

**Experiment Number:** 20305-01  
**Test Type:** 18-33 DAYS  
**Route:** INTRADUCTAL CANNULATION  
**Species/Strain:** Mouse/BALB/C

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)**

**Test Compound:** Adeno-associated viral vector (hEPO)

**CAS Number:** HEPO

**Date Report Requested:** 10/23/2014

**Time Report Requested:** 09:05:29

**First Dose M/F:** NA / NA

**Lab:** MBA

<b>C Number:</b>	C20305
<b>Lock Date:</b>	08/29/2005
<b>Cage Range:</b>	All
<b>Date Range:</b>	All
<b>Reasons For Removal:</b>	All
<b>Removal Date Range:</b>	All
<b>Treatment Groups:</b>	All
<b>Study Gender:</b>	Both
<b>PWG Approval Date</b>	NONE

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BALB/C Mouse MALE	ISORMCONSALINE	TRTRMCONSALINE	1-7	SALINE	1-8	SALINE	1-9	SALINE	1-10	SALINE
<b>Disposition Summary</b>										
Animals Initially In Study	21	12		21		21		21		21
Scheduled Sacrifice	13	9		11		13		13		11
Early Deaths										
Natural Death	3			4		2		3		4
Survivors										
Natural Death	1	1								
Terminal Sacrifice	4	2		6		6		5		6
Animals Examined Microscopically	21	12		21		21		21		21
<b>ALIMENTARY SYSTEM</b>										
Esophagus	(19)	(12)		(20)		(20)		(20)		(21)
Gallbladder	(19)	(10)		(19)		(19)		(20)		(21)
Intestine Large, Cecum	(21)	(12)		(21)		(21)		(20)		(20)
Intestine Large, Colon	(20)	(12)		(21)		(21)		(20)		(20)
Intestine Large, Rectum	(20)	(12)		(21)		(21)		(20)		(20)
Intestine Small, Duodenum	(20)	(12)		(21)		(21)		(20)		(21)
Intestine Small, Ileum	(20)	(12)		(21)		(21)		(20)		(20)
Intestine Small, Jejunum	(20)	(12)		(21)		(21)		(21)		(21)
Liver	(21)	(12)		(21)		(21)		(21)		(21)
Hematopoietic Cell Proliferation										1 (5%)
Hepatocyte, Necrosis						1 (5%)				
Hepatocyte, Vacuolization Cytoplasmic	3 (14%)	4 (33%)		3 (14%)		3 (14%)		6 (29%)		2 (10%)
Inflammation, Chronic Active				1 (5%)						
Necrosis, Focal								1 (5%)		
Pancreas	(21)	(12)		(21)		(21)		(21)		(21)
Salivary Glands	(21)	(12)		(21)		(21)		(21)		(21)
Left, Parotid GI, Vacuolization Cytoplasmic		1 (8%)		1 (5%)		1 (5%)		1 (5%)		3 (14%)
Left, Sublingual GI, Inflammation						1 (5%)				
Left, Submandibular GI, Inflammation						1 (5%)				

a - Number of animals examined microscopically at site and number of animals with lesion

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Lab: MBA

BALB/C Mouse MALE	ISORMCONSALINE	TRTRMCONSALINE	1-7 SALINE	1-8 SALINE	1-9 SALINE	1-10 SALINE
Left, Submandibul GI, Regeneration					1 (5%)	
Parotid GI, Right, Inflammation				2 (10%)		1 (5%)
Parotid GI, Right, Vacuolization Cytoplasmic	1 (5%)	1 (8%)		1 (5%)		1 (5%)
Right, Submandibul GI, Degeneration		1 (8%)	1 (5%)	2 (10%)		2 (10%)
Right, Submandibul GI, Inflammation		1 (8%)	4 (19%)	2 (10%)		2 (10%)
Right, Submandibul GI, Necrosis		1 (8%)		2 (10%)		2 (10%)
Right, Submandibul GI, Regeneration		2 (17%)	3 (14%)			1 (5%)
Stomach, Forestomach	(21)	(12)	(21)	(21)	(21)	(21)
Stomach, Glandular	(21)	(12)	(21)	(21)	(21)	(21)
<b>CARDIOVASCULAR SYSTEM</b>						
Blood Vessel	(21)	(12)	(21)	(21)	(21)	(20)
Hemorrhage					1 (5%)	
Heart	(21)	(12)	(21)	(21)	(21)	(21)
Artery, Inflammation, Chronic Active				1 (5%)		1 (5%)
Mineralization	4 (19%)		9 (43%)	4 (19%)	3 (14%)	10 (48%)
Ventricle, Thrombosis, Focal				1 (5%)		
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(21)	(11)	(21)	(21)	(20)	(21)
Subcapsular, Hyperplasia, Focal	1 (5%)		2 (10%)	2 (10%)	3 (15%)	1 (5%)
Adrenal Medulla	(21)	(11)	(21)	(19)	(20)	(19)
Islets, Pancreatic	(20)	(12)	(21)	(20)	(21)	(20)
Parathyroid Gland	(11)	(4)	(11)	(11)	(13)	(16)
Pituitary Gland	(17)	(10)	(16)	(19)	(19)	(16)
Thyroid Gland	(20)	(11)	(21)	(21)	(21)	(21)
Follicle, Cyst					1 (5%)	
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						

