

TABLE A4
Summary of the Incidence of Nonneoplastic Lesions in Male Rats in the 2-Year Feed Study of Fumonisin B₁^a

	0 ppm	5 ppm	15 ppm	50 ppm	150 ppm
Disposition Summary					
6-Week evaluation	4	4	4	4	4
10-Week evaluation	4	4	4	4	4
14-Week evaluation	4	4	4	4	4
26-Week evaluation	4	4	4	4	4
Animals initially in 2-year study	48	40	48	48	48
Early deaths					
Removed from study	2			2	
Moribund	24	19	19	19	21
Natural deaths	6	4	4	9	2
Survivors					
Terminal sacrifice	16	17	25	18	25
Animals examined microscopically	64	56	64	64	64
6-Week Evaluation					
Kidney	(4)	(4)	(4)	(4)	(4)
Apoptosis, cortex, renal tubule			4 (100%)	4 (100%)	4 (100%)
Cyst, medulla	1 (25%)				
Cytoplasmic alter, cortex, renal tubule	1 (25%)				
Liver	(4)	(4)	(4)	(4)	(4)
Fatty change, centrilobular		1 (25%)			
Inflammation, chronic		1 (25%)			
10-Week Evaluation					
Kidney	(4)	(4)	(4)	(4)	(4)
Apoptosis, cortex, renal tubule			4 (100%)	4 (100%)	4 (100%)
Cyst, medulla					1 (25%)
Inflammation, chronic, pelvis	1 (25%)	2 (50%)			
Nephropathy	1 (25%)	1 (25%)	1 (25%)	1 (25%)	
Liver	(4)	(4)	(4)	(4)	(4)
Angiectasis, focal, sinusoid					1 (25%)
Hyperplasia, bile duct					1 (25%)
Necrosis, focal		1 (25%)			
Mesentery				(1)	
Necrosis, focal, fat				1 (100%)	
14-Week Evaluation					
Kidney	(4)	(4)	(4)	(4)	(4)
Apoptosis, cortex, renal tubule			4 (100%)	4 (100%)	4 (100%)
Cyst, medulla				1 (25%)	
Cytoplasmic alter, cortex, renal tubule	2 (50%)				
Nephropathy		3 (75%)	1 (25%)	1 (25%)	2 (50%)
Liver	(4)	(4)	(4)	(4)	(4)
Hyperplasia, bile duct		2 (50%)	1 (25%)	1 (25%)	
Inflammation, chronic			1 (25%)	1 (25%)	
Necrosis, multifocal			1 (25%)		
Testes		(1)			
Hemorrhage		1 (100%)			

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

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26-Week Evaluation					
Intestine large					(1)
Hemorrhage, focal, cecum, submucosa					1 (100%)
Kidney	(4)	(4)	(4)	(4)	(4)
Apoptosis, cortex, renal tubule		1 (25%)		4 (100%)	4 (100%)
Mineralization	2 (50%)				1 (25%)
Nephropathy	4 (100%)	3 (75%)	1 (25%)	3 (75%)	4 (100%)
Liver	(4)	(4)	(4)	(4)	(4)
Devel malfor			1 (4%)		
Fatty change, centrilobular	4 (100%)	4 (100%)		4 (100%)	4 (100%)
Hyperplasia, bile duct	1 (25%)	2 (50%)	3 (75%)	4 (100%)	2 (50%)
Inflammation, chronic	4 (100%)	3 (75%)	3 (75%)	3 (75%)	2 (50%)
Necrosis, focal	1 (25%)			1 (25%)	
Necrosis, multifocal			1 (25%)		
Vacuoliz cyto, focal	2 (50%)		1 (25%)	1 (25%)	1 (25%)
2-Year Study					
Adrenal gland	(47)	(22)	(25)	(31)	(47)
Angiectasis, bilateral, cortex					1 (2%)
Angiectasis, cortex				1 (3%)	
