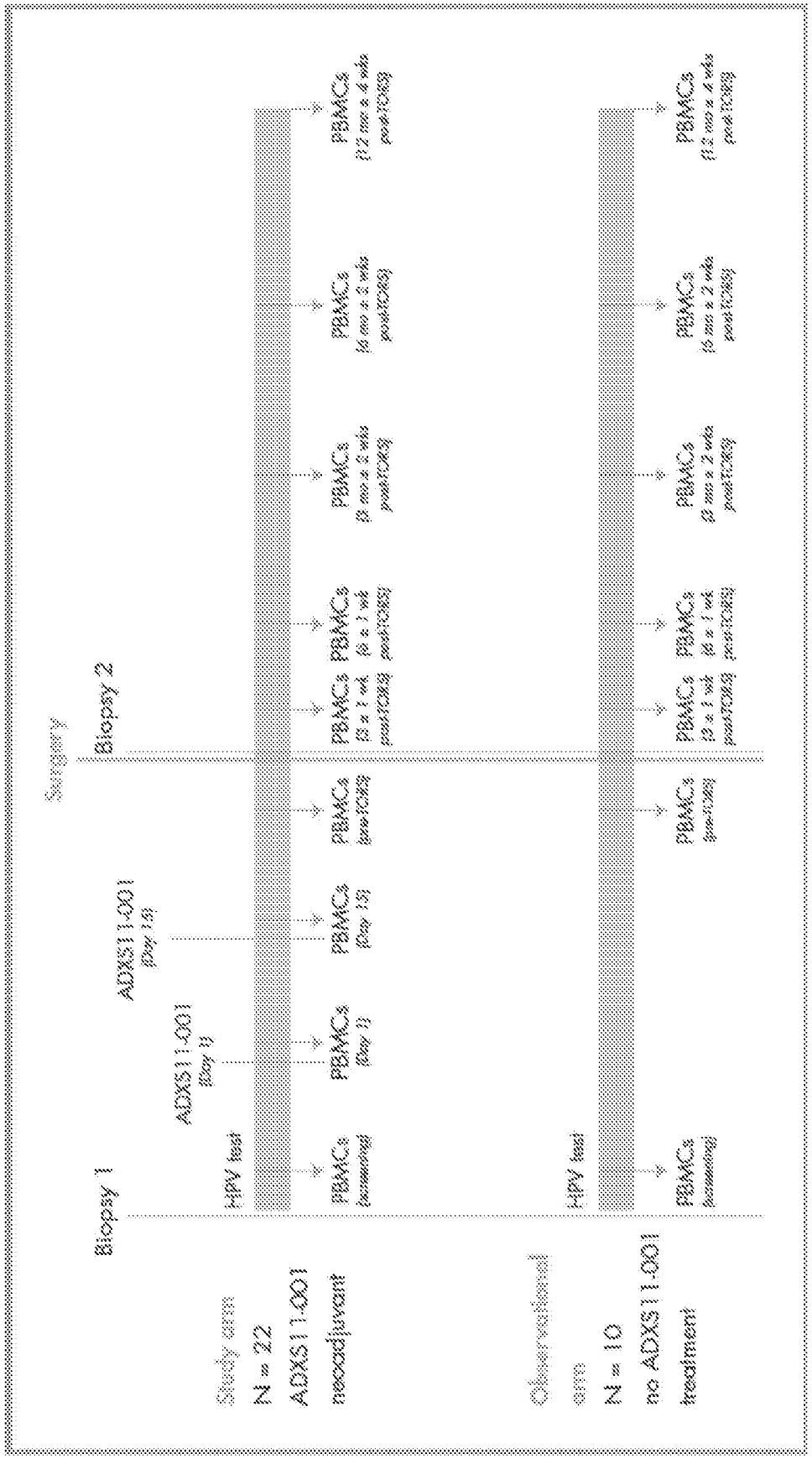
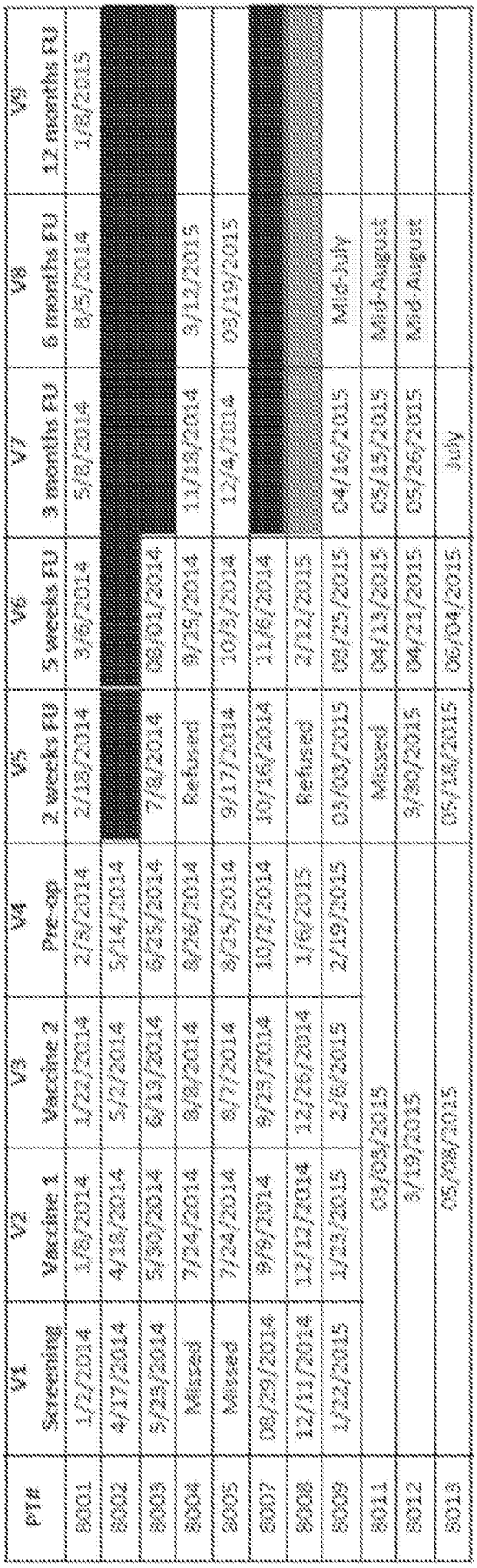

