

Experiment Number: 20108-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/TRAMP

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate
CAS Number: 989-51-5

Date Report Requested: 10/23/2014
Time Report Requested: 09:15:25
First Dose M/F: NA / NA
Lab: ILS

C Number:	C20108B
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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P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate

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

MALE MOUSE

Organ

Prostate, Dorsal Lobe

Morphology

Hyperplasia Grade 3 Diffuse

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

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Epididymis		
Aspermia		
LESION RATES		
OVERALL(a)	1/10 (10%)	0/31 (0%)
POLY-3 RATE (b)	1/6.00	0/20.34
POLY-3 PERCENT (g)	16.7%	0%
INT SACRIFICE 1	1/4 (25%)	0/6 (0%)
INT SACRIFICE 2	0/1 (0%)	0/5 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	32(l)	---
STATISTICAL TESTS		
POLY 3	P=0.255N	P=0.255N
POLY 1.5	P=0.258N	P=0.258N
POLY 6	P=0.254N	P=0.254N
COCH-ARM / FISHERS	P=0.273N	P=0.244N
MAX-ISO-POLY-3	P=0.068N	P=0.068N
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(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Epididymis		
Inflammation Focal		
LESION RATES		
OVERALL(a)	0/10 (0%)	1/31 (3%)
POLY-3 RATE (b)	0/5.05	1/20.47
POLY-3 PERCENT (g)	0%	4.9%
INT SACRIFICE 1	0/4 (0%)	0/6 (0%)
INT SACRIFICE 2	0/1 (0%)	0/5 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	85(l)
STATISTICAL TESTS		
POLY 3	P=0.758	P=0.758
POLY 1.5	P=0.749	P=0.749
POLY 6	P=0.763	P=0.763
COCH-ARM / FISHERS	P=0.727	P=0.756
MAX-ISO-POLY-3	P=0.362	P=0.362
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	EGCG 200MG/KG
<hr/>		
Epididymis: Duct		
Atypia Cellular		
<hr/>		
LESION RATES		
OVERALL(a)	0/10 (0%)	1/31 (3%)
POLY-3 RATE (b)	0/5.05	1/20.44
POLY-3 PERCENT (g)	0%	4.9%
INT SACRIFICE 1	0/4 (0%)	0/6 (0%)
INT SACRIFICE 2	0/1 (0%)	0/5 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	86(l)
<hr/>		
STATISTICAL TESTS		
POLY 3	P=0.758	P=0.758
POLY 1.5	P=0.749	P=0.749
POLY 6	P=0.763	P=0.763
COCH-ARM / FISHERS	P=0.727	P=0.756
MAX-ISO-POLY-3	P=0.362	P=0.362
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(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Kidney		
Hydronephrosis		
LESION RATES		
OVERALL(a)	1/10 (10%)	0/32 (0%)
POLY-3 RATE (b)	1/5.77	0/20.61
POLY-3 PERCENT (g)	17.3%	0%
INT SACRIFICE 1	0/4 (0%)	0/6 (0%)
INT SACRIFICE 2	1/1 (100%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	58(l)	---
STATISTICAL TESTS		
POLY 3	P=0.246N	P=0.246N
POLY 1.5	P=0.247N	P=0.247N
POLY 6	P=0.250N	P=0.250N
COCH-ARM / FISHERS	P=0.267N	P=0.238N
MAX-ISO-POLY-3	P=0.066N	P=0.066N
