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

3'-Azido-3'-deoxythymidine (AIDS) **CAS Number:** 30516-87-1

Date Report Requested: 06/29/2009 Time Report Requested: 16:30:29 First Dose M/F: NA / 11/18/04

Lab: NCTR

Route: GAVAGE Species/Strain:

MICE/C3B6F1-+/Trp53(tm1Brd)

C Number: C20310C

Lock Date: 12/01/2008

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

Study Gender: Female

TDMSE Version: 2.1.0

3'-Azido-3'-deoxythymidine (AIDS)

CAS Number: 30516-87-1

Date Report Requested: 06/29/2009 Time Report Requested: 16:30:29 First Dose M/F: NA / 11/18/04

Lab: NCTR

MICE/C3B6F1-+/Trp53(tm1Brd)

TDMS No. 20310 - 01 **Test Type:** 26-39 WEEKS

Route: GAVAGE

Species/Strain:

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicle 6 mo F	AZT 120 6 mo F	Vehicle 9 mo F	AZT 40 9 mo F	AZT 80 9 mo F	AZT 120 9 mo F
Disposition Summary						
Animals Initially in Study	27	26	26	27	27	27
Early Deaths Moribund Sacrifice	1		1			1
Natural Death	1		•	1	1	·
Survivors						
Moribund Sacrifice Natural Death	1		1 1	2 1	1 1	2 3
Terminal Sacrifice	24	26	23	23	1 24	3 21
Animals Examined Microscopically	27	26	26	27	27	27
ALIMENTARY SYSTEM						
Esophagus	(23)	(25)	(26)	(27)	(27)	(27)
Adventitia, Foreign Body	1 (4%)	, ,	, ,		, ,	, ,
Adventitia, Necrosis	1 (4%)			1 (4%)		
Gallbladder	(24)	(25)	(25)	(26)	(27)	(25)
Intestine Large, Cecum	(26)	(26)	(25)	(27)	(25)	(24)
Hyperplasia, Lymphoid		2 (8%)	2 (8%)	2 (7%)	3 (12%)	2 (8%)
Epithelium, Hyperplasia	(00)	(00)	(00)	(00)	1 (4%)	(05)
Intestine Large, Colon	(26) (26)	(26)	(26) (25)	(26) (27)	(27)	(25) (25)
Intestine Large, Rectum Hyperplasia, Lymphoid	(26)	(26)	(25)	1 (4%)	(27) 1 (4%)	(25)
Intestine Small, Ileum	(26)	(26)	(25)	(27)	(25)	(25)
Intestine Small, Jejunum	(26)	(26)	(25)	(27)	(25)	(25)
Liver	(26)	(26)	(26)	(27)	(27)	(27)
Basophilic Focus	(20)	(20)	(20)	(21)	(21)	1 (4%)
Hematopoietic Cell Proliferation					1 (4%)	1 (170)
Infiltration Cellular, Lymphocyte		1 (4%)			. (179)	1 (4%)
Inflammation, Chronic Active	3 (12%)	2 (8%)		2 (7%)	1 (4%)	()
Necrosis	,	,		` ,	1 (4%)	
Tension Lipidosis	1 (4%)	3 (12%)	3 (12%)	5 (19%)	7 (26%)	4 (15%)
Vacuolization Cytoplasmic	1 (4%)	1 (4%)	6 (23%)	4 (15%)	3 (11%)	10 (37%)
Mesentery	(0)	(0)	(1)	(0)	(1)	(1)
Hemorrhage			1 (100%)			1 (100%)
Fat, Necrosis					1 (100%)	1 (100%)
Pancreas	(26)	(26)	(26)	(27)	(27)	(26)
Cytoplasmic Alteration						1 (4%)
Infiltration Cellular, Lymphocyte		1 (4%)			1 (4%)	3 (12%)
Inflammation, Chronic Active		1 (4%)				4.4404
Acinar Cell, Degeneration Salivary Glands	(26)	(26)	(26)	(27)	1 (4%) (26)	1 (4%) (27)

