

TDMS No. 96019 - 05
 Test Type: CHRONIC
 Route: DOSED WATER
 Species/Strain: RATS/F 344

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
 WATER DISINFECTION BYPRODUCTS (BROMOCHLOROACETIC ACID)
 CAS Number: 5589-96-8
 Pathologist: GILES, H. - HEATH, J. - Blackshear, P.

Date Report Requested: 03/28/2006
 Time Report Requested: 15:00:22
 First Dose M/F: 09/26/01 / 09/26/01
 Lab: SRI

FISCHER 344 RATS MALE	0 MG/L	250 MG/L	500 MG/L	1000 MG/L
Disposition Summary				
Animals Initially in Study	66	66	66	66
Early Deaths				
Moribund Sacrifice	15	17	17	17
Natural Death	4	7	8	4
Survivors				
Terminal Sacrifice	31	26	25	29
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(48)	(48)	(47)	(49)
Edema	5 (10%)	1 (2%)	1 (2%)	6 (12%)
Inflammation	1 (2%)			1 (2%)
Intestine Large, Colon	(50)	(49)	(50)	(48)
Inflammation		1 (2%)		
Intestine Large, Rectum	(50)	(50)	(50)	(49)
Intestine Small, Duodenum	(50)	(49)	(50)	(49)
Intestine Small, Ileum	(49)	(46)	(47)	(49)
Inflammation				1 (2%)
Intestine Small, Jejunum	(47)	(46)	(46)	(48)
Inflammation	1 (2%)			
Liver	(50)	(50)	(50)	(50)
Amyloid Deposition		1 (2%)		
Angiectasis	2 (4%)	5 (10%)	2 (4%)	2 (4%)
Basophilic Focus	6 (12%)	5 (10%)	4 (8%)	3 (6%)
Clear Cell Focus	22 (44%)	21 (42%)	23 (46%)	20 (40%)
Degeneration, Cystic	13 (26%)	13 (26%)	12 (24%)	18 (36%)
Eosinophilic Focus	2 (4%)	5 (10%)	4 (8%)	8 (16%)
Hepatodiaphragmatic Nodule	11 (22%)	13 (26%)	7 (14%)	4 (8%)
Inflammation, Chronic	10 (20%)	12 (24%)	12 (24%)	8 (16%)
Malformation				1 (2%)
Mixed Cell Focus	4 (8%)	3 (6%)	4 (8%)	2 (4%)
Necrosis, Focal		2 (4%)	2 (4%)	
Bile Duct, Hyperplasia	45 (90%)	49 (98%)	46 (92%)	44 (88%)
Centrilobular, Necrosis	4 (8%)	7 (14%)	8 (16%)	8 (16%)
Hepatocyte, Vacuolization Cytoplasmic	3 (6%)	6 (12%)	3 (6%)	2 (4%)

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

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FISCHER 344 RATS MALE	0 MG/L	250 MG/L	500 MG/L	1000 MG/L
Mesentery	(6)	(16)	(15)	(15)
Accessory Spleen			1 (7%)	1 (7%)
Angiectasis			1 (7%)	
Degeneration				1 (7%)
Fat, Necrosis	6 (100%)	8 (50%)	9 (60%)	9 (60%)
Oral Mucosa	(0)	(0)	(1)	(1)
Pancreas	(50)	(50)	(50)	(50)
Atrophy	29 (58%)	28 (56%)	26 (52%)	29 (58%)
Cyst				1 (2%)
Acinus, Hyperplasia, Focal	7 (14%)	3 (6%)	2 (4%)	7 (14%)
Salivary Glands	(50)	(50)	(50)	(50)
Inflammation				1 (2%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Edema	4 (8%)	4 (8%)	4 (8%)	6 (12%)
Erosion			1 (2%)	1 (2%)
Inflammation, Chronic Active		1 (2%)		
Ulcer	3 (6%)	3 (6%)	2 (4%)	5 (10%)
Epithelium, Hyperplasia	6 (12%)	5 (10%)	5 (10%)	8 (16%)
Stomach, Glandular	(50)	(50)	(50)	(50)
Edema	4 (8%)	3 (6%)	1 (2%)	6 (12%)
Erosion	7 (14%)	5 (10%)	7 (14%)	8 (16%)
Hyperplasia	1 (2%)			
Ulcer	2 (4%)	3 (6%)	2 (4%)	
Tongue	(0)	(1)	(0)	(1)
Hyperplasia				1 (100%)
Tooth	(0)	(0)	(0)	(2)
Malformation				2 (100%)
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	47 (94%)	46 (92%)	48 (96%)	48 (96%)
Thrombosis	4 (8%)	3 (6%)	4 (8%)	6 (12%)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Accessory Adrenal Cortical Nodule	23 (46%)	27 (54%)	28 (56%)	19 (38%)
Hyperplasia, Focal	11 (22%)	13 (26%)	12 (24%)	9 (18%)
Hyperplasia, Diffuse		1 (2%)		