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	EGCG 200MG/KG
Kidney: Cortex, Renal Tubule Regeneration Focal		
LESION RATES		
OVERALL(a)	0/10 (0%)	3/32 (9%)
POLY-3 RATE (b)	0/5.05	3/21.79
POLY-3 PERCENT (g)	0%	13.8%
INT SACRIFICE 1	0/4 (0%)	1/6 (17%)
INT SACRIFICE 2	0/1 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	32(l)
STATISTICAL TESTS		
POLY 3	P=0.464	P=0.464
POLY 1.5	P=0.443	P=0.443
POLY 6	P=0.475	P=0.475
COCH-ARM / FISHERS	P=0.382	P=0.432
MAX-ISO-POLY-3	P=0.270	P=0.270
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	EGCG 200MG/KG
Kidney: Medulla, Renal Tubule		
Dilatation Focal		
LESION RATES		
OVERALL(a)	0/10 (0%)	1/32 (3%)
POLY-3 RATE (b)	0/5.05	1/20.74
POLY-3 PERCENT (g)	0%	4.8%
INT SACRIFICE 1	0/4 (0%)	0/6 (0%)
INT SACRIFICE 2	0/1 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	85(l)
STATISTICAL TESTS		
POLY 3	P=0.761	P=0.761
POLY 1.5	P=0.754	P=0.754
POLY 6	P=0.766	P=0.766
COCH-ARM / FISHERS	P=0.733	P=0.762
MAX-ISO-POLY-3	P=0.362	P=0.362
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	VEHICLE CONTROL	EGCG 200MG/KG	MALE
Kidney: Medulla, Renal Tubule			
Regeneration Focal			
LESION RATES			
OVERALL(a)	0/10 (0%)	1/32 (3%)	
POLY-3 RATE (b)	0/5.05	1/21.56	
POLY-3 PERCENT (g)	0%	4.6%	
INT SACRIFICE 1	0/4 (0%)	1/6 (17%)	
INT SACRIFICE 2	0/1 (0%)	0/6 (0%)	
TERMINAL (d)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	---	33(l)	
STATISTICAL TESTS			
POLY 3	P=0.765	P=0.765	
POLY 1.5	P=0.757	P=0.757	
POLY 6	P=0.770	P=0.770	
COCH-ARM / FISHERS	P=0.733	P=0.762	
MAX-ISO-POLY-3	P=0.367	P=0.367	
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(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Liver		
Inflammation Focal		
LESION RATES		
OVERALL(a)	3/10 (30%)	8/32 (25%)
POLY-3 RATE (b)	3/7.68	8/23.45
POLY-3 PERCENT (g)	39.1%	34.1%
INT SACRIFICE 1	2/4 (50%)	1/6 (17%)
INT SACRIFICE 2	1/1 (100%)	2/6 (33%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	32(l)	33(l)
STATISTICAL TESTS		
POLY 3	P=0.574N	P=0.574N
POLY 1.5	P=0.557N	P=0.557N
POLY 6	P=0.589N	P=0.589N
COCH-ARM / FISHERS	P=0.539N	P=0.524N
MAX-ISO-POLY-3	P=0.418N	P=0.418N
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	EGCG 200MG/KG
Liver		
Tension Lipidosis		
LESION RATES		
OVERALL(a)	0/10 (0%)	2/32 (6%)
POLY-3 RATE (b)	0/5.05	2/20.71
POLY-3 PERCENT (g)	0%	9.7%
INT SACRIFICE 1	0/4 (0%)	0/6 (0%)
INT SACRIFICE 2	0/1 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	87(l)
STATISTICAL TESTS		
POLY 3	P=0.573	P=0.573
POLY 1.5	P=0.559	P=0.559
POLY 6	P=0.580	P=0.580
COCH-ARM / FISHERS	P=0.516	P=0.576
MAX-ISO-POLY-3	P=0.304	P=0.304
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(TRAMP)
LAST REMOVAL AT 13 WEEKS

