

Experiment Number: 00058 - 03

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS
ABRIDGED) (a)**

Date Report Requested: 11/13/2020

Test Type: CHRONIC

Black Cohosh

Time Report Requested: 09:33:45

Route: GAVAGE

CAS Number: 84776-26-1

First Dose M/F: 07/03/12 / 07/02/12

Species/Strain: RATS/HSD

Lab: BAT

Rats Final 2

NTP Study Number: C00058B
Lock Date: 10/02/2018
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 3.0.2.3_002
PWG Approval Date: NONE

Test Type: CHRONIC

Black Cohosh

Time Report Requested: 09:33:45

Route: GAVAGE

CAS Number: 84776-26-1

First Dose M/F: 07/03/12 / 07/02/12

Species/Strain: RATS/HSD

Lab: BAT

Harlan Sprague Dawley RATS MALE	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	16	14	11	8
Natural Death	19	20	18	26
Survivors				
Natural Death		1		
Terminal Sacrifice	15	15	21	16
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(50)	(49)	(50)	(49)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Schwannoma Malignant			1 (2%)	
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(49)	(49)
Intestine Small, Ileum	(49)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Carcinoma		2 (4%)		
Liver	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Kidney				1 (2%)
Cholangioma		1 (2%)		
Hepatocellular Adenoma		1 (2%)		2 (4%)
Mesentery	(0)	(3)	(1)	(0)
Oral Mucosa	(0)	(0)	(1)	(0)
Buccal, Squamous Cell Carcinoma			1 (100%)	
Pancreas	(50)	(50)	(50)	(50)
Schwannoma Malignant			1 (2%)	
Acinus, Adenoma	4 (8%)	3 (6%)		2 (4%)
Acinus, Adenoma, Multiple	2 (4%)	2 (4%)	6 (12%)	2 (4%)
Acinus, Carcinoma	1 (2%)			
Salivary Glands	(50)	(50)	(50)	(50)
Fibrosarcoma, Metastatic, Skin	1 (2%)			

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

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Lab: BAT

Harlan Sprague Dawley RATS MALE	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(50)
Tongue	(0)	(1)	(0)	(0)
Tooth	(0)	(3)	(0)	(0)

CARDIOVASCULAR SYSTEM

Blood Vessel	(32)	(33)	(32)	(33)
Heart	(50)	(50)	(50)	(50)
Neuroendocrine Tumor, Benign			1 (2%)	

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma			1 (2%)	
Carcinoma				1 (2%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	12 (24%)	8 (16%)	5 (10%)	7 (14%)
Pheochromocytoma Malignant				1 (2%)
Bilateral, Pheochromocytoma Benign	2 (4%)	2 (4%)	1 (2%)	3 (6%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	4 (8%)		2 (4%)	1 (2%)
Adenoma, Mixed Cell		1 (2%)		
Carcinoma				1 (2%)
Parathyroid Gland	(49)	(47)	(44)	(39)
Adenoma		1 (2%)		
Pituitary Gland	(50)	(50)	(50)	(50)
Meningioma Malignant, Metastatic, Brain			1 (2%)	
Pars Distalis, Adenoma	12 (24%)	7 (14%)	12 (24%)	6 (12%)
Thyroid Gland	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Kidney			2 (4%)	
Bilateral, C-cell, Adenoma			1 (2%)	
Bilateral, C-cell, Adenoma, Multiple	1 (2%)			
C-cell, Adenoma	10 (20%)	5 (10%)	7 (14%)	7 (14%)
C-cell, Adenoma, Multiple		1 (2%)	1 (2%)	

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C-cell, Carcinoma	1 (2%)			1 (2%)
Follicular Cell, Adenoma				1 (2%)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Epididymis	(50)	(50)	(50)	(50)
Preputial Gland	(50)	(50)	(50)	(50)
Papilloma, Squamous		1 (2%)		
Prostate	(50)	(50)	(50)	(50)
Seminal Vesicle	(50)	(50)	(50)	(50)
Testis	(50)	(50)	(50)	(50)
Bilateral, Interstitial Cell, Adenoma, Multiple			1 (2%)	
Interstitial Cell, Adenoma	1 (2%)	1 (2%)		1 (2%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(5)	(4)	(3)	(4)
Bronchial, Carcinoma, Metastatic, Thyroid Gland		1 (25%)		
Lymph Node, Mandibular	(50)	(50)	(50)	(50)
Lymph Node, Mesenteric	(50)	(50)	(49)	(48)
Carcinoma, Metastatic, Kidney				1 (2%)
Spleen	(50)	(50)	(49)	(50)
Hemangiosarcoma				1 (2%)
Thymus	(46)	(48)	(46)	(49)

