

TDMS No. 20537 - 01
Test Type: 90-DAY
Route: INTRADUCTAL CANNULATION
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Adenoviral Vector (AdhAQP1)
CAS Number: ADN VIRVECAQP

Date Report Requested: 09/10/2009
Time Report Requested: 09:38:44
First Dose M/F: 07/18/05 / NA
Lab: MBA

F1_R2_3Wk_SSAC

C Number:	C20537
Lock Date:	11/19/2007
Cage Range:	ALL
Date Range:	ALL
Reasons For Removal:	25017 SSAC
Removal Date Range:	ALL
Treatment Groups:	Include 002 VEHCONTRCOHRTB Include 007 2-8ADHAQP1COHTB Include 012 8-9ADHAQP1COHTB Include 017 2-11ADHAQP1COHTB
Study Gender:	Male
TDMSE Version:	2.1.0

TDMS No. 20537 - 01

Test Type: 90-DAY

Route: INTRADUCTAL CANNULATION

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Adenoviral Vector (AdhAQP1)

CAS Number: ADN VIRVECAQP

Date Report Requested: 09/10/2009

Time Report Requested: 09:38:44

First Dose M/F: 07/18/05 / NA

Lab: MBA

SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF ADENOVIRAL VECTOR (ADHAQP1)

MALE RATS

Organ

Liver

Prostate

Morphology

Inflammation

Inflammation

TDMS No. 20537 - 01
 Test Type: 90-DAY
 Route: INTRADUCTAL CANNULATION
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Adenoviral Vector (AdhAQP1)
 CAS Number: ADN VIRVECAQP

Date Report Requested: 09/10/2009
 Time Report Requested: 09:38:44
 First Dose M/F: 07/18/05 / NA
 Lab: MBA

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N) LAST REMOVAL AT 3 WEEKS

Males			
DOSE	VEHCONTRCOHRTB	2-11ADHAQP1COHTB	8-9ADHAQP1COHTB
Liver Inflammation			
LESION RATES			
OVERALL (a)	2/5 (40%)	0/10 (0%)	0/5 (0%)
POLY-3 RATE (b)	2/5.00	0/10.00	0/5.00
POLY-3 PERCENT (g)	40%	0%	0%
INT SACRIFICE 1	2/5 (40%	0/10 (0%	0/5 (0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	15 (l)	---	---
STATISTICAL TESTS			
POLY 3	P=0.200N	P=0.067N	P=0.207N
POLY 1.5	P=0.200N	P=0.067N	P=0.207N
POLY 6	P=0.200N	P=0.067N	P=0.207N
COCH-ARM / FISHERS	P=0.228N	P=0.095N	P=0.222N
MAX-ISO-POLY-3	P=0.013N*	P=0.019N*	P=0.051N

TDMS No. 20537 - 01
 Test Type: 90-DAY
 Route: INTRADUCTAL CANNULATION
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Adenoviral Vector (AdhAQP1)
 CAS Number: ADN VIRVECAQP

Date Report Requested: 09/10/2009
 Time Report Requested: 09:38:44
 First Dose M/F: 07/18/05 / NA
 Lab: MBA

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N) LAST REMOVAL AT 3 WEEKS

Males			
DOSE	VEHCONTRCOHRTB	2-11ADHAQP1COHTB	8-9ADHAQP1COHTB
Prostate Inflammation			
LESION RATES			
OVERALL (a)	2/5 (40%)	0/10 (0%)	0/5 (0%)
POLY-3 RATE (b)	2/5.00	0/10.00	0/5.00
POLY-3 PERCENT (g)	40%	0%	0%
INT SACRIFICE 1	2/5 (40%)	0/10 (0%)	0/5 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	15 (l)	---	---
STATISTICAL TESTS			
POLY 3	P=0.200N	P=0.067N	P=0.207N
POLY 1.5	P=0.200N	P=0.067N	P=0.207N
POLY 6	P=0.200N	P=0.067N	P=0.207N
COCH-ARM / FISHERS	P=0.228N	P=0.095N	P=0.222N
MAX-ISO-POLY-3	P=0.013N*	P=0.019N*	P=0.051N

TDMS No. 20537 - 01
Test Type: 90-DAY
Route: INTRADUCTAL CANNULATION
Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Adenoviral Vector (AdhAQP1)
CAS Number: ADN VIRVECAQP

Date Report Requested: 09/10/2009
Time Report Requested: 09:38:44
First Dose M/F: 07/18/05 / NA
Lab: MBA

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
LAST REMOVAL AT 3 WEEKS**

Males			
DOSE	VEHCONTRCOHRTB	2-11ADHAQP1COHTB	8-9ADHAQP1COHTB
Salivary Glands: Submandibular Gland, Left Inflammation			
LESION RATES			
OVERALL (a)	0/5 (0%)	2/10 (20%)	1/5 (20%)
POLY-3 RATE (b)	0/5.00	2/10.00	1/5.00
POLY-3 PERCENT (g)	0%	20%	20%
INT SACRIFICE 1	0/5 (0%)	2/10 (20%)	1/5 (20%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	15 (I)	15 (I)
STATISTICAL TESTS			
POLY 3	P=0.500	P=0.397	P=0.500
POLY 1.5	P=0.500	P=0.397	P=0.500
POLY 6	P=0.500	P=0.397	P=0.500
COCH-ARM / FISHERS	P=0.500	P=0.429	P=0.500
MAX-ISO-POLY-3	P=0.283	P=0.184	P=0.159

