

TDMS No. 20537 - 02
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: 11:33:57
First Dose M/F: NA / 07/25/05
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 007 2-8ADHAQP1COHTB Include 012 8-9ADHAQP1COHTB Include 017 2-11ADHAQP1COHTB Include 021 VEHCONTRCOHRTB
Study Gender:	Female
TDMSE Version:	2.1.0

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

FEMALE RATS

Organ

Salivary Glands: Submandibular Gland, Right
Stomach, Glandular

Morphology

Inflammation
Mineralization

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

Females			
DOSE	VEHCONTRCOHRTB	2-11ADHAQP1COHTB	8-9ADHAQP1COHTB
Heart Cardiomyopathy			
LESION RATES			
OVERALL (a)	0/5 (0%)	2/10 (20%)	0/5 (0%)
POLY-3 RATE (b)	0/5.00	2/10.00	0/5.00
POLY-3 PERCENT (g)	0%	20%	0%
INT SACRIFICE 1	0/5 (0%	2/10 (20%	0/5 (0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	15 (l)	---
STATISTICAL TESTS			
POLY 3	P=0.596N	P=0.397	(e)
POLY 1.5	P=0.596N	P=0.397	(e)
POLY 6	P=0.596N	P=0.397	(e)
COCH-ARM / FISHERS	P=0.598N	P=0.429	(e)
MAX-ISO-POLY-3	P=0.346	P=0.184	(e)

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Females			
DOSE	VEHCONTRCOHRTB	2-11ADHAQP1COHTB	8-9ADHAQP1COHTB
Salivary Glands: Submandibular Gland, Right Infiltration Cellular Lymphocyte			
LESION RATES			
OVERALL (a)	0/5 (0%)	2/9 (22%)	0/5 (0%)
POLY-3 RATE (b)	0/5.00	2/9.00	0/5.00
POLY-3 PERCENT (g)	0%	22.2%	0%
INT SACRIFICE 1	0/5 (0%	2/9 (22%	0/5 (0%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	15 (l)	---
STATISTICAL TESTS			
POLY 3	P=0.585N	P=0.370	(e)
POLY 1.5	P=0.585N	P=0.370	(e)
POLY 6	P=0.585N	P=0.370	(e)
COCH-ARM / FISHERS	P=0.586N	P=0.396	(e)
MAX-ISO-POLY-3	P=0.330N	P=0.165	(e)

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

Females			
DOSE	VEHCONTRCOHRTB	2-11ADHAQP1COHTB	8-9ADHAQP1COHTB
Salivary Glands: Submandibular Gland, Right Inflammation			
LESION RATES			
OVERALL (a)	1/5 (20%)	6/9 (67%)	5/5 (100%)
POLY-3 RATE (b)	1/5.00	6/9.00	5/5.00
POLY-3 PERCENT (g)	20%	66.7%	100%
INT SACRIFICE 1	1/5 (20%)	6/9 (67%)	5/5 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	15 (I)	15 (I)	15 (I)
STATISTICAL TESTS			
POLY 3	P=0.014*	P=0.124	P<0.001**
POLY 1.5	P=0.014*	P=0.124	P<0.001**
POLY 6	P=0.014*	P=0.124	P<0.001**
COCH-ARM / FISHERS	P=0.028*	P=0.133	P=0.024*
MAX-ISO-POLY-3	P=0.002**	P=0.063	P<0.001**

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

Females			
DOSE	VEHCONTRCOHRTB	2-11ADHAQP1COHTB	8-9ADHAQP1COHTB
Salivary Glands: Submandibular Gland, Right Regeneration			
LESION RATES			
OVERALL (a)	4/5 (80%)	9/9 (100%)	5/5 (100%)
POLY-3 RATE (b)	4/5.00	9/9.00	5/5.00
POLY-3 PERCENT (g)	80%	100%	100%
INT SACRIFICE 1	4/5 (80%)	9/9 (100%)	5/5 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	15 (I)	15 (I)	15 (I)
STATISTICAL TESTS			
POLY 3	P=0.493	P=0.379	P=0.500
POLY 1.5	P=0.493	P=0.379	P=0.500
POLY 6	P=0.493	P=0.379	P=0.500
COCH-ARM / FISHERS	P=0.493	P=0.357	P=0.500
MAX-ISO-POLY-3	P=0.112	P=0.110	P=0.159

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Females			
DOSE	VEHCONTRCOHRTB	2-11ADHAQP1COHTB	8-9ADHAQP1COHTB
Stomach, Glandular Mineralization			
LESION RATES			
OVERALL (a)	2/5 (40%)	0/10 (0%)	1/5 (20%)
POLY-3 RATE (b)	2/5.00	0/10.00	1/5.00
POLY-3 PERCENT (g)	40%	0%	20%
INT SACRIFICE 1	2/5 (40%)	0/10 (0%)	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=0.668N	P=0.067N	P=0.500N
POLY 1.5	P=0.668N	P=0.067N	P=0.500N
POLY 6	P=0.668N	P=0.067N	P=0.500N
COCH-ARM / FISHERS	P=0.662N	P=0.095N	P=0.500N
MAX-ISO-POLY-3	P=0.089N	P=0.019N*	P=0.264N

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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 ***