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FISCHER 344 RATS MALE	0 MG/L	250 MG/L	500 MG/L	1000 MG/L
Hypertrophy, Focal	5 (10%)	3 (6%)	3 (6%)	4 (8%)
Necrosis	1 (2%)			
Bilateral, Atrophy			1 (2%)	
Adrenal Medulla	(50)	(50)	(50)	(50)
Hyperplasia	19 (38%)	22 (44%)	20 (40%)	28 (56%)
Necrosis				1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia		1 (2%)		1 (2%)
Pituitary Gland	(48)	(50)	(50)	(50)
Pars Distalis, Angiectasis	23 (48%)	27 (54%)	23 (46%)	20 (40%)
Pars Distalis, Cyst	5 (10%)	1 (2%)	4 (8%)	4 (8%)
Pars Distalis, Hemorrhage	1 (2%)			
Pars Distalis, Hyperplasia				1 (2%)
Pars Distalis, Hyperplasia, Focal	10 (21%)	8 (16%)	9 (18%)	9 (18%)
Pars Intermedia, Cyst			1 (2%)	
Thyroid Gland	(50)	(50)	(50)	(50)
Ultimobranchial Cyst	2 (4%)	3 (6%)	3 (6%)	1 (2%)
C-cell, Hyperplasia	21 (42%)	15 (30%)	15 (30%)	24 (48%)
Follicle, Cyst	11 (22%)	11 (22%)	5 (10%)	9 (18%)
GENERAL BODY SYSTEM				
Peritoneum	(0)	(4)	(2)	(3)
GENITAL SYSTEM				
Epididymis	(50)	(50)	(50)	(50)
Hyperplasia, Mesothelium		1 (2%)		
Preputial Gland	(50)	(49)	(50)	(49)
Cyst	4 (8%)	4 (8%)	3 (6%)	7 (14%)
Inflammation, Chronic	3 (6%)	2 (4%)	8 (16%)	6 (12%)
Prostate	(50)	(50)	(50)	(50)
Inflammation, Chronic	36 (72%)	32 (64%)	35 (70%)	34 (68%)
Epithelium, Hyperplasia	7 (14%)	4 (8%)	7 (14%)	5 (10%)
Seminal Vesicle	(50)	(50)	(50)	(50)
Inflammation				1 (2%)
Testes	(50)	(50)	(50)	(50)
Germinal Epithelium, Atrophy	13 (26%)	12 (24%)	7 (14%)	10 (20%)

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FISCHER 344 RATS MALE	0 MG/L	250 MG/L	500 MG/L	1000 MG/L
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Hyperplasia	5 (10%)	7 (14%)	8 (16%)	3 (6%)
Myelofibrosis		1 (2%)		2 (4%)
Lymph Node	(14)	(31)	(19)	(25)
Deep Cervical, Hemorrhage		1 (3%)		
Mediastinal, Congestion	1 (7%)			
Mediastinal, Hemorrhage		6 (19%)	1 (5%)	4 (16%)
Mediastinal, Hyperplasia, Lymphoid	6 (43%)	8 (26%)	9 (47%)	7 (28%)
Pancreatic, Amyloid Deposition		1 (3%)		
Pancreatic, Hyperplasia, Lymphoid		4 (13%)	4 (21%)	
Lymph Node, Mandibular	(1)	(3)	(0)	(0)
Hyperplasia, Lymphoid		1 (33%)		
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Hyperplasia, Lymphoid		9 (18%)	4 (8%)	
Spleen	(50)	(50)	(50)	(50)
Accessory Spleen				1 (2%)
Amyloid Deposition		1 (2%)		
Fibrosis	1 (2%)	2 (4%)	2 (4%)	3 (6%)
Hematopoietic Cell Proliferation	5 (10%)	7 (14%)	6 (12%)	3 (6%)
Necrosis		1 (2%)		
Pigmentation		1 (2%)	2 (4%)	1 (2%)
Lymphoid Follicle, Hyperplasia		1 (2%)		
Thymus	(49)	(50)	(50)	(48)
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Cyst	21 (42%)	14 (28%)	16 (32%)	18 (36%)
Hyperplasia	2 (4%)			1 (2%)
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion	2 (4%)	2 (4%)	1 (2%)	3 (6%)
Hyperplasia	2 (4%)			2 (4%)
Inflammation, Chronic	1 (2%)			
Epidermis, Hyperplasia			1 (2%)	
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)