TDMS No. 20537 - 01
 Test Type: 90-DAY
 Route: INTRADUCTAL CANNULATION
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Adenoviral Vector (AdhAQP1)
 CAS Number: ADN VIRVECAQP

Date Report Requested: 09/10/2009
 Time Report Requested: 09:38:44
 First Dose M/F: 07/18/05 / NA
 Lab: MBA

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N) LAST REMOVAL AT 3 WEEKS

Males			
DOSE	VEHCONTRCOHRTB	2-11ADHAQP1COHTB	8-9ADHAQP1COHTB
Salivary Glands: Submandibular Gland, Right Inflammation			
LESION RATES			
OVERALL (a)	4/5 (80%)	7/10 (70%)	4/5 (80%)
POLY-3 RATE (b)	4/5.00	7/10.00	4/5.00
POLY-3 PERCENT (g)	80%	70%	80%
INT SACRIFICE 1	4/5 (80%)	7/10 (70%)	4/5 (80%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	15 (I)	15 (I)	15 (I)
STATISTICAL TESTS			
POLY 3	P=0.625	P=0.577N	P=0.760
POLY 1.5	P=0.625	P=0.577N	P=0.760
POLY 6	P=0.625	P=0.577N	P=0.760
COCH-ARM / FISHERS	P=0.635	P=0.593N	P=0.778N
MAX-ISO-POLY-3	P=0.559	P=0.368N	P=1.000

TDMS No. 20537 - 01
 Test Type: 90-DAY
 Route: INTRADUCTAL CANNULATION
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Adenoviral Vector (AdhAQP1)
 CAS Number: ADN VIRVECAQP

Date Report Requested: 09/10/2009
 Time Report Requested: 09:38:44
 First Dose M/F: 07/18/05 / NA
 Lab: MBA

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N) LAST REMOVAL AT 3 WEEKS

Males			
DOSE	VEHCONTRCOHRTB	2-11ADHAQP1COHTB	8-9ADHAQP1COHTB
Salivary Glands: Submandibular Gland, Right Regeneration			
LESION RATES			
OVERALL (a)	5/5 (100%)	10/10 (100%)	4/5 (80%)
POLY-3 RATE (b)	5/5.00	10/10.00	4/5.00
POLY-3 PERCENT (g)	100%	100%	80%
INT SACRIFICE 1	5/5 (100%)	10/10 (100%)	4/5 (80%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	15 (I)	15 (I)	15 (I)
STATISTICAL TESTS			
POLY 3	P=0.246N	(e)	P=0.500N
POLY 1.5	P=0.246N	(e)	P=0.500N
POLY 6	P=0.246N	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.247N	(e)	P=0.500N
MAX-ISO-POLY-3	P=0.103N	(e)	P=0.159N

TDMS No. 20537 - 01
 Test Type: 90-DAY
 Route: INTRADUCTAL CANNULATION
 Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Adenoviral Vector (AdhAQP1)
 CAS Number: ADN VIRVECAQP

Date Report Requested: 09/10/2009
 Time Report Requested: 09:38:44
 First Dose M/F: 07/18/05 / NA
 Lab: MBA

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N) LAST REMOVAL AT 3 WEEKS

Males			
DOSE	VEHCONTRCOHRTB	2-11ADHAQP1COHTB	8-9ADHAQP1COHTB
Stomach, Glandular Mineralization			
LESION RATES			
OVERALL (a)	1/5 (20%)	2/10 (20%)	1/5 (20%)
POLY-3 RATE (b)	1/5.00	2/10.00	1/5.00
POLY-3 PERCENT (g)	20%	20%	20%
INT SACRIFICE 1	1/5 (20%)	2/10 (20%)	1/5 (20%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	15 (I)	15 (I)	15 (I)
STATISTICAL TESTS			
POLY 3	P=0.697	P=0.738	P=0.760
POLY 1.5	P=0.697	P=0.738	P=0.760
POLY 6	P=0.697	P=0.738	P=0.760
COCH-ARM / FISHERS	P=0.712	P=0.736N	P=0.778N
MAX-ISO-POLY-3	P=1.000	P=1.000	P=1.000

TDMS No. 20537 - 01

Test Type: 90-DAY

Route: INTRADUCTAL CANNULATION

Species/Strain: RATS/F 344/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Adenoviral Vector (AdhAQP1)

CAS Number: ADN VIRVECAQP

Date Report Requested: 09/10/2009

Time Report Requested: 09:38:44

First Dose M/F: 07/18/05 / NA

Lab: MBA

LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
 - (b) Number of tumor-bearing animals/Poly-3 number
 - (d) Observed incidence at terminal kill.
 - (e) Value of Statistic cannot be computed.
 - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
 - (g) Poly-3 adjusted lifetime tumor incidence.
 - (I) Interim sacrifice
 - (T) Terminal sacrifice
 - # Tumor rates based on numbers of animals necropsied.
 - * To the right of any statistical result, indicates significance at ($P \leq 0.05$).
 - ** To the right of any statistical result, indicates significance at ($P \leq 0.01$).
 - N Indicates a negative trend for all tests
- The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

*** END OF REPORT ***