

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: 09:42:14
First Dose M/F: 07/18/05 / NA
Lab: MBA

F1_R2_9Wk_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 004 VEHCONTRCOHRTD Include 009 2-8ADHAQP1COHTD Include 014 8-9ADHAQP1COHTD Include 019 2-11ADHAQP1COHTD
Study Gender:	Male
TDMSE Version:	2.1.0

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

MALE RATS

Organ

Intestine Large, Colon

Morphology

Hemorrhage

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N)
LAST REMOVAL AT 9 WEEKS**

Males			
DOSE	VEHCONTRCOHRTD	2-11ADHAQP1COHTD	8-9ADHAQP1COHTD
Heart Cardiomyopathy			
LESION RATES			
OVERALL (a)	1/5 (20%)	6/10 (60%)	3/5 (60%)
POLY-3 RATE (b)	1/5.00	6/10.00	3/5.00
POLY-3 PERCENT (g)	20%	60%	60%
INT SACRIFICE 1	1/5 (20%)	6/10 (60%)	3/5 (60%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	57 (I)	57 (I)	57 (I)
STATISTICAL TESTS			
POLY 3	P=0.330	P=0.179	P=0.264
POLY 1.5	P=0.330	P=0.179	P=0.264
POLY 6	P=0.330	P=0.179	P=0.264
COCH-ARM / FISHERS	P=0.327	P=0.182	P=0.262
MAX-ISO-POLY-3	P=0.152	P=0.101	P=0.103

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Males			
DOSE	VEHCONTRCOHRTD	2-11ADHAQP1COHTD	8-9ADHAQP1COHTD
Intestine Large, Colon Hemorrhage			
LESION RATES			
OVERALL (a)	0/5 (0%)	0/10 (0%)	2/5 (40%)
POLY-3 RATE (b)	0/5.00	0/10.00	2/5.00
POLY-3 PERCENT (g)	0%	0%	40%
INT SACRIFICE 1	0/5 (0%)	0/10 (0%)	2/5 (40%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	---	57 (I)
STATISTICAL TESTS			
POLY 3	P=0.025*	(e)	P=0.207
POLY 1.5	P=0.025*	(e)	P=0.207
POLY 6	P=0.025*	(e)	P=0.207
COCH-ARM / FISHERS	P=0.041*	(e)	P=0.222
MAX-ISO-POLY-3	P=0.013*	(e)	P=0.051

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Males			
DOSE	VEHCONTRCOHRTD	2-11ADHAQP1COHTD	8-9ADHAQP1COHTD
Liver Inflammation			
LESION RATES			
OVERALL (a)	2/5 (40%)	3/10 (30%)	0/5 (0%)
POLY-3 RATE (b)	2/5.00	3/10.00	0/5.00
POLY-3 PERCENT (g)	40%	30%	0%
INT SACRIFICE 1	2/5 (40%)	3/10 (30%)	0/5 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	57 (I)	57 (I)	---
STATISTICAL TESTS			
POLY 3	P=0.155N	P=0.572N	P=0.207N
POLY 1.5	P=0.155N	P=0.572N	P=0.207N
POLY 6	P=0.155N	P=0.572N	P=0.207N
COCH-ARM / FISHERS	P=0.151N	P=0.566N	P=0.222N
MAX-ISO-POLY-3	P=0.107N	P=0.375N	P=0.051N

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LAST REMOVAL AT 9 WEEKS**

Males			
DOSE	VEHCONTRCOHRTD	2-11ADHAQP1COHTD	8-9ADHAQP1COHTD
Salivary Glands: Submandibular Gland, Right Regeneration			
LESION RATES			
OVERALL (a)	3/3 (100%)	9/9 (100%)	5/5 (100%)
POLY-3 RATE (b)	3/3.00	9/9.00	5/5.00
POLY-3 PERCENT (g)	100%	100%	100%
INT SACRIFICE 1	3/3 (100%	9/9 (100%	5/5 (100%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	57 (l)	57 (l)	57 (l)
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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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 ***