Hema cell prol, cortex				1 (3%)	1 (2%)
Hyperplasia, focal, bilateral, cortex					1 (2%)
Hyperplasia, focal, bilateral, medulla	1 (2%)	1 (5%)	1 (4%)	2 (6%)	
Hyperplasia, focal, cortex	5 (11%)	1 (5%)	1 (4%)	1 (3%)	1 (2%)
Hyperplasia, focal, medulla	7 (15%)	3 (14%)	2 (8%)	3 (10%)	5 (11%)
Infiltrat cell, lymphocytic	1 (2%)				
Vacuoliz cyto, diffuse, bilateral, cortex	1 (2%)			1 (3%)	
Vacuoliz cyto, diffuse, cortex	2 (4%)		1 (4%)		1 (2%)
Vacuoliz cyto, focal, bilateral, cortex	1 (2%)				1 (2%)
Vacuoliz cyto, focal, cortex	11 (23%)	4 (18%)		5 (17%)	8 (17%)
Blood vessel	(47)	(23)	(23)	(30)	(47)
Inflammation, chronic, mesent artery		1 (4%)			
Bone	(48)	(23)	(23)	(30)	(48)
Degen, epiphysis					1 (2%)
Degen, joint, cartilage		1 (4%)			
Hyperostosis, turbinate	1 (2%)				
Inflammation, chronic, joint				1 (3%)	
Bone, femur	(48)	(23)	(23)	(29)	(48)
Hyperplasia, cartilage, epiphysis			2 (9%)		
Bone marrow	(47)	(23)	(23)	(30)	(48)
Angiectasis					1 (2%)
Atrophy				1 (3%)	
Depletion	1 (2%)		3 (13%)	2 (7%)	3 (6%)
Hyperplasia	7 (15%)	3 (13%)	3 (13%)	7 (23%)	12 (25%)
Myelofibrosis	1 (2%)				
Brain	(48)	(24)	(23)	(31)	(48)
Compression, hypothalamus	11 (23%)	7 (29%)	6 (26%)	8 (26%)	4 (8%)
Hemorrhage, hypothalamus				1 (3%)	
Hemorrhage, ventricle				1 (3%)	
Necrosis, hippocampus, neuron					1 (2%)
Brain, cerebrum	(48)	(24)	(23)	(31)	(48)
Compression		1 (4%)			
Hemorrhage				1 (3%)	

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2-Year Study (continued)					
Coagulating gland	(48)	(22)	(23)	(29)	(48)
Atrophy	9 (19%)	2 (9%)	2 (9%)	1 (3%)	3 (6%)
Atrophy, bilateral	14 (29%)	4 (18%)	8 (35%)	6 (21%)	16 (33%)
Degen, bilateral			1 (4%)		
Infiltrat cell, lymphocytic					1 (2%)
Inflammation, acute				1 (3%)	
Inflammation, chronic active		1 (5%)			
Epididymis	(48)	(23)	(22)	(28)	(47)
Atrophy					1 (2%)
Atrophy, bilateral	2 (4%)		3 (14%)	1 (4%)	
Degen, mucoid, bilateral, epithelium	2 (4%)	1 (4%)	1 (5%)		2 (4%)
Degen, mucoid, epithelium	6 (13%)		1 (5%)	1 (4%)	6 (13%)
Hyperplasia, epithelium		1 (4%)			
Inflammation, chronic	1 (2%)				1 (2%)
Esophagus	(48)	(22)	(23)	(30)	(48)
Inflammation, chronic, muscularis				1 (3%)	
Eye	(47)	(24)	(26)	(35)	(48)
Atrophy, bilateral, retina	32 (68%)	7 (29%)	14 (54%)	20 (57%)	27 (56%)
Atrophy, retina	5 (11%)	5 (21%)	3 (12%)	3 (9%)	5 (10%)
Cataract, bilateral, lens	21 (45%)	4 (17%)	7 (27%)	13 (37%)	15 (31%)
Cataract, lens	4 (9%)	1 (4%)	2 (9%)	3 (9%)	3 (6%)
Degen, optic nerve					1 (2%)
Inflammation, acute, cornea			1 (4%)		
Inflammation, acute, iris		1 (4%)			
Inflammation, chronic, cornea	1 (2%)				
