

Experiment Number: 20108-05
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/C57BL/6

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Test Compound: Antioxidant model (TRAMP) - N-acetylcysteine
CAS Number: 616-91-1

Date Report Requested: 10/17/2014
Time Report Requested: 16:19:52
First Dose M/F: NA / NA
Lab: ILS

C Number:	C20108C
Lock Date:	Not Entered.
Cage Range:	All
Date Range:	All
Reasons For Removal:	All
Removal Date Range:	All
Treatment Groups:	All
Study Gender:	Male
PWG Approval Date	NONE

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF ANTIOXIDANT MODEL (TRAMP) - N-

MALE MOUSE

Organ

Prostate, Anterior Lobe

Morphology

Hyperplasia Grade 1 Focal

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(C57BL/6)
LAST REMOVAL AT 13 WEEKS

			MALE
DOSE	VEHICLE CONTROL	NAC	125MG/KG
<hr/>			
Epididymis			
Granuloma Sperm			
<hr/>			
LESION RATES			
OVERALL(a)	0/10 (0%)	1/30 (3%)	
POLY-3 RATE (b)	0/6.72	1/18.71	
POLY-3 PERCENT (g)	0%	5.3%	
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)	
INT SACRIFICE 2	0/1 (0%)	0/6 (0%)	
TERMINAL (d)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	---	88(l)	
<hr/>			
STATISTICAL TESTS			
POLY 3	P=0.707	P=0.707	
POLY 1.5	P=0.711	P=0.711	
POLY 6	P=0.707	P=0.707	
COCH-ARM / FISHERS	P=0.721	P=0.750	
MAX-ISO-POLY-3	P=0.305	P=0.305	
HISTCONT SAME RTE			
HISTCONT ALL RTES			
CURR VS HC SAME RTE			
CURR VS HC ALL RTES			

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LAST REMOVAL AT 13 WEEKS

			MALE
DOSE	VEHICLE CONTROL	NAC	125MG/KG
Kidney			
Hydronephrosis			
LESION RATES			
OVERALL(a)	0/12 (0%)	2/30 (7%)	
POLY-3 RATE (b)	0/7.89	2/18.87	
POLY-3 PERCENT (g)	0%	10.6%	
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)	
INT SACRIFICE 2	0/2 (0%)	0/6 (0%)	
TERMINAL (d)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	---	86(l)	
STATISTICAL TESTS			
POLY 3	P=0.443	P=0.443	
POLY 1.5	P=0.445	P=0.445	
POLY 6	P=0.448	P=0.448	
COCH-ARM / FISHERS	P=0.454	P=0.505	
MAX-ISO-POLY-3	P=0.210	P=0.210	
HISTCONT SAME RTE			
HISTCONT ALL RTES			
CURR VS HC SAME RTE			
CURR VS HC ALL RTES			

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(C57BL/6)
LAST REMOVAL AT 13 WEEKS

			MALE
DOSE	VEHICLE CONTROL	NAC	125MG/KG
Kidney: Medulla, Renal Tubule			
Dilatation Focal			
LESION RATES			
OVERALL(a)	0/12 (0%)	1/30 (3%)	
POLY-3 RATE (b)	0/7.89	1/18.80	
POLY-3 PERCENT (g)	0%	5.3%	
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)	
INT SACRIFICE 2	0/2 (0%)	0/6 (0%)	
TERMINAL (d)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	---	85(l)	
STATISTICAL TESTS			
POLY 3	P=0.675	P=0.675	
POLY 1.5	P=0.676	P=0.676	
POLY 6	P=0.678	P=0.678	
COCH-ARM / FISHERS	P=0.684	P=0.714	
MAX-ISO-POLY-3	P=0.289	P=0.289	
HISTCONT SAME RTE			
HISTCONT ALL RTES			
CURR VS HC SAME RTE			
CURR VS HC ALL RTES			