Biopsy 1
HPV test
ADXS11-001 (Boost 1)
ADXS11-001 (Boost 15)
Surgery
Biopsy 2
Study arm
N = 22
ADXS11-001
neoadjuvant
treatment
PBMCs (screening)
PBMCs (Day 1)
PBMCs (Day 15)
PBMCs (pre-TCB)
PBMCs (3 x 1 wk post-TCB)
PBMCs (6 x 1 wk post-TCB)
PBMCs (6 mo x 2 wks post-TCB)
PBMCs (12 mo x 4 wks post-TCB)
Observational
arm
N = 10
no ADXS11-001
treatment
HPV test
PBMCs (screening)
PBMCs (pre-TCB)
PBMCs (3 x 1 wk post-TCB)
PBMCs (6 x 1 wk post-TCB)
PBMCs (6 mo x 2 wks post-TCB)
PBMCs (12 mo x 4 wks post-TCB)

Figure 28A



Pt #	V1 Screening	V2 Vaccine 1	V3 Vaccine 2	V4 Pre-op	V5 2 weeks FU	V6 5 weeks FU	V7 3 months FU	V8 6 months FU	V9 12 months FU
8001	1/2/2014	1/6/2014	1/22/2014	2/5/2014	2/18/2014	3/6/2014	5/8/2014	8/5/2014	1/8/2015
8002	4/17/2014	4/18/2014	5/2/2014	5/14/2014					
8003	5/23/2014	5/30/2014	6/19/2014	6/25/2014	7/8/2014	8/01/2014			
8004	Missed	7/24/2014	8/8/2014	8/26/2014	Refused	9/25/2014	11/18/2014	3/12/2015	
8005	Missed	7/24/2014	8/7/2014	8/25/2014	9/17/2014	10/2/2014	12/4/2014	08/19/2015	
8007	08/29/2014	9/9/2014	9/29/2014	10/7/2014	10/16/2014	11/6/2014			
8008	12/11/2014	12/12/2014	12/26/2014	1/6/2015	Refused	2/12/2015			
8009	1/22/2015	1/23/2015	2/6/2015	2/19/2015	03/09/2015	03/25/2015	04/16/2015	Mid-July	
8011	09/09/2015				Missed	04/13/2015	05/15/2015	Mid-August	
8012	8/19/2015				9/30/2015	04/21/2015	05/26/2015	Mid-August	
8013	05/08/2015				05/18/2015	06/04/2015	July		