Necrosis, optic nerve	1 (2%)				
Harderian gland	(48)	(23)	(23)	(30)	(48)
Atrophy, focal	2 (4%)				
Hyperplasia, focal				1 (3%)	
Infiltrat cell, lymphocytic	15 (31%)	4 (17%)	5 (22%)	11 (37%)	18 (38%)
Infiltrat cell, lymphocytic, bilateral	9 (19%)	3 (13%)	1 (4%)	2 (7%)	5 (10%)
Inflammation, chronic				2 (7%)	1 (2%)
Heart	(48)	(23)	(24)	(30)	(48)
Cardiomyopathy	42 (89%)	15 (65%)	14 (58%)	23 (77%)	37 (77%)
Inflammation, chronic, coron artery		1 (4%)			
Inflammation, chronic, epicardium		1 (4%)			
Inflammation, chronic, pericardium		1 (4%)			
Inflammation, chronic, valve		1 (4%)			3 (6%)
Thrombus, atrium	1 (2%)	2 (9%)	1 (4%)		1 (2%)
Intestine large, cecum	(45)	(23)	(23)	(25)	(47)
Parasite meta					1 (2%)
Intestine large, colon	(47)	(23)	(23)	(28)	(47)
Hyperplasia, lymphoid			1 (4%)		
Parasite meta					1 (2%)
Ulcer		1 (4%)			
Intestine large, rectum	(48)	(23)	(23)	(30)	(47)
Hemorrhage				1 (3%)	
Hyperplasia, focal, epithelium				1 (3%)	
Parasite meta					1 (2%)
Intestine small, ileum	(45)	(23)	(22)	(26)	(47)
Hyperplasia, lymphoid			1 (5%)		

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2-Year Study (continued)					
Kidney	(48)	(40)	(48)	(48)	(48)
Acc hyaline d, bilateral, renal tubule	1 (2%)			1 (2%)	1 (2%)
Cyst	2 (4%)	1 (3%)		3 (6%)	7 (15%)
Cyst, bilateral					1 (2%)
Cytoplas alter, bilateral, renal tubule					1 (2%)
Hydronephrosis	1 (2%)				
Hyperplasia, focal, renal tubule	2 (4%)	1 (3%)	4 (8%)	14 (29%)	8 (17%)
Inflammation, acute, bilateral, pelvis				1 (2%)	
Inflammation, chronic, artery			1 (2%)	1 (2%)	
Inflammation, chronic, artery, pelvis		1 (3%)			
Inflammation, chronic, bilateral, artery	1 (2%)	1 (3%)	1 (2%)		
Mineralization	1 (2%)		1 (2%)	1 (2%)	1 (2%)
Mineralization, bilateral		1 (3%)			
Nephropathy			1 (2%)	4 (8%)	3 (6%)
Nephropathy, bilateral	44 (92%)	38 (95%)	43 (90%)	34 (71%)	39 (81%)
Pigment, bilateral, renal tubule	13 (27%)	8 (20%)	8 (17%)	2 (4%)	6 (13%)
Pigment, renal tubule		1 (3%)		1 (2%)	1 (2%)
Lacrimal gland	(47)	(23)	(22)	(30)	(48)
Atrophy, diffuse		1 (4%)			
Atrophy, focal		2 (9%)	1 (5%)	4 (13%)	1 (2%)
Cyst					1 (2%)
Hyperplasia, duct					1 (2%)
Infiltrat cell, lymphocytic	11 (23%)	11 (48%)	5 (23%)	9 (30%)	20 (42%)
Larynx	(46)	(21)	(22)	(29)	(46)
Cyst	2 (4%)	2 (10%)	2 (9%)		2 (4%)
Inflammation, chronic	1 (2%)	2 (10%)		1 (3%)	3 (7%)
Inflammation, chronic active	2 (4%)	1 (5%)			
Liver	(48)	(40)	(48)	(48)	(48)
Angiectasis, focal	1 (2%)	1 (3%)		1 (2%)	
Basoph focus	3 (6%)	11 (28%)	7 (15%)	9 (19%)	23 (48%)
Clear cl focus	5 (10%)	10 (25%)	14 (29%)	6 (13%)	10 (21%)