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LAST REMOVAL AT 13 WEEKS

			MALE
DOSE	VEHICLE CONTROL	NAC	125MG/KG
Kidney: Renal Tubule			
Casts Protein			
LESION RATES			
OVERALL(a)	1/12 (8%)	0/30 (0%)	
POLY-3 RATE (b)	1/8.01	0/18.67	
POLY-3 PERCENT (g)	12.5%	0%	
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)	
INT SACRIFICE 2	0/2 (0%)	0/6 (0%)	
TERMINAL (d)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	85(l)	---	
STATISTICAL TESTS			
POLY 3	P=0.325N	P=0.325N	
POLY 1.5	P=0.321N	P=0.321N	
POLY 6	P=0.326N	P=0.326N	
COCH-ARM / FISHERS	P=0.316N	P=0.286N	
MAX-ISO-POLY-3	P=0.087N	P=0.087N	
HISTCONT SAME RTE			
HISTCONT ALL RTES			
CURR VS HC SAME RTE			
CURR VS HC ALL RTES			

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LAST REMOVAL AT 13 WEEKS

			MALE
DOSE	VEHICLE CONTROL	NAC 125MG/KG	
<hr/>			
Liver			
Inflammation Focal			
<hr/>			
LESION RATES			
OVERALL(a)	5/12 (42%)	11/30 (37%)	
POLY-3 RATE (b)	5/9.92	11/21.90	
POLY-3 PERCENT (g)	50.4%	50.2%	
INT SACRIFICE 1	1/2 (50%)	2/6 (33%)	
INT SACRIFICE 2	1/2 (50%)	1/6 (17%)	
TERMINAL (d)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	32(l)	32(l)	
<hr/>			
STATISTICAL TESTS			
POLY 3	P=0.651N	P=0.651N	
POLY 1.5	P=0.607N	P=0.607N	
POLY 6	P=0.641	P=0.641	
COCH-ARM / FISHERS	P=0.520N	P=0.515N	
MAX-ISO-POLY-3	P=0.497N	P=0.497N	
HISTCONT SAME RTE			
HISTCONT ALL RTES			
CURR VS HC SAME RTE			
CURR VS HC ALL RTES			

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LAST REMOVAL AT 13 WEEKS

			MALE
DOSE	VEHICLE CONTROL	NAC	125MG/KG
<hr/>			
Liver			
Necrosis Focal			
<hr/>			
LESION RATES			
OVERALL(a)	1/12 (8%)	0/30 (0%)	
POLY-3 RATE (b)	1/8.62	0/18.67	
POLY-3 PERCENT (g)	11.6%	0%	
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)	
INT SACRIFICE 2	1/2 (50%)	0/6 (0%)	
TERMINAL (d)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	57(l)	---	
<hr/>			
STATISTICAL TESTS			
POLY 3	P=0.338N	P=0.338N	
POLY 1.5	P=0.329N	P=0.329N	
POLY 6	P=0.344N	P=0.344N	
COCH-ARM / FISHERS	P=0.316N	P=0.286N	
MAX-ISO-POLY-3	P=0.088N	P=0.088N	
HISTCONT SAME RTE			
HISTCONT ALL RTES			
CURR VS HC SAME RTE			
CURR VS HC ALL RTES			

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LAST REMOVAL AT 13 WEEKS

			MALE
DOSE	VEHICLE CONTROL	NAC	125MG/KG
<hr/>			
Liver			
Tension Lipidosis			
<hr/>			
LESION RATES			
OVERALL(a)	0/12 (0%)	2/30 (7%)	
POLY-3 RATE (b)	0/7.89	2/18.87	
POLY-3 PERCENT (g)	0%	10.6%	
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)	
INT SACRIFICE 2	0/2 (0%)	0/6 (0%)	
TERMINAL (d)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	---	86(l)	
<hr/>			
STATISTICAL TESTS			
POLY 3	P=0.443	P=0.443	
POLY 1.5	P=0.445	P=0.445	
POLY 6	P=0.448	P=0.448	
COCH-ARM / FISHERS	P=0.454	P=0.505	
MAX-ISO-POLY-3	P=0.210	P=0.210	
HISTCONT SAME RTE			
HISTCONT ALL RTES			
CURR VS HC SAME RTE			
CURR VS HC ALL RTES			