Figure 28B

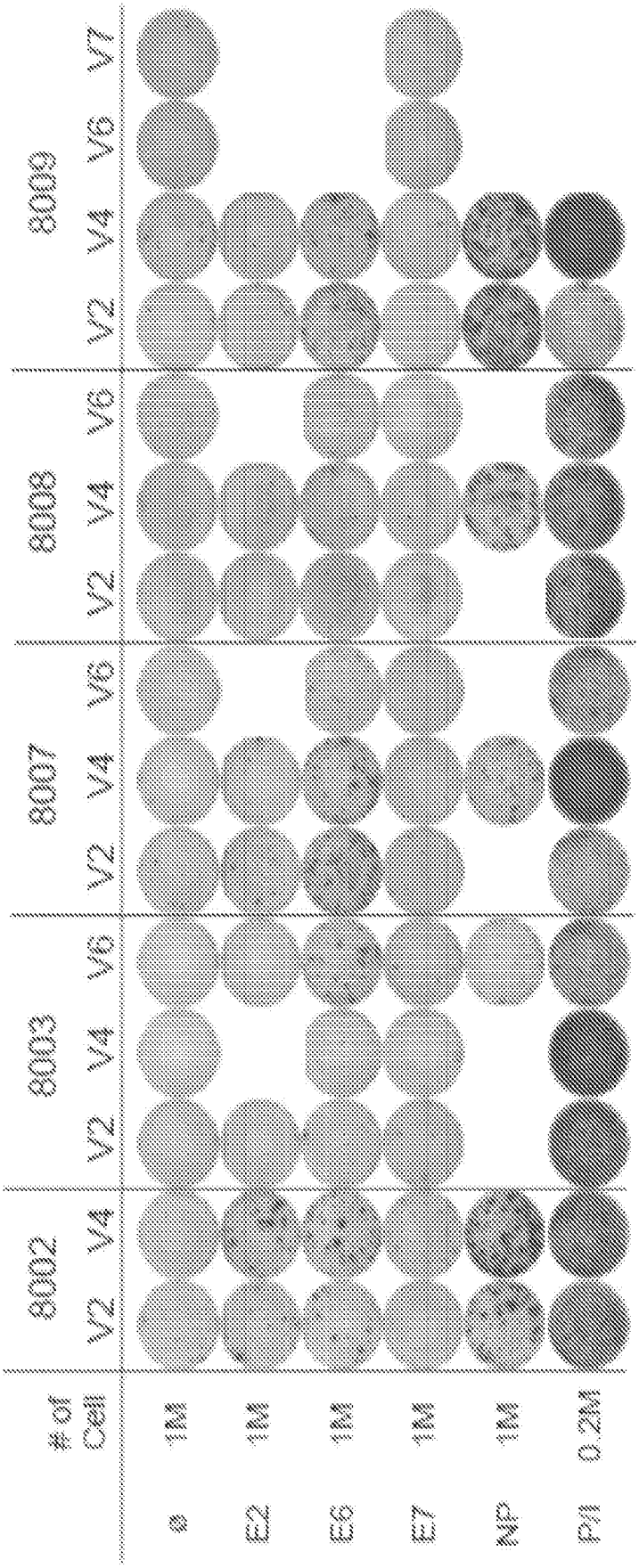


Figure 29

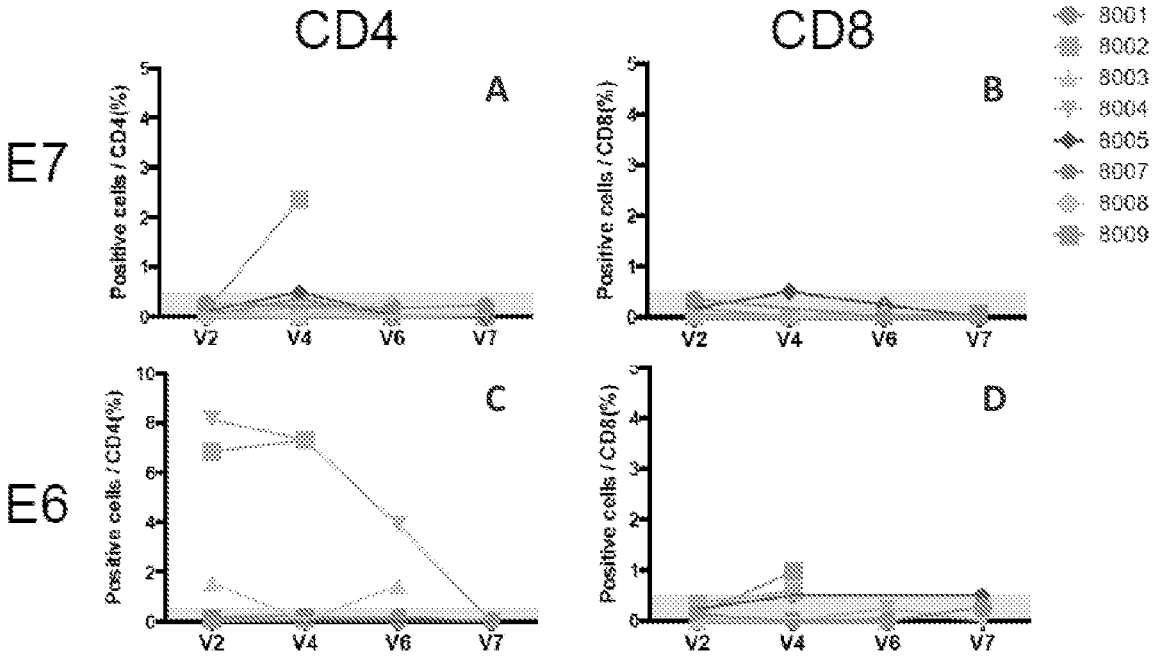


Figure 30

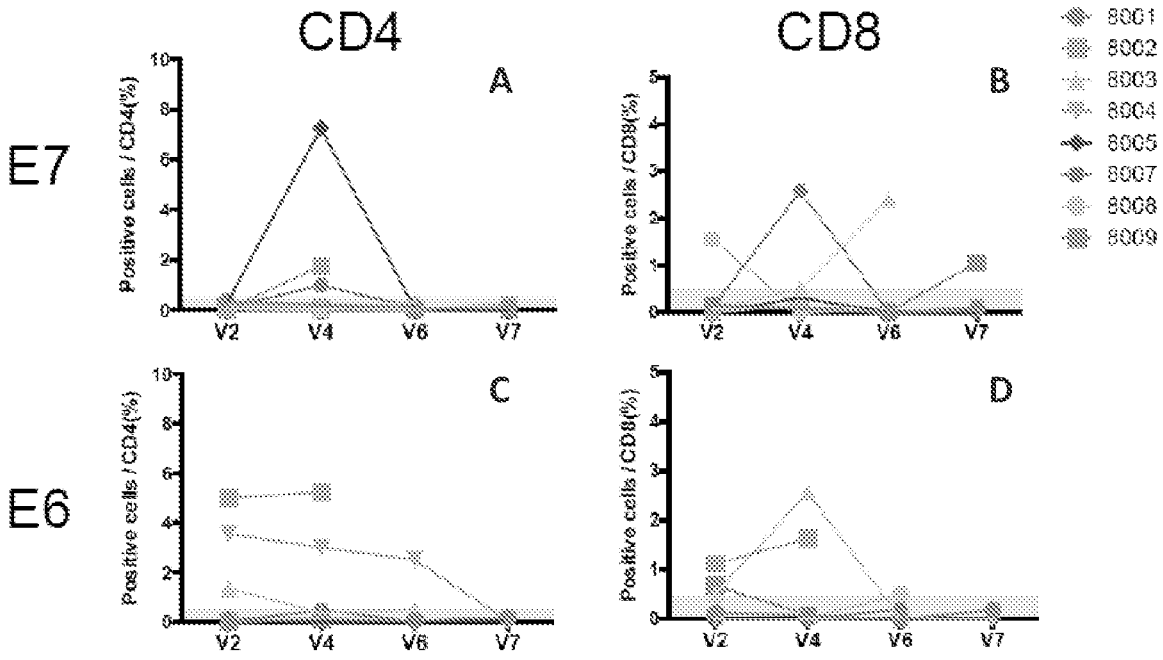


Figure 31

A

E6 or E7

PATIENT #	ExVivo ELI	IFNg ELI	IFNg ICS	TNFa ICS
8001	+	+		
8002	+	+	+	+
8003	+	+		+
8004		+		
8005				+
8007				+
8008				
8009		+	+	+

B

E7

PATIENT #	ExVivo ELI	IFNg ELI	IFNg ICS	TNFa ICS
8001	10.2014			
8002	+	+	+	+
8003		+		+
8004	(borderline)	+		
8005				+
8007				+
8008				
8009				+

C

E6

PATIENT #	ExVivo ELI	IFNg ELI	IFNg ICS	TNFa ICS
8001		+		
8002	+	(borderline)	+	+
8003	+			+
8004				
8005				
8007				
8008				(borderline)
8009		+	+	