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Prostate, Anterior Lobe		
Hyperplasia Grade 3 Focal		
LESION RATES		
OVERALL(a)	9/10 (90%)	29/32 (91%)
POLY-3 RATE (b)	9/9.87	29/31.80
POLY-3 PERCENT (g)	91.2%	91.2%
INT SACRIFICE 1	4/4 (100%)	6/6 (100%)
INT SACRIFICE 2	1/1 (100%)	6/6 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	32(l)	32(l)
STATISTICAL TESTS		
POLY 3	P=0.742	P=0.742
POLY 1.5	P=0.725	P=0.725
POLY 6	P=0.741N	P=0.741N
COCH-ARM / FISHERS	P=0.712	P=0.679
MAX-ISO-POLY-3	P=0.500	P=0.500
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	EGCG 200MG/KG	
Prostate, Anterior Lobe			
Hyperplasia Grade 4 Focal			
LESION RATES			
OVERALL(a)	0/10 (0%)	3/32 (9%)	
POLY-3 RATE (b)	0/5.05	3/20.80	
POLY-3 PERCENT (g)	0%	14.4%	
INT SACRIFICE 1	0/4 (0%)	0/6 (0%)	
INT SACRIFICE 2	0/1 (0%)	0/6 (0%)	
TERMINAL (d)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	---	86(l)	
STATISTICAL TESTS			
POLY 3	P=0.451	P=0.451	
POLY 1.5	P=0.434	P=0.434	
POLY 6	P=0.461	P=0.461	
COCH-ARM / FISHERS	P=0.382	P=0.432	
MAX-ISO-POLY-3	P=0.260	P=0.260	
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	EGCG 200MG/KG
Prostate, Anterior Lobe		
Hyperplasia Grade 5 Focal		
LESION RATES		
OVERALL(a)	1/10 (10%)	0/32 (0%)
POLY-3 RATE (b)	1/5.18	0/20.61
POLY-3 PERCENT (g)	19.3%	0%
INT SACRIFICE 1	0/4 (0%)	0/6 (0%)
INT SACRIFICE 2	0/1 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	85(l)	---
STATISTICAL TESTS		
POLY 3	P=0.232N	P=0.232N
POLY 1.5	P=0.239N	P=0.239N
POLY 6	P=0.232N	P=0.232N
COCH-ARM / FISHERS	P=0.267N	P=0.238N
MAX-ISO-POLY-3	P=0.065N	P=0.065N
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	EGCG 200MG/KG
Prostate, Dorsal Lobe		
Hyperplasia Grade 3 Diffuse		
LESION RATES		
OVERALL(a)	4/9 (44%)	1/32 (3%)
POLY-3 RATE (b)	4/6.87	1/20.64
POLY-3 PERCENT (g)	58.2%	4.8%
INT SACRIFICE 1	1/3 (33%)	0/6 (0%)
INT SACRIFICE 2	1/1 (100%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	32(l)	88(l)
STATISTICAL TESTS		
POLY 3	P=0.001N**	P=0.001N**
POLY 1.5	P=0.001N**	P=0.001N**
POLY 6	P=0.001N**	P=0.001N**
COCH-ARM / FISHERS	P=0.003N**	P=0.006N**
MAX-ISO-POLY-3	P=0.001N**	P=0.001N**
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	VEHICLE CONTROL	EGCG 200MG/KG
MALE		
Prostate, Dorsal Lobe		
Hyperplasia Grade 3 Focal		
LESION RATES		
OVERALL(a)	2/9 (22%)	12/32 (38%)
POLY-3 RATE (b)	2/6.90	12/28.76
POLY-3 PERCENT (g)	29%	41.7%
INT SACRIFICE 1	2/3 (67%)	6/6 (100%)
INT SACRIFICE 2	0/1 (0%)	3/6 (50%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	32(l)	32(l)
STATISTICAL TESTS		
POLY 3	P=0.431	P=0.431
POLY 1.5	P=0.402	P=0.402
POLY 6	P=0.458	P=0.458
COCH-ARM / FISHERS	P=0.324	P=0.333
MAX-ISO-POLY-3	P=0.324	P=0.324
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	EGCG 200MG/KG
Prostate, Dorsal Lobe		
Hyperplasia Grade 4 Focal		
LESION RATES		
OVERALL(a)	3/9 (33%)	16/32 (50%)
POLY-3 RATE (b)	3/5.23	16/23.55
POLY-3 PERCENT (g)	57.4%	67.9%
INT SACRIFICE 1	0/3 (0%)	0/6 (0%)
INT SACRIFICE 2	0/1 (0%)	3/6 (50%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	85(l)	57(l)
STATISTICAL TESTS		
POLY 3	P=0.520	P=0.520
POLY 1.5	P=0.446	P=0.446
POLY 6	P=0.571	P=0.571
COCH-ARM / FISHERS	P=0.306	P=0.308
MAX-ISO-POLY-3	P=0.366	P=0.366
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