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LAST REMOVAL AT 13 WEEKS

			MALE
DOSE	VEHICLE CONTROL	NAC 125MG/KG	
Prostate, Anterior Lobe			
Hyperplasia Grade 1 Focal			
LESION RATES			
OVERALL(a)	0/12 (0%)	23/30 (77%)	
POLY-3 RATE (b)	0/7.89	23/27.03	
POLY-3 PERCENT (g)	0%	85.1%	
INT SACRIFICE 1	0/2 (0%)	4/6 (67%)	
INT SACRIFICE 2	0/2 (0%)	5/6 (83%)	
TERMINAL (d)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	---	32(l)	
STATISTICAL TESTS			
POLY 3	P=0.000**	P=0.000**	
POLY 1.5	P=0.000**	P=0.000**	
POLY 6	P=0.000**	P=0.000**	
COCH-ARM / FISHERS	P=0.000**	P=0.000**	
MAX-ISO-POLY-3	P=0.000**	P=0.000**	
HISTCONT SAME RTE			
HISTCONT ALL RTES			
CURR VS HC SAME RTE			
CURR VS HC ALL RTES			

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(C57BL/6)
 LAST REMOVAL AT 13 WEEKS**

			MALE
DOSE	VEHICLE CONTROL	NAC	125MG/KG
Prostate, Anterior Lobe			
Hyperplasia Grade 2 Focal			
LESION RATES			
OVERALL(a)	1/12 (8%)	0/30 (0%)	
POLY-3 RATE (b)	1/8.01	0/18.67	
POLY-3 PERCENT (g)	12.5%	0%	
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)	
INT SACRIFICE 2	0/2 (0%)	0/6 (0%)	
TERMINAL (d)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	85(l)	---	
STATISTICAL TESTS			
POLY 3	P=0.325N	P=0.325N	
POLY 1.5	P=0.321N	P=0.321N	
POLY 6	P=0.326N	P=0.326N	
COCH-ARM / FISHERS	P=0.316N	P=0.286N	
MAX-ISO-POLY-3	P=0.087N	P=0.087N	
HISTCONT SAME RTE			
HISTCONT ALL RTES			
CURR VS HC SAME RTE			
CURR VS HC ALL RTES			

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LAST REMOVAL AT 13 WEEKS

			MALE
DOSE	VEHICLE CONTROL	NAC	125MG/KG
Prostate, Dorsal Lobe			
Hyperplasia Grade 1 Focal			
LESION RATES			
OVERALL(a)	0/12 (0%)	3/30 (10%)	
POLY-3 RATE (b)	0/7.89	3/19.66	
POLY-3 PERCENT (g)	0%	15.3%	
INT SACRIFICE 1	0/2 (0%)	1/6 (17%)	
INT SACRIFICE 2	0/2 (0%)	0/6 (0%)	
TERMINAL (d)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	---	32(l)	
STATISTICAL TESTS			
POLY 3	P=0.313	P=0.313	
POLY 1.5	P=0.315	P=0.315	
POLY 6	P=0.318	P=0.318	
COCH-ARM / FISHERS	P=0.318	P=0.354	
MAX-ISO-POLY-3	P=0.166	P=0.166	
HISTCONT SAME RTE			
HISTCONT ALL RTES			
CURR VS HC SAME RTE			
CURR VS HC ALL RTES			