Figure 32

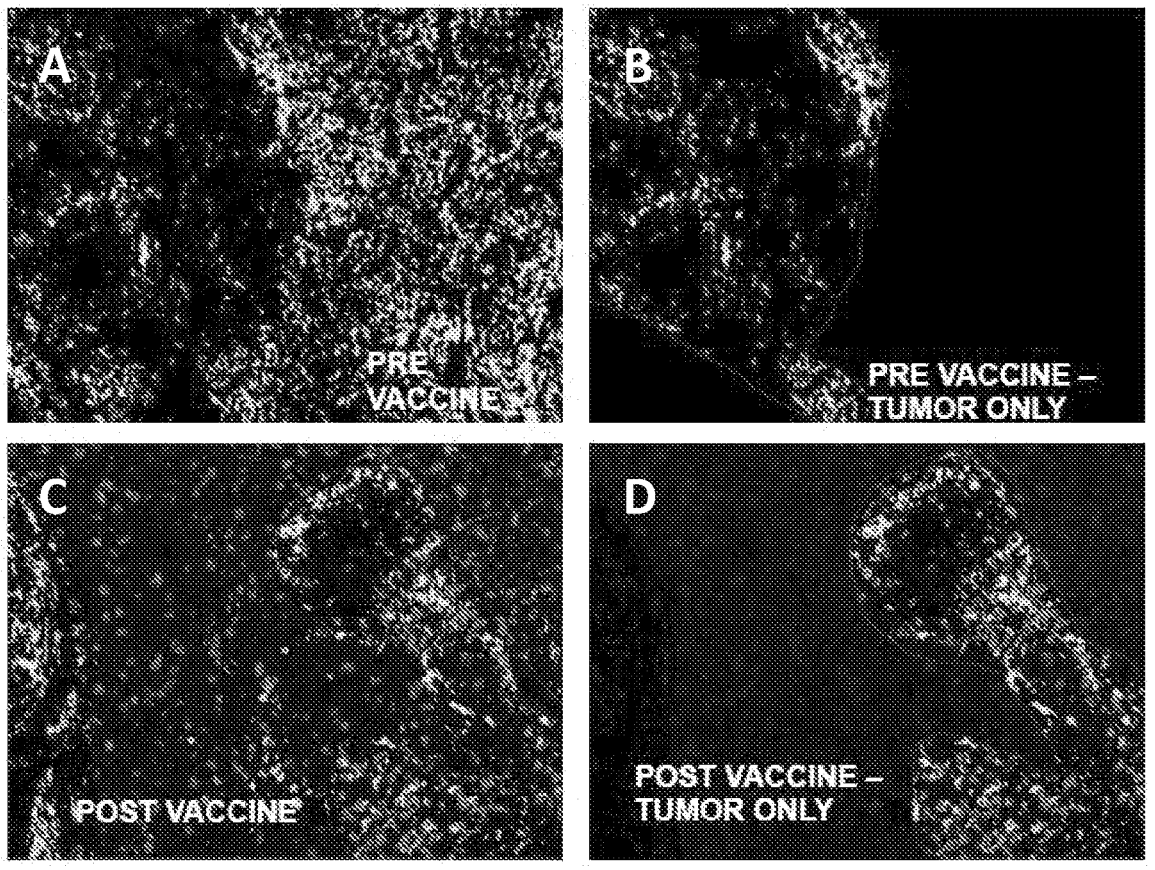

A
PRE VACCINE
B
PRE VACCINE – TUMOR ONLY
C
POST VACCINE
D