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

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FISCHER 344 RATS MALE	0 MG/L	250 MG/L	500 MG/L	1000 MG/L
Cranium, Osteopetrosis		4 (8%)		2 (4%)
Femur, Osteopetrosis	1 (2%)			1 (2%)
Skeletal Muscle	(1)	(4)	(0)	(1)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Compression	5 (10%)	8 (16%)	11 (22%)	5 (10%)
Hemorrhage	2 (4%)	3 (6%)	4 (8%)	1 (2%)
Necrosis	1 (2%)			
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Hemorrhage	2 (4%)	2 (4%)		3 (6%)
Infiltration Cellular, Histiocyte	24 (48%)	23 (46%)	27 (54%)	25 (50%)
Inflammation, Chronic	5 (10%)	3 (6%)	7 (14%)	6 (12%)
Alveolar Epithelium, Hyperplasia	7 (14%)	14 (28%)	14 (28%)	10 (20%)
Nose	(50)	(50)	(50)	(50)
Foreign Body	14 (28%)	9 (18%)	14 (28%)	18 (36%)
Inflammation, Chronic	18 (36%)	9 (18%)	16 (32%)	21 (42%)
Nasolacrimal Duct, Cyst	1 (2%)	1 (2%)		
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Cataract	2 (4%)	3 (6%)	3 (6%)	2 (4%)
Harderian Gland	(50)	(50)	(50)	(50)
Hyperplasia, Focal	1 (2%)	1 (2%)		
Inflammation, Chronic	1 (2%)	1 (2%)		3 (6%)
Zymbal's Gland	(1)	(1)	(1)	(0)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Cyst	1 (2%)			1 (2%)
Infarct	1 (2%)	2 (4%)		2 (4%)
Nephropathy	47 (94%)	47 (94%)	43 (86%)	45 (90%)
Pelvis, Inflammation				1 (2%)

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FISCHER 344 RATS MALE	0 MG/L	250 MG/L	500 MG/L	1000 MG/L
Renal Tubule, Pigmentation Transitional Epithelium, Hyperplasia	1 (2%)		1 (2%)	2 (4%)
Urinary Bladder	(50)	(50)	(50)	(49)
Hemorrhage				1 (2%)
Inflammation				1 (2%)

*** END OF MALE ***

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FISCHER 344 RATS FEMALE	0 MG/L	250 MG/L	500 MG/L	1000 MG/L
Disposition Summary				
Animals Initially in Study	66	66	66	66
Early Deaths				
Moribund Sacrifice	12	14	9	13
Natural Death	4	5	4	2
Survivors				
Natural Death			1	
Terminal Sacrifice	34	31	36	35
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Intestine Large, Cecum	(48)	(47)	(48)	(49)
Intestine Large, Colon	(50)	(49)	(50)	(50)
Hyperplasia				1 (2%)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Hyperplasia			1 (2%)	
Inflammation				1 (2%)
Intestine Small, Duodenum	(49)	(48)	(49)	(49)
Ectopic Tissue		1 (2%)		
Intestine Small, Ileum	(47)	(47)	(48)	(48)
Intestine Small, Jejunum	(47)	(47)	(48)	(48)
Liver	(50)	(50)	(50)	(50)
Angiectasis		2 (4%)	2 (4%)	
Basophilic Focus	39 (78%)	37 (74%)	37 (74%)	31 (62%)
Clear Cell Focus	14 (28%)	11 (22%)	16 (32%)	17 (34%)
Degeneration, Cystic	1 (2%)			
Eosinophilic Focus	1 (2%)	6 (12%)	9 (18%)	15 (30%)
Hemorrhage	1 (2%)			
Hepatodiaphragmatic Nodule	11 (22%)	10 (20%)	5 (10%)	8 (16%)
Inflammation, Chronic	14 (28%)	17 (34%)	19 (38%)	10 (20%)
Mixed Cell Focus	1 (2%)	4 (8%)	6 (12%)	10 (20%)
Necrosis, Focal			1 (2%)	2 (4%)
Bile Duct, Hyperplasia	19 (38%)	19 (38%)	21 (42%)	16 (32%)
Hepatocyte, Vacuolization Cytoplasmic	6 (12%)	4 (8%)	3 (6%)	3 (6%)
Mesentery	(9)	(9)	(9)	(6)
Accessory Spleen	1 (11%)		1 (11%)	
Hemorrhage				1 (17%)