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LAST REMOVAL AT 13 WEEKS

DOSE	MALE	
	VEHICLE CONTROL	NAC 125MG/KG
Prostate, Lateral Lobe		
Inflammation Focal		
LESION RATES		
OVERALL(a)	0/11 (0%)	1/26 (4%)
POLY-3 RATE (b)	0/6.98	1/16.48
POLY-3 PERCENT (g)	0%	6.1%
INT SACRIFICE 1	0/2 (0%)	1/6 (17%)
INT SACRIFICE 2	0/2 (0%)	0/5 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	32(l)
STATISTICAL TESTS		
POLY 3	P=0.672	P=0.672
POLY 1.5	P=0.670	P=0.670
POLY 6	P=0.676	P=0.676
COCH-ARM / FISHERS	P=0.674	P=0.703
MAX-ISO-POLY-3	P=0.291	P=0.291
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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LAST REMOVAL AT 13 WEEKS

			MALE
DOSE	VEHICLE CONTROL	NAC	125MG/KG
Prostate, Ventral Lobe			
Hyperplasia Grade 1 Focal			
LESION RATES			
OVERALL(a)	1/12 (8%)	0/19 (0%)	
POLY-3 RATE (b)	1/8.84	0/9.75	
POLY-3 PERCENT (g)	11.3%	0%	
INT SACRIFICE 1	1/2 (50%)	0/6 (0%)	
INT SACRIFICE 2	0/2 (0%)	0/4 (0%)	
TERMINAL (d)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	32(l)	---	
STATISTICAL TESTS			
POLY 3	P=0.480N	P=0.480N	
POLY 1.5	P=0.458N	P=0.458N	
POLY 6	P=0.490N	P=0.490N	
COCH-ARM / FISHERS	P=0.407N	P=0.387N	
MAX-ISO-POLY-3	P=0.156N	P=0.156N	
HISTCONT SAME RTE			
HISTCONT ALL RTES			
CURR VS HC SAME RTE			
CURR VS HC ALL RTES			

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STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MOUSE(C57BL/6)
LAST REMOVAL AT 13 WEEKS

			MALE
DOSE	VEHICLE CONTROL	NAC 125MG/KG	
Testes: Germinal Epith			
Vacuolization Cytoplasmic Focal			
LESION RATES			
OVERALL(a)	0/12 (0%)	1/29 (3%)	
POLY-3 RATE (b)	0/7.89	1/18.40	
POLY-3 PERCENT (g)	0%	5.4%	
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)	
INT SACRIFICE 2	0/2 (0%)	0/5 (0%)	
TERMINAL (d)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	---	89(T)(I)	
STATISTICAL TESTS			
POLY 3	P=0.670	P=0.670	
POLY 1.5	P=0.670	P=0.670	
POLY 6	P=0.674	P=0.674	
COCH-ARM / FISHERS	P=0.678	P=0.707	
MAX-ISO-POLY-3	P=0.287	P=0.287	
HISTCONT SAME RTE			
HISTCONT ALL RTES			
CURR VS HC SAME RTE			
CURR VS HC ALL RTES			

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LAST REMOVAL AT 13 WEEKS

			MALE
DOSE	VEHICLE CONTROL	NAC	125MG/KG
Testes: Seminif Tub			
Atrophy			
LESION RATES			
OVERALL(a)	0/12 (0%)	2/29 (7%)	
POLY-3 RATE (b)	0/7.89	2/19.26	
POLY-3 PERCENT (g)	0%	10.4%	
INT SACRIFICE 1	0/2 (0%)	0/6 (0%)	
INT SACRIFICE 2	0/2 (0%)	1/5 (20%)	
TERMINAL (d)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	---	57(l)	
STATISTICAL TESTS			
POLY 3	P=0.448	P=0.448	
POLY 1.5	P=0.444	P=0.444	
POLY 6	P=0.460	P=0.460	
COCH-ARM / FISHERS	P=0.446	P=0.495	
MAX-ISO-POLY-3	P=0.218	P=0.218	
HISTCONT SAME RTE			
HISTCONT ALL RTES			
CURR VS HC SAME RTE			
CURR VS HC ALL RTES			

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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.
 - (n) No statistics are calculated if all dose groups have fewer than two tumors.
 - (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 ****