Congestion		1 (3%)	1 (2%)	1 (2%)	
Degen, cystic, focal	6 (13%)	4 (10%)	5 (10%)	3 (6%)	2 (4%)
Degen, cystic, focal, hepatocyte			1 (2%)		
Eosin focus	5 (10%)	6 (15%)	10 (21%)	5 (10%)	10 (21%)
Hdn	3 (6%)	3 (8%)	2 (4%)	3 (6%)	5 (10%)
Hema cell prol			1 (2%)	1 (2%)	
Hemorrhage	1 (2%)				
Hyperplasia, bile duct	38 (79%)	35 (88%)	45 (94%)	42 (88%)	43 (90%)
Inflammation, chronic	2 (4%)	4 (10%)	2 (4%)	1 (2%)	4 (8%)
Mixed cl focus	5 (10%)	6 (15%)	5 (10%)	4 (8%)	9 (19%)
Necrosis	4 (8%)		1 (2%)	5 (10%)	1 (2%)
Pigment					1 (2%)
Tension lipoid	3 (6%)	5 (13%)	7 (15%)	7 (15%)	7 (15%)
Thrombus, vein			1 (2%)		
Vacuoliz cyto, hepatocyte	13 (27%)	8 (20%)	12 (25%)	9 (19%)	13 (27%)
Lung	(48)	(24)	(23)	(32)	(48)
Congestion					1 (2%)
Foreign body			1 (4%)		
Hyperplasia, focal, alveolar epith		1 (4%)		2 (6%)	1 (2%)
Infiltrat cell, histiocytic		1 (4%)	1 (4%)	1 (3%)	1 (2%)
Infiltrat cell, lymphocytic					1 (2%)
Inflammation, chronic, interstitium	1 (2%)		1 (4%)	2 (6%)	1 (2%)
Lung, bronchus	(48)	(24)	(23)	(31)	(48)
Inflammation, chronic active			1 (4%)		

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2-Year Study (continued)					
Lymph node	(48)	(24)	(27)	(33)	(48)
Degen, cystic, deep cervical			1 (4%)		
Degen, cystic, mediastinal		1 (4%)			
Degen, cystic, renal		1 (4%)			
Lymph node, mandibular	(48)	(23)	(26)	(32)	(48)
Degen, cystic	6 (13%)		2 (8%)	3 (9%)	6 (13%)
Hemorrhage	1 (2%)			3 (9%)	1 (2%)
Hyperplasia, lymphoid	5 (10%)	4 (17%)		5 (16%)	10 (21%)
Infiltrat cell, histiocytic	1 (2%)	1 (4%)		2 (6%)	
Lymph node, mesenteric	(47)	(23)	(23)	(30)	(48)
Atrophy	1 (2%)		1 (4%)	1 (3%)	
Degen, cystic	3 (6%)	1 (4%)	1 (4%)	1 (3%)	3 (6%)
Hemorrhage	1 (2%)	1 (4%)	2 (9%)	3 (10%)	1 (2%)
Hyperplasia, lymphoid		1 (4%)		2 (7%)	
Infiltrat cell, histiocytic	27 (57%)	9 (39%)	11 (48%)	15 (50%)	27 (56%)
Inflammation, chronic					1 (2%)
Mammary gland	(40)	(20)	(24)	(24)	(42)
Cyst	11 (28%)	3 (15%)	3 (13%)	5 (21%)	4 (10%)
Galactocele	5 (13%)	3 (15%)	7 (29%)		8 (19%)
Hyperplasia, epithelium			1 (4%)	1 (4%)	
Hyperplasia, focal, epithelium					1 (2%)
Mesentery	(4)	(3)	(3)	(4)	(4)
Accessory spln		1 (33%)			
Inflammation, chronic, artery		1 (33%)			
Necrosis, fat	3 (75%)	1 (33%)	3 (100%)	3 (75%)	3 (75%)
Nose	(48)	(23)	(23)	(29)	(48)
Cytoplas alter, olfactory epi	20 (42%)	7 (30%)	10 (43%)	6 (21%)	18 (38%)
Foreign body	2 (4%)	3 (13%)	1 (4%)	1 (3%)	3 (6%)
Inflammation, acute			1 (4%)	1 (3%)	1 (2%)
Inflammation, acute, nasolacrim dct	1 (2%)	1 (4%)	1 (4%)	2 (7%)	1 (2%)
Inflammation, chronic	1 (2%)	2 (9%)	1 (4%)	1 (3%)	
Inflammation, chronic active	1 (2%)	2 (9%)	1 (4%)	2 (7%)	2 (4%)
