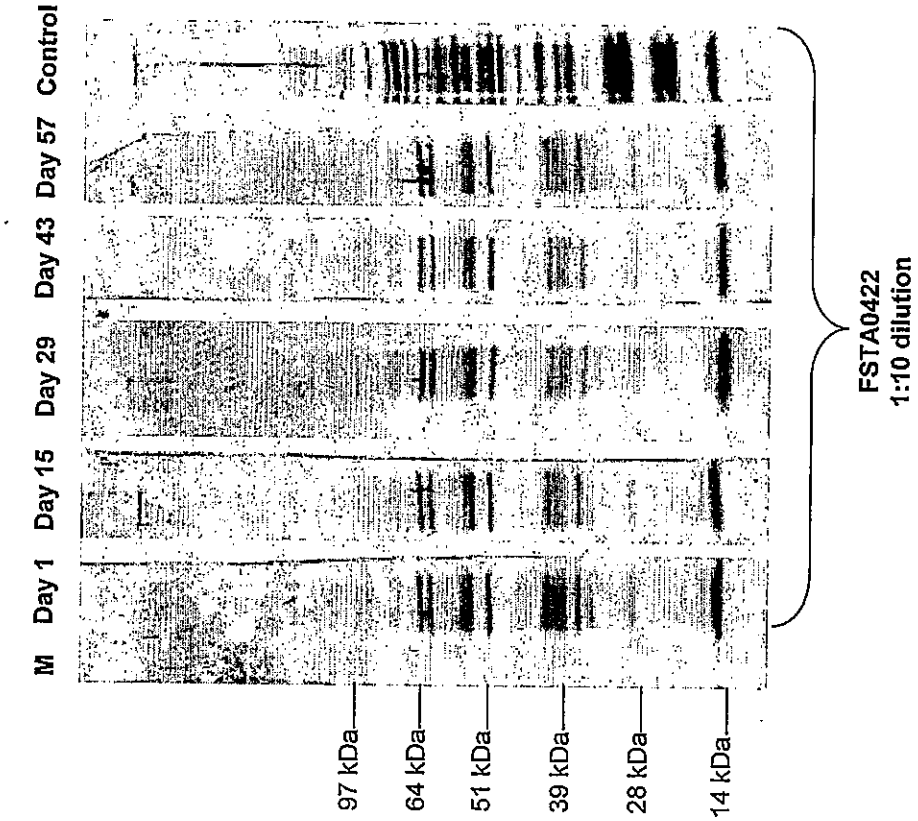
Figure 1


M
Day 1
Day 15
Day 29
Day 43
Day 57
Control
97 kDa
64 kDa
51 kDa
39 kDa
28 kDa
14 kDa
FSTA0422
1:10 dilution