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

TDMS No. 20310 - 01

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

Test Type: 26-39 WEEKS

Route: GAVAGE

Species/Strain:

MICE/C3B6F1-+/Trp53(tm1Brd)

3'-Azido-3'-deoxythymidine (AIDS) **CAS Number:** 30516-87-1

Date Report Requested: 06/29/2009 Time Report Requested: 16:30:29 First Dose M/F: NA / 11/18/04

Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicle 6 mo F	AZT 120 6 mo F	Vehicle 9 mo F	AZT 40 9 mo F	AZT 80 9 mo F	AZT 120 9 mo
Infiltration Cellular, Lymphocyte Stomach, Forestomach Stomach, Glandular	14 (54%) (26) (26)	7 (27%) (26) (26)	15 (58%) (26) (25)	14 (52%) (27) (27)	10 (38%) (27) (25)	10 (37%) (27) (25)
CARDIOVASCULAR SYSTEM						
Heart	(26)	(26)	(26)	(27)	(27)	(26)
Bacterium Cardiomyopathy	1 (4%)			1 (4%)		
Congestion Inflammation, Chronic Active Pericardium, Inflammation, Chronic Pericardium, Inflammation, Chronic Active	1 (4%)	1 (4%)	1 (4%)		2 (7%) 1 (4%)	1 (4%)
Pericardium, Mineralization Pericardium, Necrosis		1 (4%)		1 (4%)		
ENDOCRINE SYSTEM						
Adrenal Cortex Accessory Adrenal Cortical Nodule Vacuolization Cytoplasmic	(26) 1 (4%) 2 (8%)	(26) 1 (4%)	(26)	(27)	(27)	(26)
Subcapsular, Hyperplasia	23 (88%)	24 (92%)	25 (96%)	25 (93%)	27 (100%)	24 (92%)
Adrenal Medulla Parathyroid Gland Cyst	(26) (22)	(26) (21)	(25) (21)	(27) (22) 1 (5%)	(27) (22)	(26) (22)
Infiltration Cellular, Lymphocyte Pituitary Gland	1 (5%) (26)	(26)	(26)	(27)	(27)	(27)
Thyroid Gland	(26)	(25)	(25)	(27)	(27)	(26)
Cyst Degeneration Ectopic Thymus	1 (4%)		1 (4%)	1 (4%) 2 (7%) 2 (7%)		1 (4%)
Infiltration Cellular, Lymphocyte	1 (4%)	1 (4%)		, ,		, ,
GENERAL BODY SYSTEM						
Tissue NOS	(0)	(1)	(0)	(1)	(0)	(1)
Abscess Mediastinum, Abscess Mediastinum, Foreign Body		1 (100%)				1 (100%) 1 (100%)

GENITAL SYSTEM

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

3'-Azido-3'-deoxythymidine (AIDS)

Test Type: 26-39 WEEKS Route: GAVAGE **CAS Number:** 30516-87-1 Species/Strain:

Date Report Requested: 06/29/2009 Time Report Requested: 16:30:29 First Dose M/F: NA / 11/18/04