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Lab: MBA

BALB/C Mouse MALE	ISORMCONSALINE	TRTRMCONSALINE	1-7 SALINE	1-8 SALINE	1-9 SALINE	1-10 SALINE
Epididymis	(21)	(12)	(21)	(21)	(21)	(20)
Penis	(1)	(0)	(0)	(0)	(0)	(0)
Preputial Gland	(21)	(11)	(21)	(21)	(20)	(21)
Inflammation, Chronic Active, Focal			1 (5%)		2 (10%)	
Prostate	(21)	(12)	(20)	(21)	(20)	(18)
Inflammation, Chronic Active, Focal	1 (5%)					
Seminal Vesicle	(21)	(12)	(21)	(21)	(21)	(21)
Testes	(21)	(12)	(21)	(19)	(20)	(18)
Germinal Epith, Degeneration, Focal				1 (5%)		
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(21)	(12)	(21)	(21)	(21)	(21)
Myeloid Cell, Hyperplasia						1 (5%)
Lymph Node, Mandibular	(17)	(11)	(14)	(15)	(19)	(10)
Left, Necrosis, Lymphocyte						1 (10%)
Right, Hyperplasia, Lymphoid		1 (9%)		1 (7%)		2 (20%)
Right, Necrosis, Lymphocyte						1 (10%)
Lymph Node, Mesenteric	(20)	(12)	(19)	(21)	(19)	(17)
Hyperplasia, Lymphoid	1 (5%)				1 (5%)	
Necrosis, Lymphocyte						1 (6%)
Spleen	(20)	(11)	(21)	(20)	(20)	(21)
Congestion, Diffuse			1 (5%)			
Hematopoietic Cell Proliferation	20 (100%)	11 (100%)	21 (100%)	20 (100%)	20 (100%)	21 (100%)
Thymus	(20)	(12)	(21)	(21)	(20)	(20)
Atrophy				2 (10%)	2 (10%)	
<b>INTEGUMENTARY SYSTEM</b>						
Skin	(21)	(12)	(21)	(21)	(21)	(21)
Dermis, Epidermis, Subcut Tiss, Inflammation, Acute, Focal						1 (5%)
Epidermis, Ulcer, Focal Inflammation			1 (5%)		1 (5%)	

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**Lab:** MBA

BALB/C Mouse MALE	ISORMCONSALINE	TRTRMCONSALINE	1-7 SALINE	1-8 SALINE	1-9 SALINE	1-10 SALINE
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(21)	(12)	(21)	(20)	(21)	(21)
Hyperplasia						1 (5%)
Skeletal Muscle	(0)	(0)	(1)	(0)	(0)	(0)
Hemorrhage, Focal			1 (100%)			
Inflammation, Acute, Focal			1 (100%)			
<b>NERVOUS SYSTEM</b>						
Brain	(21)	(12)	(21)	(21)	(21)	(21)
<b>RESPIRATORY SYSTEM</b>						
Lung	(21)	(12)	(21)	(21)	(21)	(21)
Alveolar Epith, Hyperplasia			1 (5%)	1 (5%)		
Alveolus, Inflammation, Acute, Focal	1 (5%)		1 (5%)			
Nose	(20)	(12)	(21)	(21)	(21)	(21)
Inflammation, Acute				2 (10%)	1 (5%)	1 (5%)
Trachea	(14)	(11)	(13)	(17)	(15)	(18)
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(21)	(11)	(21)	(21)	(19)	(21)
Harderian Gland	(20)	(12)	(21)	(21)	(21)	(21)
Degeneration						1 (5%)
Inflammation						1 (5%)
<b>URINARY SYSTEM</b>						
Kidney	(21)	(12)	(21)	(21)	(21)	(21)
Bilateral, Renal Tubule, Dilatation					1 (5%)	
Cyst					1 (5%)	
Nephropathy					1 (5%)	
Renal Tubule, Casts Protein						1 (5%)
Right, Infarct, Multiple					1 (5%)	
Urinary Bladder	(19)	(12)	(20)	(21)	(19)	(20)