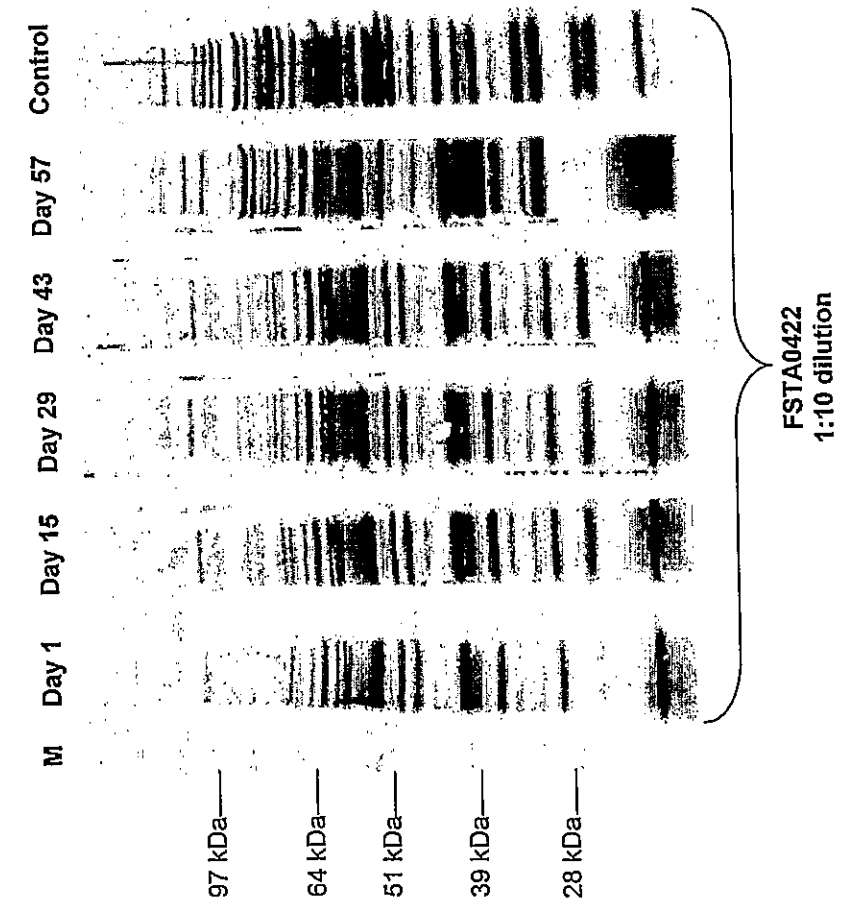

M
Day 1
Day 15
Day 29
Day 43
Day 57
Control
97 kDa
64 kDa
51 kDa
39 kDa
28 kDa
FSTA0422
1:10 dilution

Figure 2

Figure 3

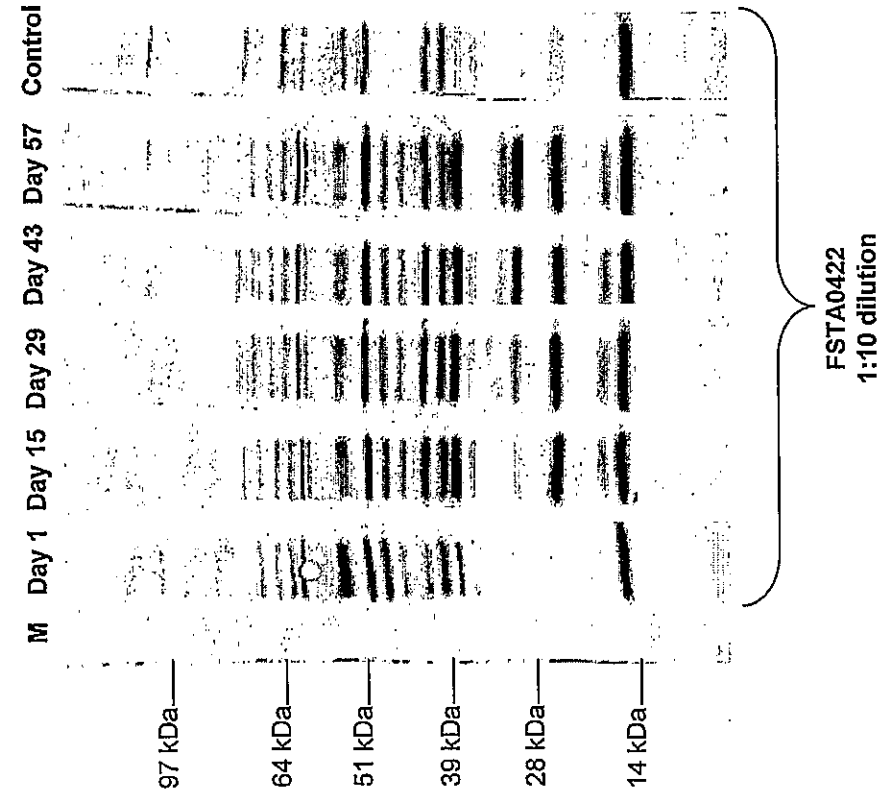

M
Day 1
Day 15
Day 29
Day 43
Day 57
Control
97 kDa
64 kDa
51 kDa
39 kDa
28 kDa
14 kDa
FSTA0422
1:10 dilution