Lab: NCTR

TDMS No. 20310 - 01

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicle 6 mo F	AZT 120 6 mo F	Vehicle 9 mo F	AZT 40 9 mo F	AZT 80 9 mo F	AZT 120 9 mo
Clitoral Gland	(24)	(25)	(25)	(26)	(26)	(27)
Degeneration	()	()	4	45-7	()	1 (4%)
Ovary	(26)	(26)	(26)	(27)	(27)	(26)
Cyst		1 (4%)		1 (4%)	1 (4%)	1 (4%)
Pigmentation					4 (40()	1 (4%)
Bilateral, Cyst	(26)	(36)	(26)	(27)	1 (4%)	(07)
Uterus Edema	(26)	(26)	(26)	(27)	(27)	(27) 1 (4%)
Infiltration Cellular, Polymorphonuclear			1 (4%)	3 (11%)	3 (11%)	3 (11%)
Endometrium, Hyperplasia, Cystic	1 (4%)	1 (4%)	3 (12%)	4 (15%)	5 (19%)	5 (11%) 5 (19%)
Lumen, Dilatation	2 (8%)	2 (8%)	10 (38%)	12 (44%)	14 (52%)	8 (30%)
Vagina	(27)	(26)	(25)	(27)	(27)	(24)
vagina	(21)	(20)	(23)	(21)	(21)	(24)
HEMATOPOIETIC SYSTEM						
Bone Marrow	(26)	(26)	(26)	(26)	(26)	(26)
Myeloid Cell, Hyperplasia	3 (12%)	2 (8%)			4 (15%)	1 (4%)
Lymph Node	(3)	(1)	(1)	(1)	(0)	(3)
Lumbar, Hyperplasia, Lymphoid			1 (100%)			1 (33%)
Mediastinal, Hyperplasia, Lymphoid	2 (67%)					
Mediastinal, Infiltration Cellular, Plasma Cell	1 (33%)					
Renal, Hyperplasia, Lymphoid						
Lymph Node, Mandibular	(26)	(25)	(26)	(27)	(25)	(26)
Hyperplasia, Lymphoid	3 (12%)	2 (8%)	4	4	2 (8%)	
Lymph Node, Mesenteric	(24)	(25)	(26)	(26)	(26)	(27)
Hyperplasia, Lymphoid	7 (29%)	11 (44%)	8 (31%)	6 (23%)	6 (23%)	6 (22%)
Spleen	(26)	(26)	(26)	(26)	(27)	(27)
Depletion Lymphoid	1 (4%)	0 (00()	5 (400()	4 (450()	5 (400()	0 (000()
Hematopoietic Cell Proliferation	3 (12%)	2 (8%)	5 (19%)	4 (15%)	5 (19%)	8 (30%)
Hyperplasia, Lymphoid	(00)	2 (8%)	4 (15%)	5 (19%)	7 (26%)	6 (22%)
Thymus	(26)	(26)	(24)	(26)	(23)	(27)
Bacterium				1 (4%)		
Cyst, Multiple				4 (40/)		
Foreign Body	2 (420/)	2 (80/)	2 (420/)	1 (4%)	2 (120/)	2 (70/)
Hyperplasia, Lymphoid Hyperplasia, Plasma Cell	3 (12%) 1 (4%)	2 (8%)	3 (13%)	2 (8%)	3 (13%)	2 (7%)
Inflammation, Chronic Active	1 (4%)					1 (4%)
Necrosis	1 (4%)			1 (4%)		1 (4%)
Adventitia, Inflammation, Chronic	1 (4%)			1 (476)		
Epithelial Cell, Hyperplasia	1 (4%)					
NTEGUMENTARY SYSTEM						
Mammary Gland	(24)	(24)	(25)	(26)	(27)	(27)

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

TDMS No. 20310 - 01

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

Test Type: 26-39 WEEKS

3'-Azido-3'-deoxythymidine (AIDS) **CAS Number:** 30516-87-1

Route: GAVAGE Species/Strain:

MICE/C3B6F1-+/Trp53(tm1Brd)