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Species/Strain: Mouse/TRAMP

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate
CAS Number: 989-51-5

Date Report Requested: 10/23/2014
Time Report Requested: 09:15:25
First Dose M/F: NA / NA
Lab: ILS

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

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Prostate, Dorsal Lobe		
Hyperplasia Grade 5 Focal		
LESION RATES		
OVERALL(a)	0/9 (0%)	3/32 (9%)
POLY-3 RATE (b)	0/5.00	3/20.87
POLY-3 PERCENT (g)	0%	14.4%
INT SACRIFICE 1	0/3 (0%)	0/6 (0%)
INT SACRIFICE 2	0/1 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	85(l)
STATISTICAL TESTS		
POLY 3	P=0.453	P=0.453
POLY 1.5	P=0.443	P=0.443
POLY 6	P=0.461	P=0.461
COCH-ARM / FISHERS	P=0.409	P=0.465
MAX-ISO-POLY-3	P=0.254	P=0.254
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

Experiment Number: 20108-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/TRAMP

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate
 CAS Number: 989-51-5

Date Report Requested: 10/23/2014
 Time Report Requested: 09:15:25
 First Dose M/F: NA / NA
 Lab: ILS

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

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Prostate, Lateral Lobe		
Hyperplasia Grade 3 Diffuse		
LESION RATES		
OVERALL(a)	2/6 (33%)	11/31 (35%)
POLY-3 RATE (b)	2/3.25	11/22.67
POLY-3 PERCENT (g)	61.5%	48.5%
INT SACRIFICE 1	0/2 (0%)	2/6 (33%)
INT SACRIFICE 2	0/1 (0%)	1/6 (17%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	85(l)	32(l)
STATISTICAL TESTS		
POLY 3	P=0.555N	P=0.555N
POLY 1.5	P=0.603N	P=0.603N
POLY 6	P=0.531N	P=0.531N
COCH-ARM / FISHERS	P=0.643	P=0.704N
MAX-ISO-POLY-3	P=0.382N	P=0.382N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

Experiment Number: 20108-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/TRAMP

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate
CAS Number: 989-51-5

Date Report Requested: 10/23/2014
Time Report Requested: 09:15:25
First Dose M/F: NA / NA
Lab: ILS

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

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Prostate, Lateral Lobe		
Hyperplasia Grade 3 Focal		
LESION RATES		
OVERALL(a)	4/6 (67%)	19/31 (61%)
POLY-3 RATE (b)	4/5.81	19/27.94
POLY-3 PERCENT (g)	68.8%	68%
INT SACRIFICE 1	2/2 (100%)	4/6 (67%)
INT SACRIFICE 2	1/1 (100%)	5/6 (83%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	32(l)	32(l)
STATISTICAL TESTS		
POLY 3	P=0.677N	P=0.677N
POLY 1.5	P=0.658N	P=0.658N
POLY 6	P=0.676N	P=0.676N
COCH-ARM / FISHERS	P=0.584N	P=0.593N
MAX-ISO-POLY-3	P=0.487N	P=0.487N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

Experiment Number: 20108-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/TRAMP

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate
CAS Number: 989-51-5

Date Report Requested: 10/23/2014
Time Report Requested: 09:15:25
First Dose M/F: NA / NA
Lab: ILS