POST VACCINE – TUMOR ONLY

Figure 33

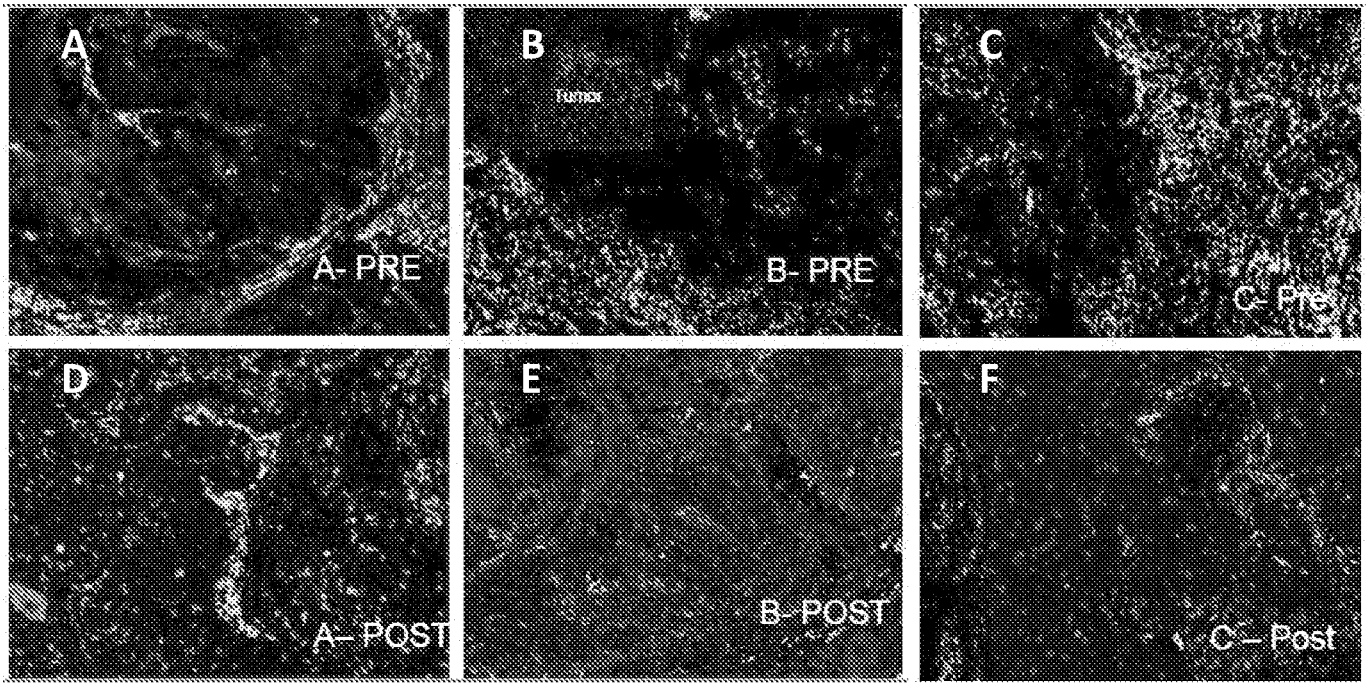


Figure 34

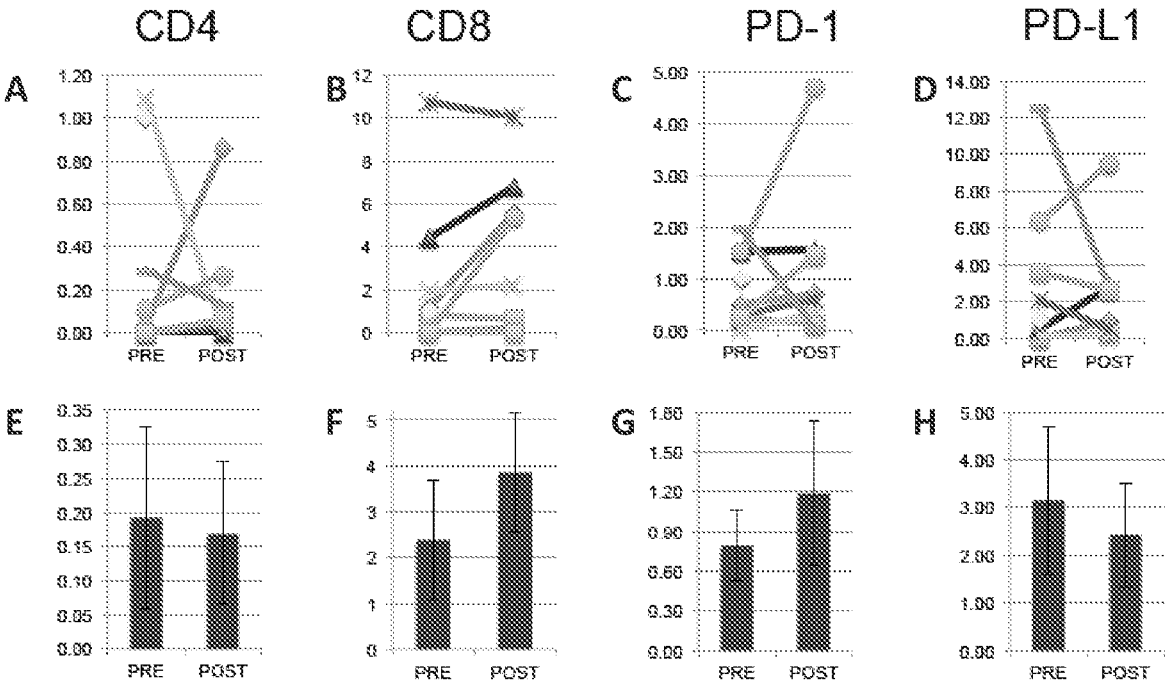