Time Report Requested: 16:30:29
First Dose M/F: NA / 11/18/04

Date Report Requested: 06/29/2009

Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicle 6 mo F	AZT 120 6 mo F	Vehicle 9 mo F	AZT 40 9 mo F	AZT 80 9 mo F	AZT 120 9 mo F
Alveolus, Hyperplasia Skin	(26)	(26)	(26)	1 (4%) (27)	(27)	(27)
MUSCULOSKELETAL SYSTEM						
Bone Bone, Femur Skeletal Muscle Atrophy Cyst	(0) (27) (27)	(0) (26) (26)	(0) (26) (26) 2 (8%) 1 (4%)	(1) (27) (27)	(0) (27) (27)	(1) (27) (27)
NERVOUS SYSTEM						
Brain, Brain Stem Gliosis Brain, Cerebellum Brain, Cerebrum Compression	(26) (26) (26)	(26) (26) (26)	(26) (26) (26)	(27) 1 (4%) (27) (27)	(27) (27) (27)	(27) (27) (27) 1 (4%)
Cyst Epithelial Inclusion Infiltration Cellular, Lymphocyte Mineralization Peripheral Nerve	1 (4%)	(0)	(2)	1 (4%) 1 (4%) (0)	4 (15%) (0)	2 (7%) (0)
Axon, Degeneration Spinal Cord Axon, Degeneration	(0)	(0)	2 (100%) (1) 1 (100%)	(0)	(0)	(0)
RESPIRATORY SYSTEM						
Lung Abscess Bacterium Foreign Body	(26) 2 (8%)	(26)	(26)	(27) 1 (4%)	(26)	(27) 1 (4%) 1 (4%)
Infiltration Cellular, Lymphocyte Inflammation, Chronic Active Necrosis	1 (4%)	1 (4%)		4 (40()		1 (4%) 1 (4%) 1 (4%)
Mediastinum, Foreign Body Mediastinum, Inflammation, Chronic Active Mediastinum, Mineralization Mediastinum, Necrosis	1 (4%)	1 (4%) 1 (4%)		1 (4%) 1 (4%)		
Nose	(26)	(26)	(26)	(27)	(27)	(27)

SPECIAL SENSES SYSTEM

TDMS No. 20310 - 01

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

Test Type: 26-39 WEEKS

WEEKS

Route: GAVAGE Species/Strain:

MICE/C3B6F1-+/Trp53(tm1Brd)

3'-Azido-3'-deoxythymidine (AIDS) **CAS Number:** 30516-87-1

Date Report Requested: 06/29/2009 Time Report Requested: 16:30:29 First Dose M/F: NA / 11/18/04

Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicle 6 mo F	AZT 120 6 mo F	Vehicle 9 mo F	AZT 40 9 mo F	AZT 80 9 mo F	AZT 120 9 mo I
Eye Cataract	(26)	(26)	(25) 1 (4%)	(25)	(26)	(24)
Harderian Gland Infiltration Cellular, Lymphocyte	(26) 1 (4%)	(26)	(26)	(27)	(27)	(25)
JRINARY SYSTEM						
Kidney Casts Protein Cyst Glomerulosclerosis	(26)	(26)	(26) 1 (4%) 1 (4%)	(27) 1 (4%)	(27) 3 (11%)	(27) 2 (7%) 1 (4%) 1 (4%)
Hydronephrosis Infiltration Cellular, Lymphocyte Inflammation, Suppurative	8 (31%)	3 (12%)	9 (35%)	6 (22%)	1 (4%) 5 (19%) 1 (4%)	4 (15%)
Inflammation, Chronic Active Metaplasia, Osseous	1 (4%)			1 (4%)		
Mineralization Nephropathy			1 (4%)	,	1 (4%)	1 (4%)
Ureter Inflammation, Suppurative Lumen, Dilatation	(0)	(0)	(0)	(0)	(1) 1 (100%) 1 (100%)	(0)
Urinary Bladder Infiltration Cellular, Lymphocyte Lumen, Dilatation	(26) 3 (12%)	(26) 1 (4%)	(26) 1 (4%)	(27) 4 (15%)	`(27) 2 (7%)	(26) 1 (4%)

3'-Azido-3'-deoxythymidine (AIDS)

CAS Number: 30516-87-1

Date Report Requested: 06/29/2009 Time Report Requested: 16:30:29 First Dose M/F: NA / 11/18/04

Lab: NCTR

MICE/C3B6E	1-+/Trp53(tm1Brd)
WIIOL/OODOI	1 1/11poo(u111bia)

TDMS No. 20310 - 01 **Test Type:** 26-39 WEEKS

Route: GAVAGE

Species/Strain:

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicl PND1-8 F	AZT 40 PND1-8 F
Disposition Summary		
Animals Initially in Study Early Deaths Moribund Sacrifice Natural Death Survivors	26	26
Moribund Sacrifice		3
Natural Death	1	00
Terminal Sacrifice Animals Examined Microscopically	25 26	23 26
Animals Examined inicroscopically	20	20
ALIMENTARY SYSTEM		
Esophagus Adventitia, Foreign Body Adventitia, Necrosis	(26)	(25)
Gallbladder	(25)	(26)
Intestine Large, Cecum	(25)	(26)
Hyperplasia, Lymphoid Epithelium, Hyperplasia	3 (12%)	45.53
Intestine Large, Colon	(25)	(26)
Intestine Large, Rectum Hyperplasia, Lymphoid	(25)	(26)
Intestine Small, Ileum	(25)	(26)
Intestine Small, Jejunum	(25)	(26)
Liver	(25)	(26)
Basophilic Focus		1 (4%)
Hematopoietic Cell Proliferation Infiltration Cellular, Lymphocyte	2 (8%)	1 (4%)
Inflammation, Chronic Active	2 (8%)	I (4 70)
Necrosis		
Tension Lipidosis	3 (12%)	4 (15%)
Vacuolization Cytoplasmic	12 (48%)	6 (23%)
Mesentery Hemorrhage	(0)	(0)
Fat, Necrosis Pancreas	(26)	(26)
Cytoplasmic Alteration Infiltration Cellular, Lymphocyte Inflammation, Chronic Active Acinar Cell, Degeneration	(20)	(20)
Salivary Glands	(25)	(26)
	(==)	(==)

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

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

3'-Azido-3'-deoxythymidine (AIDS) **CAS Number:** 30516-87-1

Date Report Requested: 06/29/2009 Time Report Requested: 16:30:29 First Dose M/F: NA / 11/18/04

Lab: NCTR

Route: GAVAGE

Species/Strain:

MICE/C3B6F1-+/Trp53(tm1Brd)

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicl PND1-8 F	AZT 40 PND1-8 F
Infiltration Cellular, Lymphocyte Stomach, Forestomach Stomach, Glandular	15 (60%) (25) (25)	12 (46%) (26) (26)
CARDIOVASCULAR SYSTEM		
Heart Bacterium Cardiomyopathy Congestion Inflammation, Chronic Active Pericardium, Inflammation, Chronic Pericardium, Inflammation, Chronic Active Pericardium, Mineralization Pericardium, Necrosis	(25)	(26)
ENDOCRINE SYSTEM		
Adrenal Cortex Accessory Adrenal Cortical Nodule Vacuolization Cytoplasmic	(26)	(26)
Subcapsular, Hyperplasia Adrenal Medulla Parathyroid Gland Cyst	23 (88%) (26) (25)	24 (92%) (26) (24)
Infiltration Cellular, Lymphocyte Pituitary Gland Thyroid Gland Cyst	(26) (26)	(26) (26)
Degeneration Ectopic Thymus Infiltration Cellular, Lymphocyte	2 (8%)	1 (4%) 1 (4%)
GENERAL BODY SYSTEM		
Tissue NOS Abscess Mediastinum, Abscess Mediastinum, Foreign Body	(0)	(0)

GENITAL SYSTEM

3'-Azido-3'-deoxythymidine (AIDS)