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

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Prostate, Lateral Lobe		
Hyperplasia Grade 4 Focal		
LESION RATES		
OVERALL(a)	0/6 (0%)	1/31 (3%)
POLY-3 RATE (b)	0/3.05	1/19.74
POLY-3 PERCENT (g)	0%	5.1%
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	---	87(l)
STATISTICAL TESTS		
POLY 3	P=0.839	P=0.839
POLY 1.5	P=0.833	P=0.833
POLY 6	P=0.845	P=0.845
COCH-ARM / FISHERS	P=0.824	P=0.838
MAX-ISO-POLY-3	P=0.393	P=0.393
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

Experiment Number: 20108-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/TRAMP

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate
CAS Number: 989-51-5

Date Report Requested: 10/23/2014
Time Report Requested: 09:15:25
First Dose M/F: NA / NA
Lab: ILS

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

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Prostate, Ventral Lobe		
Hyperplasia Grade 2 Diffuse		
LESION RATES		
OVERALL(a)	1/8 (12%)	0/23 (0%)
POLY-3 RATE (b)	1/4.16	0/12.16
POLY-3 PERCENT (g)	24%	0%
INT SACRIFICE 1	1/4 (25%)	0/6 (0%)
INT SACRIFICE 2	0/1 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	33(l)	---
STATISTICAL TESTS		
POLY 3	P=0.277N	P=0.277N
POLY 1.5	P=0.275N	P=0.275N
POLY 6	P=0.283N	P=0.283N
COCH-ARM / FISHERS	P=0.287N	P=0.258N
MAX-ISO-POLY-3	P=0.071N	P=0.071N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

Experiment Number: 20108-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/TRAMP

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate
CAS Number: 989-51-5

Date Report Requested: 10/23/2014
Time Report Requested: 09:15:25
First Dose M/F: NA / NA
Lab: ILS

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

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Prostate, Ventral Lobe		
Hyperplasia Grade 2 Focal		
LESION RATES		
OVERALL(a)	0/8 (0%)	3/23 (13%)
POLY-3 RATE (b)	0/3.21	3/13.18
POLY-3 PERCENT (g)	0%	22.8%
INT SACRIFICE 1	0/4 (0%)	1/6 (17%)
INT SACRIFICE 2	0/1 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	32(l)
STATISTICAL TESTS		
POLY 3	P=0.449	P=0.449
POLY 1.5	P=0.423	P=0.423
POLY 6	P=0.460	P=0.460
COCH-ARM / FISHERS	P=0.352	P=0.394
MAX-ISO-POLY-3	P=0.258	P=0.258
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

Experiment Number: 20108-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/TRAMP

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate
CAS Number: 989-51-5

Date Report Requested: 10/23/2014
Time Report Requested: 09:15:25
First Dose M/F: NA / NA
Lab: ILS

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

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Prostate, Ventral Lobe		
Hyperplasia Grade 3 Diffuse		
LESION RATES		
OVERALL(a)	1/8 (12%)	0/23 (0%)
POLY-3 RATE (b)	1/3.21	0/12.16
POLY-3 PERCENT (g)	31.2%	0%
INT SACRIFICE 1	0/4 (0%)	0/6 (0%)
INT SACRIFICE 2	0/1 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	89(T)(l)	---
STATISTICAL TESTS		
POLY 3	P=0.240N	P=0.240N
POLY 1.5	P=0.251N	P=0.251N
POLY 6	P=0.236N	P=0.236N
COCH-ARM / FISHERS	P=0.287N	P=0.258N
MAX-ISO-POLY-3	P=0.069N	P=0.069N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

Experiment Number: 20108-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/TRAMP

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate
CAS Number: 989-51-5

Date Report Requested: 10/23/2014
Time Report Requested: 09:15:25
First Dose M/F: NA / NA
Lab: ILS

