Protocol for the Examination of Specimens from Patients with Malignant Germ Cell and Sex Cord-Stromal Tumors of the Testis

Protocol applies to all malignant germ cell and sex cord-stromal tumors of the testis. Paratesticular malignancies are excluded.

Based on AJCC/UICC TNM, 7th edition
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Procedures
- Radical Orchiectomy
- Retroperitoneal Lymphadenectomy (RPLND)

Authors
Satish K. Tickoo, MD*
Department of Pathology, Memorial Sloan-Kettering Cancer Center, New York, NY
Victor E. Reuter, MD
Department of Pathology, Memorial Sloan-Kettering Cancer Center, New York, NY
Mahul B. Amin, MD, FCAP
Department of Pathology and Laboratory Medicine, Cedars-Sinai Medical Center, Los Angeles, California
Sam S. Chang, MD
Department of Urologic Surgery, Vanderbilt-Ingram Cancer Center, Nashville, Tennessee
Peter A. Humphrey, MD, PhD, FCAP
Department of Pathology and Immunology, Washington University School of Medicine and Barnes-Jewish Hospital, St. Louis, Missouri
James McKiernan MD
Department of Urology, Columbia University NY, NY
John R. Srigley, MD, FCAP
Department of Laboratory Medicine, Credit Valley Hospital, Mississauga, Ontario, Canada
Thomas M. Ulbright, MD
Department of Pathology, Indiana University School of Medicine, Indianapolis, Indiana
For the Members of the Cancer Committee, College of American Pathologists

* primary author.

Previous contributors: Richard S. Foster, MD; Patrick J. Loehrer, MD; Judd W. Moul, MD; Jae Y. Ro, MD; Robert E. Scully, MD; Gillian M. Thomas, MD

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Surgical Pathology Cancer Case Summary (Checklist)

Protocol web posting date: October 2009

TESTIS: Radical Orchiectomy

Select a single response unless otherwise indicated.

***Serum Tumor Markers (select all that apply) (Note A)**
(see Serum Tumor Markers [S] classification below)
*___ Unknown
*___ Serum marker studies within normal limits
*___ Alpha-fetoprotein (AFP) elevation
*___ Beta-subunit of human chorionic gonadotropin (b-hCG) elevation
*___ Lactate dehydrogenase (LDH) elevation

Specimen Laterality
___ Right
___ Left
___ Both
___ Not specified

Tumor Focality
___ Unifocal
___ Multifocal

Tumor Size
Greatest dimension of main tumor mass: ___ cm
*Additional dimensions: ___ x ___ cm
Greatest dimensions of additional tumor nodules: ___cm, ___ cm, etc
___ Cannot be determined (see Comment)

Macroscopic Extent of Tumor (select all that apply)
___ Confined to the testis
___ Invades hilar soft tissues
___ Invades tunica vaginalis (perforates mesothelium)
___ Invades epididymis
___ Invades spermatic cord
___ Other (specify): _____

Histologic Type (select all that apply) (Note B, Note C)
___ Intratubular germ cell neoplasia, unclassified only
___ Seminoma, classic type
___ Seminoma with associated scar (**Note D**)
___ Seminoma with syncytiotrophoblastic cells
___ Mixed germ cell tumor (specify components and approximate percentages):
_____
_____

* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

___ Embryonal carcinoma
___ Yolk sac tumor
___ Choriocarcinoma, biphasic
___ Choriocarcinoma, monophasic
___ Placental site trophoblastic tumor
___ Teratoma
___ Teratoma with a secondary somatic-type malignant component
(specify type): _____
___ Monodermal teratoma, carcinoid
___ Monodermal teratoma, primitive neuroectodermal tumor
___ Monodermal teratoma, other (specify): _____
___ Spermatocytic seminoma
___ Spermatocytic seminoma with a sarcomatous component
___ Mixed germ cell-sex cord-stromal tumor, gonadoblastoma
___ Mixed germ cell-sex cord-stromal tumor, others
(specify): _____
___ Testicular scar **(Note D)**
__ Scar only
__ Scar with intratubular germ cell neoplasia
___ Sex cord-stromal tumor
___ Leydig cell tumor
___ Sertoli cell tumor
___ Classic
___ Sclerosing
___ Large cell calcifying
___ Granulosa cell tumor
___ Adult-type
___ Juvenile-type
___ Mixed, with components (specify components and approximate percentages): _____
_____

___Unclassified
___ Malignant neoplasm, type cannot be determined
___ Other (specify): _____

Margins

Spermatic Cord Margin
___ Cannot be assessed
___ Uninvolved by tumor
___ Involved by tumor

Other Margin(s)
___ Cannot be assessed
___ Uninvolved by tumor (specify): _____
___ Involved by tumor (specify): _____
___ Not applicable

* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

Microscopic Tumor Extension (select all that apply) (Note E)
*___ Rete testis
*___ Epididymis
*___ Hilar fat
___ Spermatic cord
___ Tunica vaginalis (perforates mesothelium)
___ Scrotal wall
___ None of the above

Lymph-Vascular Invasion (Note F)
___ Absent
___ Present
___ Indeterminate

Pathologic Staging (pTNM) (Note G)

TNM Descriptors (required only if applicable) (select all that apply)
___ m (multiple)
___ r (recurrent)
___ y (post-treatment)

Primary Tumor (pT)
___ pTX: Cannot be assessed
___ pT0: No evidence of primary tumor
___ pTis: Intratubular germ cell neoplasia (carcinoma in situ)
___ pT1: Tumor limited to the testis and epididymis without vascular/lymphatic invasion; tumor may invade tunica albuginea but not tunica vaginalis
___ pT2: Tumor limited to the testis and epididymis with vascular/lymphatic invasion, or tumor extending through the tunica albuginea with involvement of the tunica vaginalis
___ pT3: Tumor invades the spermatic cord with or without vascular/lymphatic invasion
___ pT4: Tumor invades the scrotum with or without vascular/lymphatic invasion

Regional Lymph Nodes (pN)
___ pNX: Cannot be assessed
___ pN0: No regional lymph node metastasis
___ pN1: Metastasis with a lymph node mass 2 cm or less in greatest dimension, or 5 or fewer positive nodes, none more than 2 cm in greatest dimension
___ pN2: Metastasis with a lymph node mass greater than 2 cm but not more than 5 cm in greatest dimension; or more than 5 nodes positive, none greater than 5 cm; or evidence of extranodal extension of tumor
___ pN3: Metastasis with a lymph node mass greater than 5 cm in greatest dimension
Specify: Number examined: ___
Number involved: ___

* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

Distant Metastasis (pM)
___ Not applicable
___ pM1: Distant metastasis present
___ pM1a: Nonregional nodal or pulmonary metastasis
___ pM1b: Distant metastasis other than to nonregional lymph nodes and lung
*Specify site(s), if known: _____

***Serum Tumor Markers (S) (Note A)**

	LDH		HCG (mIU/mL)		AFP (ng/mL)
*___ S1:	<1.5 X N[#]	and	<5,000	and	<1,000
*___ S2:	1.5-10 X N	or	5,000-50,000	or	1,000-10,000
*___ S3:	>10 X N	or	>50,000	or	>10,000

[#] *N indicates the upper limit of normal for the LDH assay.*

***Additional Pathologic Findings (select all that apply) (Note H)**
*___ None identified
*___ Intratubular germ cell neoplasia
*___ Hemosiderin-laden macrophages
*___ Atrophy
*___ Other (specify): _____

***Comment(s)**

Surgical Pathology Cancer Case Summary (Checklist)

Protocol web posting date: October 2009

TESTIS: Retroperitoneal Lymphadenectomy (Note B)

Select a single response unless otherwise indicated.

***Prelymphadenectomy Treatment**
*___ Chemo/radiation therapy
*___ No chemo/radiation therapy
*___ Unknown

***Serum Tumor Markers (select all that apply) (Note A)**
*___ Unknown
*___ Serum marker studies within normal limits
*___ Alpha-fetoprotein (AFP) elevation
*___ Beta subunit of human chorionic gonadotropin (b-hCG) elevation
*___ Lactate dehydrogenase (LDH) elevation

***Specimen Site(s)**
*Specify: _____

***Number of Nodal Groups Present**
*Specify: ___
*___ Cannot be determined

Size of Largest Metastatic Deposit in Lymph Node
Greatest dimension: ___ cm
*Additional dimensions: ___ x ___ cm

Histologic Viability of Tumor (if applicable)
___ Viable teratoma present
___ Viable non-teratomatous tumor present
___ No viable tumor present

* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

Histologic Type of Metastatic Tumor (Note C)

___ Seminoma, classic type
___ Seminoma with syncytiotrophoblastic cells
___ Mixed germ cell tumor (specify components and approximate percentages):
_____
_____
___ Embryonal carcinoma
___ Yolk sac tumor
___ Choriocarcinoma, biphasic
___ Choriocarcinoma, monophasic
___ Cystic trophoblastic tumor
___ Placental site trophoblastic tumor
___ Teratoma
___ Teratoma with a secondary somatic-type malignant component
(specify type): _____
___ Monodermal teratoma (specify type): _____
___ Spermatocytic seminoma
___ Spermatocytic seminoma with a sarcomatous component
___ Malignant neoplasm, type cannot be determined
___ Other (specify): _____