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**BALB/C Mouse MALE**

**ISORMCONSALINE**

**TRTRMCONSALINE**

**1-7 SALINE**

**1-8 SALINE**

**1-9 SALINE**

**1-10 SALINE**

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\*\*\*END OF MALE DATA\*\*\*

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BALB/C Mouse FEMALE	ISORMCONSALINE	TRTRMCONSALINE	1-7	SALINE	1-8	SALINE	1-9	SALINE	1-10	SALINE
<b>Disposition Summary</b>										
Animals Initially In Study	21	12		21		21		21		21
Scheduled Sacrifice	15	9		13		15		14		15
Early Deaths										
Natural Death				2				1		2
Survivors										
Terminal Sacrifice	6	3		6		6		6		4
Animals Examined Microscopically	21	12		21		21		21		21
<b>ALIMENTARY SYSTEM</b>										
Esophagus	(21)	(12)		(20)		(21)		(21)		(21)
Gallbladder	(20)	(12)		(21)		(21)		(20)		(20)
Intestine Large, Cecum	(21)	(12)		(21)		(21)		(21)		(20)
Intestine Large, Colon	(21)	(12)		(21)		(21)		(21)		(20)
Intestine Large, Rectum	(21)	(12)		(21)		(21)		(21)		(20)
Intestine Small, Duodenum	(21)	(12)		(21)		(21)		(21)		(19)
Intestine Small, Ileum	(21)	(12)		(21)		(21)		(21)		(19)
Intestine Small, Jejunum	(21)	(12)		(21)		(21)		(21)		(19)
Liver	(21)	(12)		(21)		(21)		(21)		(21)
Bile Duct, Concretion										1 (5%)
Clear Cell Focus										1 (5%)
Hematocyst										1 (5%)
Inflammation, Chronic Active	1 (5%)			1 (5%)		2 (10%)		1 (5%)		
Necrosis, Focal						1 (5%)				
Pancreas	(21)	(12)		(21)		(21)		(21)		(21)
Salivary Glands	(21)	(12)		(21)		(21)		(21)		(21)
Left, Parotid GI, Vacuolization Cytoplasmic										1 (5%)
Left, Submandibul GI, Inflammation	1 (5%)									
Left, Submandibul GI, Inflammation, Chronic										1 (8%)
Parotid GI, Right, Inflammation								1 (5%)		