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

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Prostate, Ventral Lobe		
Hyperplasia Grade 3 Focal		
LESION RATES		
OVERALL(a)	6/8 (75%)	20/23 (87%)
POLY-3 RATE (b)	6/7.05	20/21.98
POLY-3 PERCENT (g)	85.1%	91%
INT SACRIFICE 1	3/4 (75%)	5/6 (83%)
INT SACRIFICE 2	1/1 (100%)	6/6 (100%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	32(l)	32(l)
STATISTICAL TESTS		
POLY 3	P=0.601	P=0.601
POLY 1.5	P=0.560	P=0.560
POLY 6	P=0.608	P=0.608
COCH-ARM / FISHERS	P=0.407	P=0.385
MAX-ISO-POLY-3	P=0.364	P=0.364
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

Experiment Number: 20108-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/TRAMP

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate
CAS Number: 989-51-5

Date Report Requested: 10/23/2014
Time Report Requested: 09:15:25
First Dose M/F: NA / NA
Lab: ILS

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

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Seminal Vesicle		
Hyperplasia		
LESION RATES		
OVERALL(a)	3/10 (30%)	4/32 (12%)
POLY-3 RATE (b)	3/5.31	4/20.93
POLY-3 PERCENT (g)	56.5%	19.1%
INT SACRIFICE 1	0/4 (0%)	0/6 (0%)
INT SACRIFICE 2	0/1 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	85(l)	85(l)
STATISTICAL TESTS		
POLY 3	P=0.124N	P=0.124N
POLY 1.5	P=0.141N	P=0.141N
POLY 6	P=0.121N	P=0.121N
COCH-ARM / FISHERS	P=0.209N	P=0.203N
MAX-ISO-POLY-3	P=0.096N	P=0.096N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

Experiment Number: 20108-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/TRAMP

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate
CAS Number: 989-51-5

Date Report Requested: 10/23/2014
Time Report Requested: 09:15:25
First Dose M/F: NA / NA
Lab: ILS

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

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Seminal Vesicle		
Hyperplasia Grade 1 Focal		
LESION RATES		
OVERALL(a)	1/10 (10%)	0/32 (0%)
POLY-3 RATE (b)	1/6.00	0/20.61
POLY-3 PERCENT (g)	16.7%	0%
INT SACRIFICE 1	1/4 (25%)	0/6 (0%)
INT SACRIFICE 2	0/1 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	33(l)	---
STATISTICAL TESTS		
POLY 3	P=0.251N	P=0.251N
POLY 1.5	P=0.253N	P=0.253N
POLY 6	P=0.252N	P=0.252N
COCH-ARM / FISHERS	P=0.267N	P=0.238N
MAX-ISO-POLY-3	P=0.066N	P=0.066N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

Experiment Number: 20108-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/TRAMP

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate
 CAS Number: 989-51-5

Date Report Requested: 10/23/2014
 Time Report Requested: 09:15:25
 First Dose M/F: NA / NA
 Lab: ILS

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

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Seminal Vesicle		
Hyperplasia Grade 2 Focal		
LESION RATES		
OVERALL(a)	3/10 (30%)	7/32 (22%)
POLY-3 RATE (b)	3/6.00	7/22.08
POLY-3 PERCENT (g)	50%	31.7%
INT SACRIFICE 1	0/4 (0%)	1/6 (17%)
INT SACRIFICE 2	1/1 (100%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	58(l)	33(l)
STATISTICAL TESTS		
POLY 3	P=0.368N	P=0.368N
POLY 1.5	P=0.375N	P=0.375N
POLY 6	P=0.388N	P=0.388N
COCH-ARM / FISHERS	P=0.460N	P=0.444N
MAX-ISO-POLY-3	P=0.264N	P=0.264N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

Experiment Number: 20108-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/TRAMP

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate
 CAS Number: 989-51-5

Date Report Requested: 10/23/2014
 Time Report Requested: 09:15:25
 First Dose M/F: NA / NA
 Lab: ILS