Figure 4

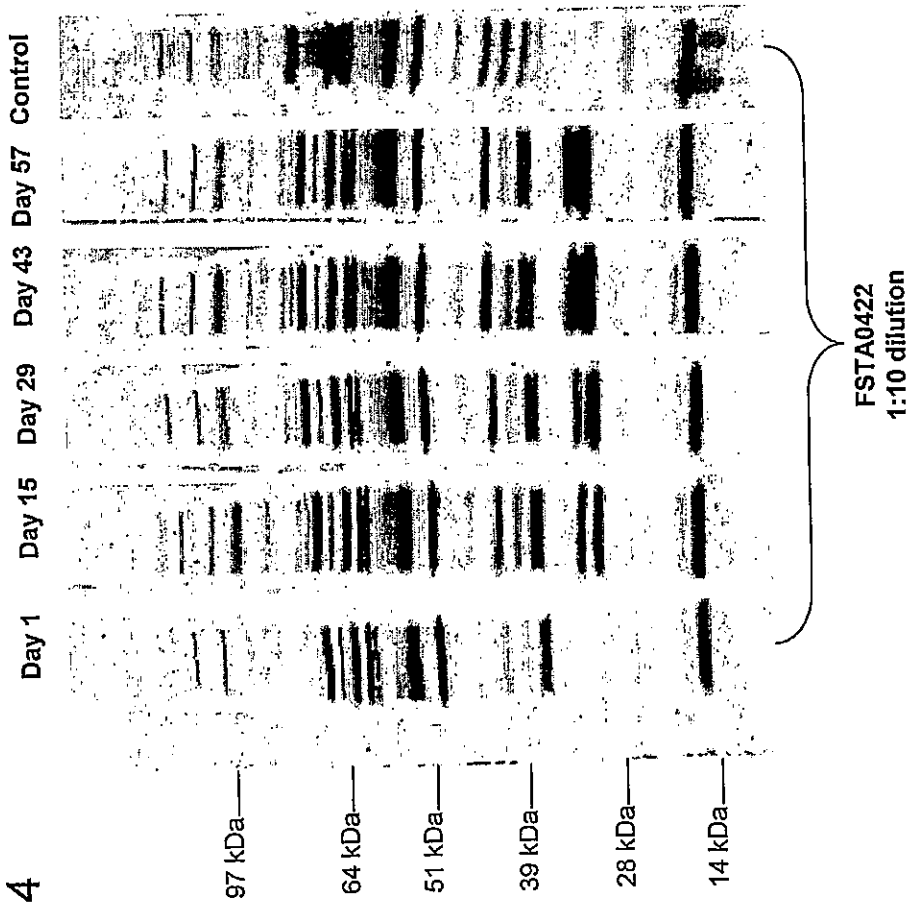

Day 1
Day 15
Day 29
Day 43
Day 57
Control
97 kDa
64 kDa
51 kDa
39 kDa
28 kDa
14 kDa
FSTA0422
1:10 dilution