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BALB/C Mouse FEMALE	ISORMCONSALINE	TRTRMCONSALINE	1-7	SALINE	1-8	SALINE	1-9	SALINE	1-10	SALINE
Parotid GI, Right, Vacuolization Cytoplasmic	1 (5%)									
Right, Submandibul GI, Degeneration	3 (14%)				1 (5%)		1 (5%)			
Right, Submandibul GI, Inflammation	3 (14%)	1 (8%)			3 (14%)		2 (10%)		1 (5%)	
Right, Submandibul GI, Inflammation, Chronic		1 (8%)								
Right, Submandibul GI, Necrosis	2 (10%)				1 (5%)		1 (5%)			
Right, Submandibul GI, Regeneration					1 (5%)		1 (5%)			
Stomach, Forestomach	(21)	(12)		(21)	(21)		(21)		(21)	
Stomach, Glandular	(21)	(12)		(21)	(21)		(21)		(21)	
Tooth	(0)	(0)		(0)	(0)		(0)		(1)	
Peridont Tiss, Inflammation, Acute, Focal									1 (100%)	
CARDIOVASCULAR SYSTEM										
Blood Vessel	(21)	(12)		(20)	(21)		(21)		(21)	
Heart	(20)	(12)		(21)	(21)		(21)		(21)	
Mineralization	1 (5%)	4 (33%)		4 (19%)	3 (14%)		8 (38%)		2 (10%)	
Valve, Thrombosis									1 (5%)	
ENDOCRINE SYSTEM										
Adrenal Cortex	(21)	(12)		(21)	(21)		(20)		(21)	
Subcapsular, Hyperplasia, Focal	5 (24%)	5 (42%)		5 (24%)	5 (24%)		7 (35%)		4 (19%)	
Adrenal Medulla	(21)	(11)		(20)	(21)		(20)		(21)	
Islets, Pancreatic	(21)	(12)		(21)	(21)		(20)		(21)	
Parathyroid Gland	(18)	(9)		(13)	(14)		(12)		(17)	
Angiectasis									1 (6%)	
Pituitary Gland	(19)	(10)		(19)	(21)		(17)		(15)	
Thyroid Gland	(21)	(12)		(19)	(20)		(20)		(21)	
GENERAL BODY SYSTEM										
None										
GENITAL SYSTEM										

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BALB/C Mouse FEMALE	ISORMCONSALINE	TRTRMCONSALINE	1-7 SALINE	1-8 SALINE	1-9 SALINE	1-10 SALINE
Clitoral Gland	(14)	(7)	(15)	(14)	(17)	(16)
Infiltration Cellular, Mononuclear Cl, Focal			1 (7%)			
Ovary	(20)	(12)	(20)	(20)	(20)	(20)
Uterus	(21)	(12)	(21)	(21)	(21)	(20)
Endometrium, Hyperplasia, Cystic	1 (5%)					
Endometrium, Hyperplasia, Cystic, Diffuse	1 (5%)	1 (8%)	2 (10%)	2 (10%)	3 (14%)	1 (5%)
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(21)	(12)	(21)	(20)	(20)	(20)
Depletion Cellular, Diffuse				1 (5%)		1 (5%)
Lymph Node, Mandibular	(15)	(10)	(11)	(19)	(17)	(19)
Left, Depletion Lymphoid					1 (6%)	
Left, Hyperplasia, Lymphoid		1 (10%)				1 (5%)
Right, Hyperplasia, Lymphoid	1 (7%)	1 (10%)			1 (6%)	
Lymph Node, Mesenteric	(20)	(11)	(19)	(21)	(20)	(18)
Spleen	(21)	(12)	(21)	(21)	(21)	(20)
Hematopoietic Cell Proliferation	21 (100%)	12 (100%)	21 (100%)	21 (100%)	21 (100%)	20 (100%)
Thymus	(21)	(12)	(21)	(21)	(21)	(18)
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(21)	(12)	(20)	(21)	(21)	(21)
Skin	(21)	(12)	(21)	(21)	(21)	(21)
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(21)	(12)	(21)	(20)	(20)	(21)
<b>NERVOUS SYSTEM</b>						
Brain	(21)	(12)	(21)	(21)	(21)	(21)
<b>RESPIRATORY SYSTEM</b>						
Lung	(21)	(12)	(20)	(21)	(21)	(21)
Nose	(21)	(11)	(21)	(21)	(21)	(21)
Inflammation, Acute						1 (5%)

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BALB/C Mouse FEMALE	ISORMCONSALINE	TRTRMCONSALINE	1-7	SALINE	1-8	SALINE	1-9	SALINE	1-10	SALINE
Trachea	(16)	(10)	(16)	(16)	(19)	(19)	(11)	(11)	(17)	(17)
SPECIAL SENSES SYSTEM										
Eye	(21)	(12)	(21)	(21)	(21)	(21)	(19)	(19)	(19)	(19)
Conjunctiva, Inflammation, Acute		1 (8%)								
Harderian Gland	(21)	(12)	(21)	(21)	(21)	(21)	(21)	(21)	(21)	(21)
URINARY SYSTEM										
Kidney	(21)	(12)	(21)	(21)	(21)	(21)	(21)	(21)	(21)	(21)
Bilateral, Renal Tubule, Dilatation									1 (5%)	
Urinary Bladder	(21)	(12)	(21)	(21)	(21)	(21)	(20)	(20)	(21)	(21)

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