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

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Seminal Vesicle		
Hyperplasia Grade 3 Focal		
LESION RATES		
OVERALL(a)	0/10 (0%)	4/32 (12%)
POLY-3 RATE (b)	0/5.05	4/22.23
POLY-3 PERCENT (g)	0%	18%
INT SACRIFICE 1	0/4 (0%)	0/6 (0%)
INT SACRIFICE 2	0/1 (0%)	2/6 (33%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	57(l)
STATISTICAL TESTS		
POLY 3	P=0.381	P=0.381
POLY 1.5	P=0.355	P=0.355
POLY 6	P=0.399	P=0.399
COCH-ARM / FISHERS	P=0.288	P=0.321
MAX-ISO-POLY-3	P=0.239	P=0.239
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

Experiment Number: 20108-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/TRAMP

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate
CAS Number: 989-51-5

Date Report Requested: 10/23/2014
Time Report Requested: 09:15:25
First Dose M/F: NA / NA
Lab: ILS

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

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Spleen		
Hematopoietic Cell Proliferation		
LESION RATES		
OVERALL(a)	1/10 (10%)	0/31 (0%)
POLY-3 RATE (b)	1/5.18	0/20.34
POLY-3 PERCENT (g)	19.3%	0%
INT SACRIFICE 1	0/4 (0%)	0/6 (0%)
INT SACRIFICE 2	0/1 (0%)	0/5 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	85(l)	---
STATISTICAL TESTS		
POLY 3	P=0.236N	P=0.236N
POLY 1.5	P=0.243N	P=0.243N
POLY 6	P=0.235N	P=0.235N
COCH-ARM / FISHERS	P=0.273N	P=0.244N
MAX-ISO-POLY-3	P=0.068N	P=0.068N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

Experiment Number: 20108-04
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: Mouse/TRAMP

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate
CAS Number: 989-51-5

Date Report Requested: 10/23/2014
Time Report Requested: 09:15:25
First Dose M/F: NA / NA
Lab: ILS

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

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Testes: Germinal Epith		
Syncytial Alteration		
LESION RATES		
OVERALL(a)	0/10 (0%)	2/32 (6%)
POLY-3 RATE (b)	0/5.05	2/20.77
POLY-3 PERCENT (g)	0%	9.6%
INT SACRIFICE 1	0/4 (0%)	0/6 (0%)
INT SACRIFICE 2	0/1 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	86(l)
STATISTICAL TESTS		
POLY 3	P=0.573	P=0.573
POLY 1.5	P=0.559	P=0.559
POLY 6	P=0.581	P=0.581
COCH-ARM / FISHERS	P=0.516	P=0.576
MAX-ISO-POLY-3	P=0.304	P=0.304
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

Experiment Number: 20108-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/TRAMP

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate
CAS Number: 989-51-5

Date Report Requested: 10/23/2014
Time Report Requested: 09:15:25
First Dose M/F: NA / NA
Lab: ILS

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

MALE		
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
Testes: Seminif Tub		
Atrophy		
LESION RATES		
OVERALL(a)	1/10 (10%)	2/32 (6%)
POLY-3 RATE (b)	1/6.00	2/20.67
POLY-3 PERCENT (g)	16.7%	9.7%
INT SACRIFICE 1	1/4 (25%)	0/6 (0%)
INT SACRIFICE 2	0/1 (0%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	32(l)	87(l)
STATISTICAL TESTS		
POLY 3	P=0.598N	P=0.598N
POLY 1.5	P=0.600N	P=0.600N
POLY 6	P=0.601N	P=0.601N
COCH-ARM / FISHERS	P=0.618N	P=0.568N
MAX-ISO-POLY-3	P=0.357N	P=0.357N
HISTCONT SAME RTE		
HISTCONT ALL RTES		
CURR VS HC SAME RTE		
CURR VS HC ALL RTES		

Experiment Number: 20108-04
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Mouse/TRAMP

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate
CAS Number: 989-51-5

Date Report Requested: 10/23/2014
Time Report Requested: 09:15:25
First Dose M/F: NA / NA
Lab: ILS

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 ****