Figure 5

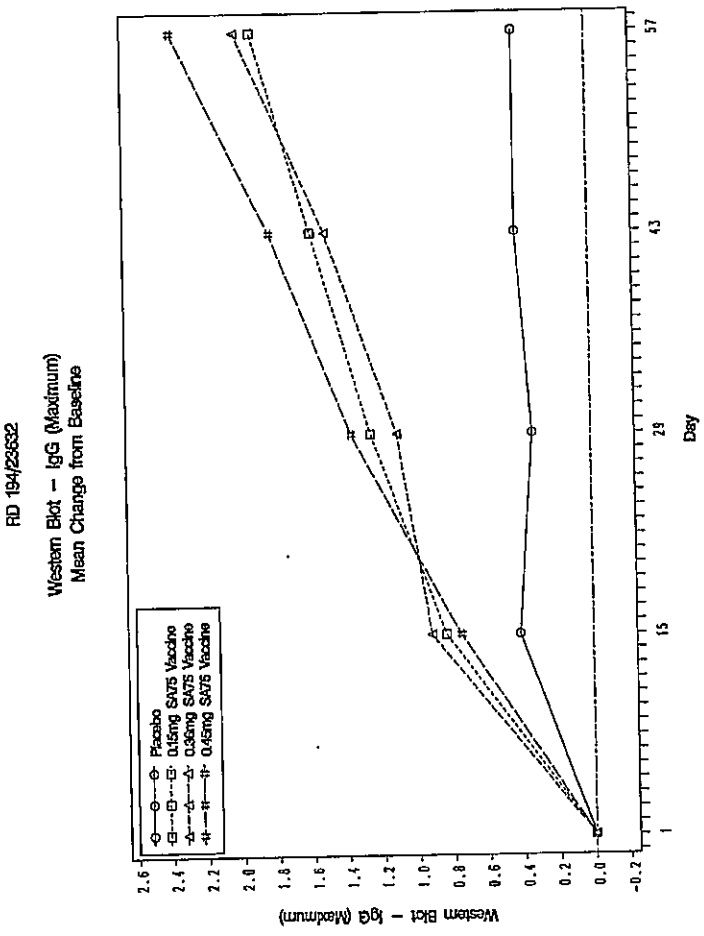

RD 194/23632
Western Blot – IgG (Maximum)
Mean Change from Baseline
Placebo
0.15mg SA75 Vaccine
0.30mg SA75 Vaccine
0.45mg SA75 Vaccine
Western Blot – IgG (Maximum)
2.6
2.4
2.2
2.0
1.8
1.6
1.4
1.2
1.0
0.8
0.6
0.4
0.2
0.0
-0.2
1
15
29
43
57
Day

Figure 6

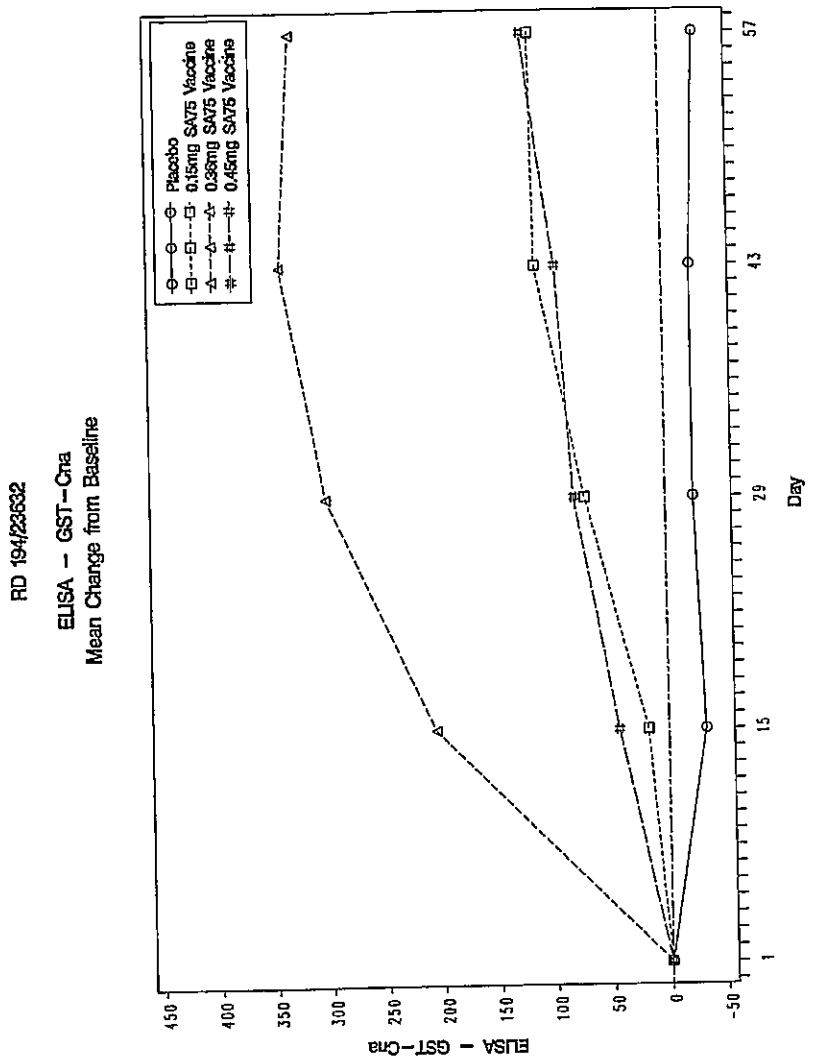

RD 194/23632
ELISA – GST-Cna
Mean Change from Baseline
Placebo
0.15mg SA75 Vaccine
0.38mg SA75 Vaccine
0.45mg SA75 Vaccine
ELISA – GST-Cna
450
400
350
300
250
200
150
100
50
0
-50
1
15
29
43
57
Day