Inflammation, chronic active, nasolacrim dct	5 (10%)	4 (17%)		3 (10%)	10 (21%)
Inflammation, chronic, nasolacrim dct	7 (15%)	2 (9%)	4 (17%)		4 (8%)
Pancreas	(47)	(24)	(25)	(30)	(48)
Atrophy, diffuse, acinar cell	2 (4%)	1 (4%)	2 (8%)	1 (3%)	1 (2%)
Atrophy, focal, acinar cell	20 (43%)	8 (33%)	9 (36%)	13 (43%)	28 (58%)
Basoph focus, acinar cell			1 (4%)		2 (4%)
Hyperplasia, focal		1 (4%)	1 (4%)		1 (2%)
Hyperplasia, focal, acinar cell	1 (2%)				1 (2%)
Hyperplasia, focal, duct	1 (2%)				
Infiltrat cell, lymphocytic				1 (3%)	2 (4%)
Inflammation, chronic, artery	1 (2%)	1 (4%)	1 (4%)		2 (4%)
Necrosis, focal		1 (4%)			
Parathyroid gland	(46)	(21)	(22)	(26)	(47)
Hyperplasia, focal					1 (2%)
Pigment					1 (2%)
Pituitary gland	(43)	(28)	(33)	(33)	(45)
Angiectasis, pars distalis				1 (3%)	1 (2%)
Atypical cells, pars nervosa					1 (2%)
Cyst, pars distalis					2 (4%)
Cyst, pars intermed	1 (2%)				1 (2%)
Cyst, pars nervosa					1 (2%)
Cyst, Rathke's cleft					1 (2%)
Hemorrhage	1 (2%)			1 (3%)	
Hemorrhage, pars distalis				1 (3%)	
Hyperplasia, focal, pars distalis	3 (7%)	1 (4%)	2 (6%)	1 (3%)	7 (16%)
Hypertrophy, focal, pars distalis		1 (4%)	2 (6%)		1 (2%)

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2-Year Study (continued)					
Preputial gland	(43)	(19)	(20)	(30)	(44)
Foreign body					1 (2%)
Hyperplasia, focal	3 (7%)				
Inflammation, acute	1 (2%)				
Inflammation, chronic	18 (42%)	6 (32%)	9 (45%)	15 (50%)	13 (30%)
Inflammation, chronic active			1 (5%)		4 (9%)
Inflammation, chronic active, bilateral		2 (11%)		2 (7%)	2 (5%)
Inflammation, chronic, bilateral	7 (16%)	3 (16%)	6 (30%)	5 (17%)	9 (20%)
Prostate	(48)	(22)	(23)	(30)	(48)
Atrophy	10 (21%)	4 (18%)	5 (22%)	6 (20%)	12 (25%)
Cyst		1 (5%)			
Cytoplas alter, epithelium					1 (2%)
Fibrosis			1 (4%)		
Hyperplasia, focal, epithelium	1 (2%)			3 (10%)	3 (6%)
Inflammation, acute	7 (15%)	3 (14%)	2 (9%)	7 (23%)	6 (13%)
Inflammation, chronic	3 (6%)		3 (13%)	2 (7%)	2 (4%)
Inflammation, chronic active	11 (23%)	8 (36%)	4 (17%)	3 (10%)	10 (21%)
Salivary glands	(48)	(23)	(23)	(30)	(48)
Atrophy, diffuse, parotid gland	2 (4%)	1 (4%)	3 (13%)	1 (3%)	4 (8%)
Cyst		1 (4%)			
Cytoplas alter, focal, submandibul gland	1 (2%)				1 (2%)
Infiltrat cell, lymphocytic					1 (2%)
Inflammation, chronic, submandibul gland					1 (2%)
Seminal vesicle	(48)	(23)	(24)	(30)	(48)
Atrophy	8 (17%)	1 (4%)	2 (8%)	1 (3%)	5 (10%)
Atrophy, bilateral	19 (40%)	11 (48%)	13 (54%)	10 (33%)	18 (38%)
Skeletal muscle, thigh	(48)	(23)	(24)	(30)	(48)
Degen		1 (4%)		1 (3%)	1 (2%)
Hemorrhage			1 (4%)		