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FISCHER 344 RATS FEMALE	0 MG/L	250 MG/L	500 MG/L	1000 MG/L
Fat, Necrosis	7 (78%)	9 (100%)	8 (89%)	4 (67%)
Oral Mucosa	(2)	(0)	(0)	(1)
Pancreas	(50)	(50)	(50)	(50)
Atrophy	21 (42%)	20 (40%)	22 (44%)	22 (44%)
Cyst	1 (2%)			
Acinus, Hyperplasia, Focal	2 (4%)	1 (2%)	1 (2%)	
Stomach, Forestomach	(50)	(50)	(50)	(50)
Edema		2 (4%)	2 (4%)	1 (2%)
Erosion			1 (2%)	
Perforation				1 (2%)
Ulcer	1 (2%)	2 (4%)		1 (2%)
Epithelium, Hyperplasia	6 (12%)	2 (4%)	3 (6%)	6 (12%)
Stomach, Glandular	(50)	(50)	(50)	(50)
Edema		1 (2%)	3 (6%)	2 (4%)
Erosion	2 (4%)		5 (10%)	2 (4%)
Ulcer		2 (4%)		1 (2%)
Tongue	(1)	(0)	(1)	(0)
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	44 (88%)	43 (86%)	48 (96%)	44 (88%)
Thrombosis		1 (2%)		
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Accessory Adrenal Cortical Nodule	17 (34%)	11 (22%)	12 (24%)	13 (26%)
Hyperplasia, Focal	17 (34%)	17 (34%)	18 (36%)	25 (50%)
Hypertrophy, Focal	5 (10%)	2 (4%)	3 (6%)	6 (12%)
Adrenal Medulla	(49)	(47)	(50)	(50)
Hemorrhage				1 (2%)
Hyperplasia	5 (10%)	6 (13%)	4 (8%)	7 (14%)
Necrosis				1 (2%)
Islets, Pancreatic	(49)	(50)	(50)	(50)
Hyperplasia	1 (2%)		1 (2%)	
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Angiectasis	32 (64%)	32 (64%)	33 (66%)	30 (60%)
Pars Distalis, Cyst	28 (56%)	27 (54%)	31 (62%)	29 (58%)
Pars Distalis, Hyperplasia				1 (2%)

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FISCHER 344 RATS FEMALE	0 MG/L	250 MG/L	500 MG/L	1000 MG/L
Pars Distalis, Hyperplasia, Focal	14 (28%)	11 (22%)	6 (12%)	17 (34%)
Pars Intermedia, Cyst	(49)	(50)	1 (2%)	(50)
Thyroid Gland	(49)	(50)	(50)	(50)
Ultimobranchial Cyst	1 (2%)	1 (2%)	2 (4%)	1 (2%)
C-cell, Hyperplasia	25 (51%)	28 (56%)	23 (46%)	23 (46%)
Follicle, Cyst	5 (10%)	3 (6%)	2 (4%)	4 (8%)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(50)	(49)	(50)	(47)
Cyst	4 (8%)	6 (12%)	7 (14%)	7 (15%)
Hyperplasia	1 (2%)			1 (2%)
Inflammation, Chronic	2 (4%)	2 (4%)	3 (6%)	2 (4%)
Inflammation, Chronic Active				1 (2%)
Ovary	(50)	(50)	(50)	(50)
Cyst	7 (14%)	10 (20%)	6 (12%)	11 (22%)
Uterus	(50)	(50)	(50)	(50)
Cyst			1 (2%)	1 (2%)
Hemorrhage		1 (2%)		1 (2%)
Hydrometra	1 (2%)	2 (4%)	4 (8%)	4 (8%)
Inflammation, Chronic		1 (2%)		
Cervix, Cyst			1 (2%)	1 (2%)
Cervix, Hypertrophy				1 (2%)
Endometrium, Cyst				1 (2%)
Endometrium, Hyperplasia	1 (2%)			
Vagina	(0)	(1)	(0)	(1)
Cyst		1 (100%)		
Inflammation, Acute				1 (100%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Hyperplasia	6 (12%)	7 (14%)	5 (10%)	6 (12%)
Myelofibrosis	1 (2%)			
Lymph Node	(15)	(20)	(11)	(16)
Deep Cervical, Hyperplasia, Lymphoid	1 (7%)			