Figure 7

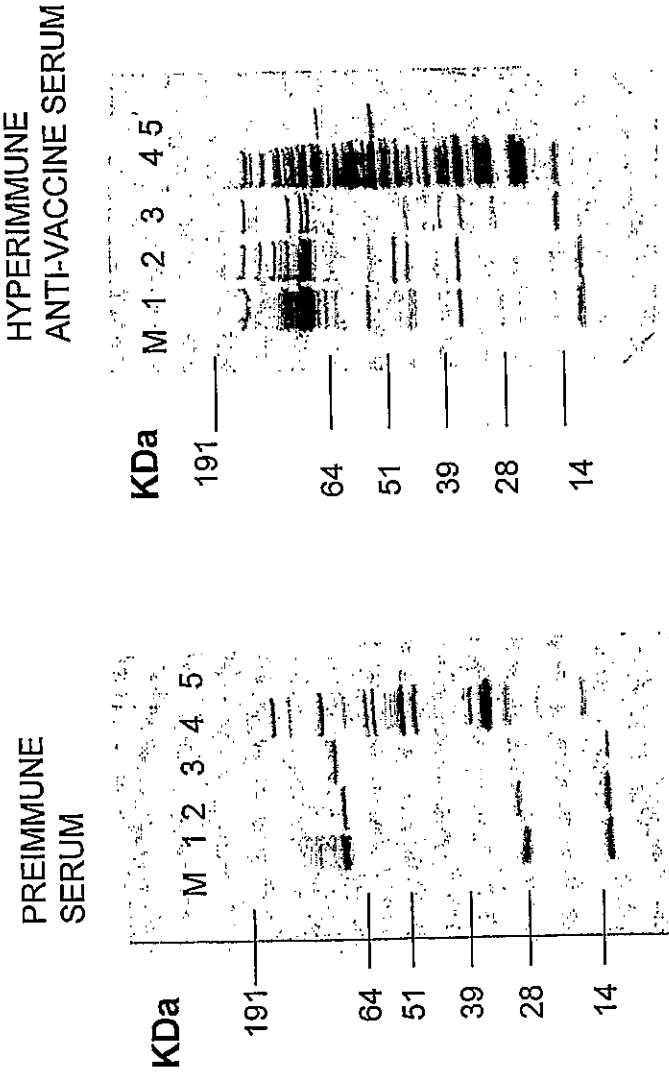

HYPERIMMUNE
ANTI-VACCINE SERUM
KDa
M 1 2 3 4 5
191
64
51
39
28
14
PREIMMUNE
SERUM
KDa
M 1 2 3 4 5
191
64
51
39
28
14

Figure 8

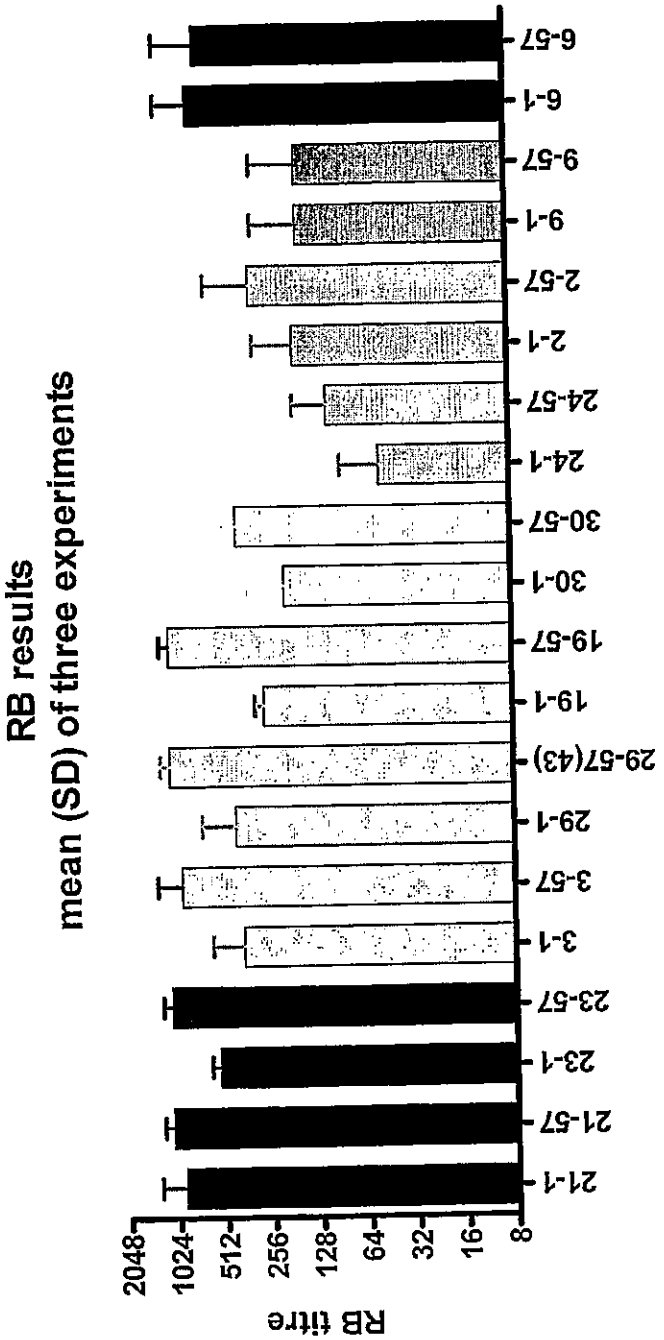

RB results
mean (SD) of three experiments
RB titre
2048
1024
512
256
128
64
32
16
8
21-1
21-57
23-1
23-57
3-1
3-57
29-1
29-57(43)
19-1
19-57
30-1
30-57
24-1
24-57
2-1
2-57
9-1
9-57
6-1
6-57

Table 1

	No. Events (Maximum Reported Grade; No. Events at Maximum Reported Grade)*								
Vaccine Dose (mg)	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**Total**
Placebo	1 (Mild; 1)	2 (Mild; 2)	1 (Mild; 1)	0	2 (Mild; 2)	0	0	0	**6**
0.15	22 (Mod.; 5)	41 (Mod.; 1)	1 (Mild; 1)	0	50 (Mild; 50)	2 (Mild; 2)	0	1 (Mild; 1)	**117**
0.36	42 (Mod.; 2)	43 (Mod.; 1)	2 (Mild; 2)	1 (Mild; 1)	45 (Mod.; 5)	5 (Mild; 5)	0	7 (Mild; 7)	**145**
0.45	38 (Sev.; 2)	51 (Sev.; 2)	3 (Mild; 3)	0	86 (Sev.; 2)	15 (Mod.; 2)	1 (Sev; 1)	3 (Mod.; 2)	**197**

A = Erythema	C = Haemmorrhage	E = Pain	G = Swelling
B = Induration	D = Burning	F = Pruritis	H = Warmth

Table 2

	No. Events (Maximum Reported Grade; No. Events at Maximum Reported Grade)*							
Vaccine Dose (mg)	**A**	**B**	**C**	**D**	**E**	**F**	**Total**	**No. Discontinuations**
Placebo	0	0	3 (Sev.; 1)	0	0	3 (Mild; 3)	**23**	0