Skin	(48)	(27)	(28)	(32)	(48)
Atrophy, hair follicle					1 (2%)
Inflammation, chronic	1 (2%)			1 (3%)	
Spinal cord, thoracic	(47)	(23)	(23)	(30)	(48)
Hemorrhage	1 (2%)				
Spleen	(48)	(29)	(33)	(41)	(48)
Atrophy, lymph follic	1 (2%)		2 (6%)	1 (2%)	
Congestion	2 (4%)	1 (3%)	1 (3%)	1 (2%)	3 (6%)
Depletion, focal	1 (2%)			2 (5%)	
Fibrosis, focal	1 (2%)	2 (7%)		3 (7%)	2 (4%)
Hema cell prol	5 (10%)	4 (14%)	3 (9%)	5 (12%)	6 (13%)
Infarct, focal			1 (3%)		
Inflammation, chronic active				1 (2%)	
Inflammation, chronic, capsule	1 (2%)		1 (3%)		
Pigment	4 (8%)		4 (12%)	3 (7%)	2 (4%)
Stomach, forestomach	(48)	(23)	(23)	(30)	(48)
Edema	2 (4%)			1 (3%)	1 (2%)
Erosion, focal	1 (2%)				
Hyperplasia, epithelium	8 (17%)	3 (13%)	4 (17%)	3 (10%)	4 (8%)
Inflammation, acute				1 (3%)	
Inflammation, chronic	4 (8%)	2 (9%)	2 (9%)	5 (17%)	1 (2%)
Inflammation, chronic active	1 (2%)				1 (2%)
Ulcer	1 (2%)			2 (7%)	2 (4%)

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2-Year Study (continued)					
Stomach, glandular	(48)	(23)	(23)	(30)	(48)
Cyst	3 (6%)	2 (9%)			
Edema		1 (4%)			1 (2%)
Erosion			1 (4%)		
Erosion, focal	1 (2%)		2 (9%)		
Inflammation, acute	1 (2%)				
Inflammation, chronic	1 (2%)	1 (4%)	1 (4%)	1 (3%)	
Necrosis	1 (2%)				1 (2%)
Testes	(48)	(39)	(46)	(46)	(48)
Atrophy, bilateral, germinal epith	3 (6%)		2 (4%)		
Atrophy, germinal epith	6 (13%)	1 (3%)	10 (22%)	6 (13%)	9 (19%)
Granuloma sperm	1 (2%)				
Hyperplasia, focal, bilateral, interstit cell	2 (4%)	2 (5%)		1 (2%)	
Hyperplasia, focal, interstit cell	4 (8%)	6 (15%)	10 (22%)	5 (11%)	2 (4%)
Inflammation, chronic, artery	1 (2%)				
Mineralization		1 (3%)	1 (2%)		1 (2%)
Thymus	(37)	(19)	(21)	(24)	(41)
Atrophy	13 (35%)	5 (26%)	9 (43%)	8 (33%)	19 (46%)
Cyst	1 (3%)				1 (2%)
Hemorrhage	2 (5%)			3 (13%)	4 (10%)
Hyperplasia, lymphoid			1 (5%)		
Thyroid gland	(48)	(24)	(25)	(31)	(48)
Cyst, follicle				2 (6%)	
Hyperplasia, focal, c cell	10 (21%)	6 (25%)	5 (20%)	3 (10%)	9 (19%)
Inflammation, chronic	1 (2%)				
Ultracyst	2 (4%)	1 (4%)			1 (2%)
Tissue NOS	(2)		(2)	(1)	(1)
Cyst	1 (50%)				
Inflammation, chronic			1 (50%)		
Inflammation, chronic, mediastinum					1 (100%)
Tongue	(48)	(23)	(23)	(30)	(48)
Inflammation, chronic			1 (4%)		1 (2%)
Inflammation, chronic, artery		1 (4%)			
Trachea	(48)	(23)	(23)	(30)	(48)
Inflammation, chronic		1 (4%)			1 (2%)
Urinary bladder	(47)	(22)	(23)	(30)	(48)
Dilatation				1 (3%)	
Hyperplasia, transit epithel		1 (5%)			
Infiltrat cell, lymphocytic	2 (4%)	2 (9%)			1 (2%)
Inflammation, acute				2 (7%)	
Inflammation, chronic		1 (5%)			