Figure 35

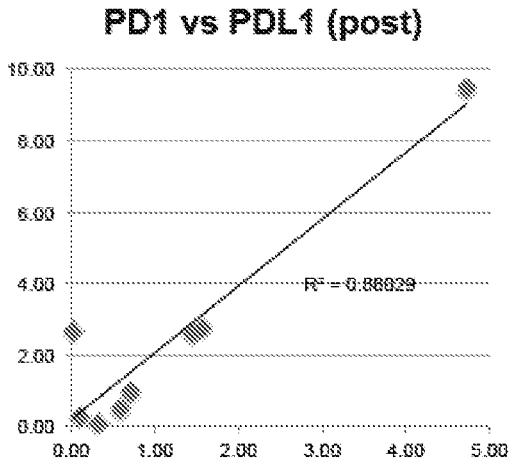


Figure 36

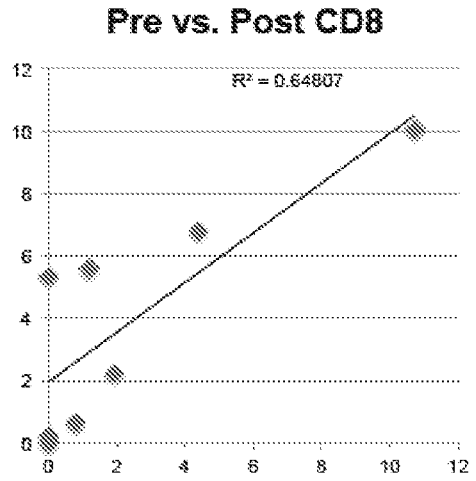


Figure 37