0.15	2 (Mild; 2)	0	3 (Mod.; 2)	0	0	6 (Mild; 6)	**29**	1 not vaccine-related
0.36	0	0	1 (Mod.; 1)	0	0	7 (Mod.; 2)	**19**	1 not vaccine-related; 1 flu-like symptoms
0.45	0	3 (Mod.; 1)	4 (Mod.; 2)	3 (Sev.; 1)	3 (Sev.; 2)	16 (Mod.; 8)	**63**	1 severe injection site erythema

A = Fatigue	C = Flu-like	E = Vomiting
B = Feeling hot/cold	D = Malaise	F = Headache

Table 3

*Weak – 0-4 positive changes

* * Strong – 5 or more positive changes

	Reaction		
Vaccine Dose (mg)	None	Weak*	Strong**
Placebo	7/12	5/12	0/12
0.15	0/12	6/12	6/12
0.36	0/12	2/12	9/12
0.45	0/12	0/12	12/12

Table 4

Vaccine Dose	Number of Subjects/Total Number of Subjects
Placebo	1/12
0.15mg Vaccine	7/12
0.36mg Vaccine	9/12
0.45mg Vaccine	7/12

Table 5

(Secondary study objective – Non-GLP testing)

Serum from 32* volunteers taken 3 and 6 months after 4th vaccination – comparison with reactivity at 2 weeks following 4th (final) vaccination:

	Group 1 (0.15mg)	**Group 2 (0.45mg)**	**Group 3 (0.36mg)**
Vaccinated Subjects			
Above pre immune level at 3 and 6 months	11/11	11/11	10/10**
Placebo			
No change in reactivity at 3 and 6 months	4/4	4/4	4/4

* Volunteers lost to follow up 007, 020, 036 and 044.

** Volunteer 047 (Group 3) who did not have a sample at 6 months