INTEGUMENTARY SYSTEM

Mammary Gland	(48)	(48)	(49)	(48)
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Harlan Sprague Dawley RATS MALE	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
Adenocarcinoma		1 (2%)		
Fibroadenoma	3 (6%)	1 (2%)	2 (4%)	1 (2%)
Skin	(50)	(50)	(50)	(50)
Fibroma	3 (6%)	1 (2%)	4 (8%)	5 (10%)
Fibroma, Multiple	1 (2%)			
Fibrosarcoma	1 (2%)	1 (2%)		1 (2%)
Hemangioma		1 (2%)		
Hemangiosarcoma			1 (2%)	
Keratoacanthoma	1 (2%)	3 (6%)	2 (4%)	3 (6%)
Keratoacanthoma, Multiple		1 (2%)		
Lipoma	1 (2%)	1 (2%)		
Lipoma, Multiple	1 (2%)			
Liposarcoma		1 (2%)		
Sarcoma	1 (2%)	1 (2%)		
Schwannoma Malignant			1 (2%)	
Squamous Cell Papilloma			1 (2%)	
Sebaceous Gland, Adenoma		1 (2%)		

MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(0)	(0)	(1)	(3)
Sarcoma			1 (100%)	

NERVOUS SYSTEM

Brain	(50)	(50)	(49)	(50)
Glioma Malignant	1 (2%)			
Granular Cell Tumor Benign	3 (6%)		1 (2%)	1 (2%)
Meningioma Malignant			1 (2%)	
Meninges, Carcinoma, Metastatic, Kidney			1 (2%)	
Meninges, Meningioma Malignant				1 (2%)
Nerve Trigeminal	(0)	(1)	(0)	(0)
Peripheral Nerve	(0)	(1)	(1)	(2)
Spinal Cord	(0)	(1)	(1)	(2)

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RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Adrenal Cortex				1 (2%)
Carcinoma, Metastatic, Thyroid Gland				1 (2%)
Nose	(50)	(50)	(50)	(50)
Trachea	(50)	(50)	(50)	(50)

SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(50)
Meningioma Malignant, Metastatic, Brain			1 (2%)	
Harderian Gland	(50)	(50)	(50)	(50)
Zymbal's Gland	(2)	(1)	(1)	(0)
Adenoma	1 (50%)			
Carcinoma	1 (50%)	1 (100%)	1 (100%)	

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Amphophilic/Vacuolar Adenoma, Multiple			2 (4%)	2 (4%)
Amphophilic/Vacuolar Carcinoma			2 (4%)	
Amphophilic/Vacuolar Carcinoma, Multiple				1 (2%)
Lipoma	1 (2%)			
Oncocytoma Benign	1 (2%)	1 (2%)		
Renal Tubule, Adenoma			1 (2%)	
Urinary Bladder	(50)	(50)	(50)	(50)

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* Number of animals with any tissue examined microscopically

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ABRIDGED) (a)**

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SYSTEMIC LESIONS

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	1 (2%)			
Leukemia Granulocytic	1 (2%)			1 (2%)
Leukemia Mononuclear		2 (4%)		
Mesothelioma Malignant	2 (4%)		1 (2%)	

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P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

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Harlan Sprague Dawley RATS MALE	0 mg/kg male	75 mg/kg male	250 mg/kg male	750 mg/kg male
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	33	34	36	35
Total Primary Neoplasms	74	53	62	53
Total Animals with Benign Neoplasms	30	30	30	30
Total Benign Neoplasms	64	44	48	42
Total Animals with Malignant Neoplasms	10	8	8	7
Total Malignant Neoplasms	10	9	9	8
Total Animals with Metastatic Neoplasms	2	1	3	3
Total Metastatic Neoplasms	2	1	5	4
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain- Benign or Malignant			3	2
Total Uncertain Neoplasms			5	3

*** END OF MALE ***

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b - Primary tumors: all tumors except metastatic tumors