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FISCHER 344 RATS FEMALE	0 MG/L	250 MG/L	500 MG/L	1000 MG/L
Mediastinal, Hemorrhage	2 (13%)	1 (5%)		2 (13%)
Mediastinal, Hyperplasia, Lymphoid	6 (40%)	14 (70%)	8 (73%)	11 (69%)
Pancreatic, Hyperplasia, Lymphoid	1 (7%)		1 (9%)	1 (6%)
Lymph Node, Mandibular	(0)	(2)	(1)	(1)
Hyperplasia, Lymphoid				1 (100%)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Edema				1 (2%)
Hyperplasia, Lymphoid	2 (4%)	3 (6%)	3 (6%)	8 (16%)
Spleen	(50)	(50)	(50)	(50)
Fibrosis			1 (2%)	2 (4%)
Hematopoietic Cell Proliferation	3 (6%)	11 (22%)	10 (20%)	8 (16%)
Necrosis	1 (2%)			
Pigmentation	3 (6%)	6 (12%)	4 (8%)	2 (4%)
Thymus	(50)	(50)	(50)	(50)
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Cyst	47 (94%)	47 (94%)	46 (92%)	45 (90%)
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion		1 (2%)		
Edema		1 (2%)		
Hyperkeratosis	1 (2%)			
Inflammation, Chronic	1 (2%)			
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Cranium, Osteopetrosis		1 (2%)		
Femur, Osteopetrosis	1 (2%)	1 (2%)		3 (6%)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Compression	10 (20%)	15 (30%)	9 (18%)	10 (20%)
Hemorrhage			3 (6%)	
RESPIRATORY SYSTEM				

TDMS No. 96019 - 05
 Test Type: CHRONIC
 Route: DOSED WATER
 Species/Strain: RATS/F 344

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
 WATER DISINFECTION BYPRODUCTS (BROMOCHLOROACETIC ACID)
 CAS Number: 5589-96-8
 Pathologist: GILES, H. - HEATH, J. - Blackshear, P.

Date Report Requested: 03/28/2006
 Time Report Requested: 15:00:22
 First Dose M/F: 09/26/01 / 09/26/01
 Lab: SRI

FISCHER 344 RATS FEMALE	0 MG/L	250 MG/L	500 MG/L	1000 MG/L
Lung	(50)	(50)	(50)	(50)
Congestion		2 (4%)		
Hemorrhage	1 (2%)			2 (4%)
Infiltration Cellular, Histiocyte	36 (72%)	44 (88%)	44 (88%)	45 (90%)
Inflammation, Chronic	8 (16%)	10 (20%)	6 (12%)	7 (14%)
Metaplasia, Osseous			1 (2%)	
Alveolar Epithelium, Hyperplasia	5 (10%)	7 (14%)	8 (16%)	18 (36%)
Pleura, Fibrosis	1 (2%)			
Nose	(50)	(50)	(50)	(50)
Foreign Body	2 (4%)	1 (2%)	3 (6%)	2 (4%)
Inflammation, Chronic	3 (6%)	1 (2%)	3 (6%)	6 (12%)
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Cataract	4 (8%)	2 (4%)	2 (4%)	3 (6%)
Harderian Gland	(50)	(50)	(50)	(50)
Inflammation, Chronic	3 (6%)	5 (10%)	4 (8%)	
Zymbal's Gland	(0)	(2)	(0)	(0)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Infarct		2 (4%)	2 (4%)	7 (14%)
Nephropathy	36 (72%)	42 (84%)	43 (86%)	40 (80%)
Cortex, Inflammation, Chronic				1 (2%)
Transitional Epithelium, Hyperplasia, Diffuse		3 (6%)	2 (4%)	6 (12%)
Transitional Epithelium, Inflammation, Chronic Active		3 (6%)	3 (6%)	6 (12%)
Urinary Bladder	(50)	(50)	(50)	(50)

*** END OF REPORT ***