CAS Number: 30516-87-1

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Lab: NCTR

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicl PND1-8 F	AZT 40 PND1-8 F	
Clitoral Gland Degeneration	(26)	(25)	
Ovary	(26)	(26)	
Cyst	4 (15%)	1 (4%)	
Pigmentation			
Bilateral, Cyst Uterus	(26)	(26)	
Edema	(20)	(20)	
Infiltration Cellular, Polymorphonuclear	1 (4%)		
Endometrium, Hyperplasia, Cystic	4 (15%)	3 (12%)	
Lumen, Dilatation	16 (62%)	13 (50%)	
Vagina	(26)	(25)	
IEMATOPOIETIC SYSTEM			
Bone Marrow	(25)	(26)	
Myeloid Cell, Hyperplasia			
Lymph Node	(0)	(2)	
Lumbar, Hyperplasia, Lymphoid			
Mediastinal, Hyperplasia, Lymphoid Mediastinal, Infiltration Cellular, Plasma Cell			
Renal, Hyperplasia, Lymphoid		1 (50%)	
Lymph Node, Mandibular	(25)	(25)	
Hyperplasia, Lymphoid	(20)	1 (4%)	
Lymph Node, Mesenteric	(25)	(26)	
Hyperplasia, Lymphoid	4 (16%)	3 (12%)	
Spleen	(26)	(26)	
Depletion Lymphoid			
Hematopoietic Cell Proliferation	2 (8%)	2 (8%)	
Hyperplasia, Lymphoid	6 (23%)	6 (23%)	
Thymus	(25)	(25)	
Bacterium Cyst, Multiple		1 (40/)	
Cyst, Multiple Foreign Body		1 (4%)	
Hyperplasia, Lymphoid	1 (4%)	3 (12%)	
Hyperplasia, Plasma Cell	1 (7/0)	3 (1270)	
Inflammation, Chronic Active			
Necrosis			
Adventitia, Inflammation, Chronic			
Epithelial Cell, Hyperplasia			

(26)

TDMS No. 20310 - 01

Route: GAVAGE

Species/Strain:

Test Type: 26-39 WEEKS

Mammary Gland

MICE/C3B6F1-+/Trp53(tm1Brd)

(26)

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

MICE/C3B6F1-+/Trp53(tm1Brd)

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Lab: NCTR

Route: GAVAGE Species/Strain:

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicl PND1-8 F	AZT 40 PND1-8 F
Alveolus, Hyperplasia Skin	(26)	(26)
MUSCULOSKELETAL SYSTEM		
Bone Bone, Femur Skeletal Muscle Atrophy Cyst	(0) (26) (26)	(0) (26) (26)
NERVOUS SYSTEM		
Brain, Brain Stem Gliosis	(26)	(26)
Brain, Cerebellum Brain, Cerebrum Compression Cyst Epithelial Inclusion	(26) (26)	(26) (26)
Infiltration Cellular, Lymphocyte Mineralization	2 (8%)	4 (15%)
Peripheral Nerve Axon, Degeneration	(0)	(0)
Spinal Cord Axon, Degeneration	(0)	(0)
RESPIRATORY SYSTEM		
Lung Abscess Bacterium	(26)	(26)
Foreign Body Infiltration Cellular, Lymphocyte Inflammation, Chronic Active Necrosis Mediastinum, Foreign Body Mediastinum, Inflammation, Chronic Active Mediastinum, Mineralization		1 (4%) 1 (4%)
Mediastinum, Necrosis Nose	(26)	(26)

SPECIAL SENSES SYSTEM

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Lab: NCTR

Route: GAVAGE Species/Strain:

MICE/C3B6F1-+/Trp53(tm1Brd)

C3B6F1-+/Trp53(tm1Brd) NCTR MICE FEMALE	Vehicl PND1-8 F	AZT 40 PND1-8 F
Eye Cataract	(25)	(26)
Harderian Gland Infiltration Cellular, Lymphocyte	(25)	(26)
URINARY SYSTEM		
Kidney Casts Protein Cyst Glomerulosclerosis	(25)	(26)
Hydronephrosis Infiltration Cellular, Lymphocyte Inflammation, Suppurative Inflammation, Chronic Active Metaplasia, Osseous Mineralization Nephropathy	9 (36%)	5 (19%)
Ureter Inflammation, Suppurative Lumen, Dilatation	(0)	(0)
Urinary Bladder	(25)	(26)
Infiltration Cellular, Lymphocyte Lumen, Dilatation	2 (8%) 1 (4%)	3 (12%)

*** END OF REPORT ***

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