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Harlan Sprague Dawley RATS FEMALE	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	13	14	15	14
Natural Death	9	12	6	16
Survivors				
Terminal Sacrifice	28	24	29	20
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(49)
Intestine Large, Cecum	(50)	(50)	(50)	(49)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Leiomyoma		1 (2%)		
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Liver	(50)	(50)	(50)	(48)
Adenocarcinoma, Metastatic, Uterus		1 (2%)		1 (2%)
Cholangioma		1 (2%)		1 (2%)
Hepatocellular Adenoma	2 (4%)	1 (2%)	1 (2%)	1 (2%)
Hepatocellular Adenoma, Multiple		1 (2%)		
Squamous Cell Carcinoma, Metastatic, Uterus				1 (2%)
Mesentery	(1)	(0)	(1)	(1)
Adenocarcinoma, Metastatic, Uterus	1 (100%)		1 (100%)	
Squamous Cell Carcinoma, Metastatic, Uterus				1 (100%)
Oral Mucosa	(0)	(0)	(1)	(0)
Gingival, Squamous Cell Papilloma			1 (100%)	
Pancreas	(50)	(50)	(50)	(49)
Adenocarcinoma, Metastatic, Uterus		1 (2%)		1 (2%)
Malignant Mixed Sex Cord Stromal Tumor, Metastatic, Ovary		1 (2%)		
Squamous Cell Carcinoma, Metastatic, Uterus				1 (2%)

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Harlan Sprague Dawley RATS FEMALE	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Acinus, Adenoma				1 (2%)
Salivary Glands	(50)	(50)	(50)	(48)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uterus				1 (2%)
Tooth	(0)	(0)	(1)	(1)

CARDIOVASCULAR SYSTEM

Blood Vessel	(49)	(48)	(48)	(43)
Heart	(50)	(50)	(50)	(48)
Schwannoma Malignant	1 (2%)	1 (2%)		1 (2%)
Squamous Cell Carcinoma, Metastatic, Uterus				1 (2%)

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(48)
Adenocarcinoma, Metastatic, Uterus			1 (2%)	
Adenoma	2 (4%)	1 (2%)		
Capsule, Squamous Cell Carcinoma, Metastatic, Uterus				1 (2%)
Adrenal Medulla	(50)	(50)	(50)	(48)
Pheochromocytoma Benign	3 (6%)	4 (8%)	2 (4%)	1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(49)
Adenoma	1 (2%)	1 (2%)	2 (4%)	
Parathyroid Gland	(46)	(40)	(39)	(38)
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	20 (40%)	18 (36%)	20 (40%)	11 (22%)
Thyroid Gland	(50)	(49)	(50)	(49)
Bilateral, C-cell, Adenoma	1 (2%)	1 (2%)	1 (2%)	1 (2%)
C-cell, Adenoma	8 (16%)	10 (20%)	9 (18%)	9 (18%)
C-cell, Carcinoma		2 (4%)		
Follicular Cell, Adenoma			1 (2%)	

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GENERAL BODY SYSTEM

Peritoneum	(0)	(2)	(1)	(0)
Adenocarcinoma, Metastatic, Uterus		1 (50%)	1 (100%)	
Malignant Mixed Sex Cord Stromal Tumor, Metastatic, Ovary		1 (50%)		

GENITAL SYSTEM

Clitoral Gland	(49)	(48)	(49)	(49)
Adenoma			1 (2%)	
Squamous Cell Carcinoma	1 (2%)			2 (4%)
Ovary	(50)	(50)	(50)	(49)
Adenocarcinoma, Metastatic, Uterus		1 (2%)		1 (2%)
Carcinoma, Metastatic, Kidney		1 (2%)		1 (2%)
Granulosa Cell Tumor Malignant			1 (2%)	
Malignant Mixed Sex Cord Stromal Tumor		1 (2%)		
Squamous Cell Carcinoma, Metastatic, Uterus				1 (2%)
Oviduct	(0)	(0)	(2)	(0)
Uterus	(50)	(50)	(50)	(49)
Hemangiosarcoma			1 (2%)	1 (2%)
Leiomyosarcoma		1 (2%)		
Malignant Mixed Sex Cord Stromal Tumor, Metastatic, Ovary		1 (2%)		
Papilloma, Squamous, Multiple	1 (2%)			
Papilloma, Squamous		1 (2%)	4 (8%)	
Polyp Stromal	5 (10%)	4 (8%)	6 (12%)	2 (4%)
Polyp Stromal, Multiple	3 (6%)			
Squamous Cell Carcinoma	1 (2%)		2 (4%)	1 (2%)
Bilateral, Polyp Stromal	1 (2%)			1 (2%)
Cervix, Sarcoma		1 (2%)		
Cervix, Squamous Cell Carcinoma			1 (2%)	
Endometrium, Adenocarcinoma	2 (4%)	2 (4%)	4 (8%)	2 (4%)
Endometrium, Adenocarcinoma, Multiple			1 (2%)	2 (4%)
Endometrium, Adenoma		1 (2%)	1 (2%)	
Vagina	(50)	(50)	(50)	(50)

