#### P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS

Test Compound: Antioxidant model (TRAMP) - Epigallocatechin gallate CAS Number: 989-51-5 Date Report Requested: 10/23/2014 Time Report Requested: 09:15:28 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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# FOR ALL DOSES THE TUMOR RATES IN THE FOLLOWING TISSUES/ORGANS ARE BASED ON NUMBER OF TISSUES IN OTHER TISSUES/ORGANS RATES ARE BASED ON THE NUMBER OF ANIMALS NECROPSIED.

Prostate

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## SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF ANTIOXIDANT MODEL (TRAMP) -

MALE MOUSE

Organ All Organs Morphology Malignant and Benign Tumors Malignant Tumors

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			MALE	
DOSE	VEHICLE CONTROL	EGCG 200MG/KG		
Prostate				
Carcinoma				
TUMOR RATES				
OVERALL(a)	2/2 (100%)	0/0 (0%)		
POLY-3 RATE (b)	2/2.00	0/0.00		
POLY-3 PERCENT (g)	100%	0%		
INT SACRIFICE 1	1/1 (100%)	0/0 (0%)		
INT SACRIFICE 2	0/0 (0%)	0/0 (0%)		
TERMINAL (d)	0/0 (0%)	0/0 (0%)		
FIRST INCIDENCE	32(I)			
HC TUMORS SAME ROUTE	0/0(0%)			
HC TUMORS ALL ROUTES	0/0(0%)			
STATISTICAL TESTS				
POLY 3	(e)	(e)		
POLY 1.5	(e)	(e)		
POLY 6	(e)	(e)		
COCH-ARM / FISHERS	(e)	(e)		
MAX-ISO-POLY-3	(e)	(e)		
HISTCONT SAME RTE				
HISTCONT ALL RTES				
CURR VS HC SAME RTE				
CURR VS HC ALL RTES				

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		MALE
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
All Organs		
Benign Tumors		
TUMOR RATES	#	#
OVERALL(a)	0/10 (0%)	0/32 (0%)
POLY-3 RATE (b)	0/5.05	0/20.61
POLY-3 PERCENT (g)	0%	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		
HC TUMORS SAME ROUTE	0/0(0%)	
HC TUMORS ALL ROUTES	0/0(0%)	
STATISTICAL TESTS		
POLY 3	(n)	(n)
POLY 1.5	(n)	(n)
POLY 6	(n)	(n)
COCH-ARM / FISHERS	(n)	(n)
MAX-ISO-POLY-3	(n)	(n)
HISTCONT SAME RTE	(n)	(n)
HISTCONT ALL RTES	(n)	(n)
CURR VS HC SAME RTE	(n)	
CURR VS HC ALL RTES	(n)	

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		MALE
DOSE	VEHICLE CONTROL	EGCG 200MG/KG
All Organs		
Malignant Tumors		
TUMOR RATES	#	#
OVERALL(a)	4/10 (40%)	1/32 (3%)
POLY-3 RATE (b)	4/6.89	1/20.74
POLY-3 PERCENT (g)	58.1%	4.8%
INT SACRIFICE 1	1/4 (25%)	0/6 (0%)
INT SACRIFICE 2	1/1 (100%)	0/6 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	32(I)	85(I)
HC TUMORS SAME ROUTE	0/0(0%)	
HC TUMORS ALL ROUTES	0/0(0%)	
STATISTICAL TESTS		
POLY 3	P=0.001N**	P=0.001N**
POLY 1.5	P=0.001N**	P=0.001N**
POLY 6	P=0.002N**	P=0.002N**
COCH-ARM / FISHERS	P=0.005N**	P=0.008N**
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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MALE				
DOSE	VEHICLE CONTROL	EGCG 200MG/KG	 	
All Organs				
Malignant and Benign Tumors				
TUMOR RATES	#	#		
OVERALL(a)	4/10 (40%)	1/32 (3%)		
POLY-3 RATE (b)	4/6.89	1/20.74		
POLY-3 PERCENT (g)	58.1%	4.8%		
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HC TUMORS SAME ROUTE	0/0(0%)			
HC TUMORS ALL ROUTES	0/0(0%)			
STATISTICAL TESTS				
POLY 3	P=0.001N**	P=0.001N**		
POLY 1.5	P=0.001N**	P=0.001N**		
POLY 6	P=0.002N**	P=0.002N**		
COCH-ARM / FISHERS	P=0.005N**	P=0.008N**		
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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## 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<=0.05).
**	To the right of any statistical result, indicates significance at (P<=0.01).
Ν	Indicates a negative trend for all tests

The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

## \*\* END OF REPORT \*\*