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Schwannoma Malignant		2 (4%)		
Squamous Cell Carcinoma				1 (2%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(0)	(6)	(0)	(3)
Deep Cervical, Carcinoma, Metastatic, Thyroid Gland		1 (17%)		
Lumbar, Squamous Cell Carcinoma, Metastatic, Uterus				1 (33%)
Mediastinal, Squamous Cell Carcinoma, Metastatic, Uterus				1 (33%)
Pancreatic, Adenocarcinoma, Metastatic, Uterus		1 (17%)		
Renal, Squamous Cell Carcinoma, Metastatic, Uterus				1 (33%)
Lymph Node, Mandibular	(50)	(50)	(50)	(49)
Carcinoma, Metastatic, Thyroid Gland		1 (2%)		
Lymph Node, Mesenteric	(50)	(50)	(50)	(49)
Spleen	(50)	(50)	(50)	(49)
Adenocarcinoma, Metastatic, Uterus			1 (2%)	1 (2%)
Thymus	(49)	(49)	(48)	(48)
Malignant Mixed Sex Cord Stromal Tumor, Metastatic, Ovary		1 (2%)		
Squamous Cell Carcinoma, Metastatic, Uterus				1 (2%)
Thymoma Malignant				1 (2%)

INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(50)	(50)	(49)
Adenocarcinoma	2 (4%)	2 (4%)	1 (2%)	2 (4%)
Adenocarcinoma, Multiple	1 (2%)			1 (2%)
Adenoma	1 (2%)		1 (2%)	
Fibroadenoma	22 (44%)	26 (52%)	15 (30%)	9 (18%)
Fibroadenoma, Multiple	7 (14%)	5 (10%)	7 (14%)	4 (8%)

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Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
Skin	(50)	(50)	(50)	(50)
Fibroma		2 (4%)		1 (2%)
Hemangiosarcoma			1 (2%)	
Keratoacanthoma		1 (2%)		
Lipoma	1 (2%)			
Schwannoma Malignant		1 (2%)		
Squamous Cell Carcinoma				1 (2%)
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(0)	(0)	(0)	(1)
Squamous Cell Carcinoma, Metastatic, Uterus				1 (100%)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Meninges, Carcinoma, Metastatic, Kidney		1 (2%)		
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(48)
Adenocarcinoma, Metastatic, Mammary Gland	2 (4%)	1 (2%)	1 (2%)	1 (2%)
Adenocarcinoma, Metastatic, Uterus			1 (2%)	1 (2%)
Alveolar/Bronchiolar Adenoma			1 (2%)	
Carcinoma, Metastatic, Kidney		1 (2%)		1 (2%)
Carcinoma, Metastatic, Thyroid Gland		1 (2%)		
Malignant Mixed Sex Cord Stromal Tumor, Metastatic, Ovary		1 (2%)		
Squamous Cell Carcinoma, Metastatic, Uterus				1 (2%)
Nose	(50)	(50)	(50)	(50)
Osteosarcoma			1 (2%)	
Trachea	(50)	(50)	(50)	(48)

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Harlan Sprague Dawley RATS FEMALE

0 mg/kg female

75 mg/kg female

250 mg/kg female

750 mg/kg female

SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Sarcoma			1 (2%)	
Lacrimal Gland	(1)	(0)	(0)	(0)

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(49)
Amphophilic/Vacuolar Adenoma, Multiple		1 (2%)	1 (2%)	1 (2%)
Amphophilic/Vacuolar Carcinoma, Multiple		2 (4%)	1 (2%)	1 (2%)
Renal Tubule, Adenoma		1 (2%)		1 (2%)
Urinary Bladder	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uterus		1 (2%)		

SYSTEMIC LESIONS

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Leukemia Mononuclear			1 (2%)	1 (2%)
Lymphoma Malignant		1 (2%)		

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

* Number of animals with any tissue examined microscopically

Test Type: CHRONIC

Black Cohosh

Time Report Requested: 09:33:45

Route: GAVAGE

CAS Number: 84776-26-1

First Dose M/F: 07/03/12 / 07/02/12

Species/Strain: RATS/HSD

Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 mg/kg female	75 mg/kg female	250 mg/kg female	750 mg/kg female
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	46	47	45	32
Total Primary Neoplasms	86	97	90	61
Total Animals with Benign Neoplasms	44	46	44	31
Total Benign Neoplasms	78	80	73	43
Total Animals with Malignant Neoplasms	7	13	13	13
Total Malignant Neoplasms	8	14	15	16
Total Animals with Metastatic Neoplasms	3	5	3	5
Total Metastatic Neoplasms	3	18	6	21
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain- Benign or Malignant		2	1	1
Total Uncertain Neoplasms		3	2	2

*** END OF REPORT ***

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

b - Primary tumors: all tumors except metastatic tumors