Regional Lymph Nodes (pN) (Note I)

___ pNX: Cannot be assessed
___ pN0: No regional lymph node metastasis
___ pN1: Metastasis with a lymph node mass less than 2 cm in greatest dimension, or 5 or fewer positive nodes, none greater than 2 cm in greatest dimension
___ pN2: Metastasis with a lymph node mass greater than 2 cm but no more than 5 cm in greatest dimension, or more than 5 nodes positive, none greater than 5 cm; or evidence of extranodal extension of tumor
___ pN3: Metastasis in a lymph node greater than 5 cm in greatest dimension
Specify: Total number examined: ___
Total number involved: ___

Nonregional Lymph Node Metastasis (M1a) (Note I)

___ Not applicable
___ Not identified
___ Present

***Comment(s)**

Explanatory Notes

A. Serum Markers

The protocol emphasizes the importance of relevant clinical information in the pathologic evaluation of specimens. Serum marker studies play a key role in the clinical management of patients with testicular germ cell tumors.[1-3] The occurrence of elevated serum levels of alpha-fetoprotein (AFP) or the beta subunit of human chorionic gonadotropin (b-hCG) may indicate the need for additional sections of certain specimens if the initial findings do not account for such elevations. Information regarding pre-orchiectomy serum marker status (lactate dehydrogenase [LDH], AFP, and b-hCG) is also important in the "S" categorization of the tumor for stage groupings.

B. Tissues Submitted for Microscopic Evaluation

The entire testicular tumor may be blocked if it requires 10 blocks or less (tissue may be retained for special studies); 10 blocks of larger tumors may be taken, unless the tumor is greater than 10 cm, in which case 1 block may be submitted for every 1 cm of maximum tumor dimension. Blocks must contain the interface with non-tumorous testis, as well as the tunica albuginea, even away from the tumor, because lymphatic invasion is best appreciated in the peritumoral tissue, as well as in the vessels within and under/parallel to the tunica. Tissues to be sampled include:

- Tumor, including interface with surrounding testis, and tunica albuginea
- All of the grossly different appearing areas in the tumor
- Testicular hilum/mediastinum testis
- Uninvolved testis, including tunica albuginea
- Epididymis
- Spermatic cord, including cord margin
- Other lesion(s)
- All identifiable lymph nodes[#]
- Other tissue(s) submitted with specimen

[#] For large masses which have obliterated individual nodes, 1 section for every centimeter of maximum tumor dimension, including grossly different looking areas, should be taken.

The margins in a specimen resected for a malignant tumor of the testis, depending on the extent of the surgery, include spermatic cord margin, the parietal layer of tunica vaginalis, and scrotal skin.

C. Histologic Type

The protocol mainly applies to malignant tumors of the testis, the vast majority of which are of germ cell origin. It may also be applied to other malignant or potentially malignant tumors of the testis included in the classification shown below.[4-15] For lymphomas and plasmacytomas of the testis, refer to the CAP non-Hodgkin lymphoma protocol.

Modified Armed Forces Institute of Pathology (AFIP) and World Health Organization (WHO) Histologic Classification of Testicular Tumors

Germ Cell Tumors
Precursor lesion
- Intratubular germ cell neoplasm, unclassified
- Intratubular germ cell neoplasm, specific type

Tumors of 1 histologic type
- Seminoma
  - Variant: Seminoma with syncytiotrophoblastic cells
  - Partially regressed tumor showing seminoma with scar
  - Spermatocytic seminoma
  - Variant: Spermatocytic seminoma with a sarcomatous component
- Embryonal carcinoma
- Yolk sac tumor
- Choriocarcinoma
  - Variant: “Monophasic” type
- Placental site trophoblastic tumor
- Trophoblastic tumor, unclassified
- Teratoma
  - With a secondary somatic-type malignant component
  - Monodermal variants
    - Carcinoid
    - Primitive neuroectodermal tumor
    - Others

Tumors of more than 1 histologic type
- Mixed germ cell tumor (specify components; estimate approximate percentage of each)

Testicular scar, consistent with regressed tumor
- Scar only
- Scar with intratubular germ cell neoplasia
- Partially regressed tumor with scar and residual germ cell tumor (specify type)

Sex Cord-Stromal Tumors
Leydig cell tumor
Sertoli cell tumor
- Variant: Large cell calcifying Sertoli cell tumor
- Variant: Sclerosing Sertoli cell tumor

Granulosa cell tumor
- Adult type
- Juvenile type

Mixed and indeterminate (unclassified) sex cord stromal tumor

Mixed Germ Cell- Sex Cord-Stromal Tumors
Gonadoblastoma
Unclassified

Miscellaneous
Sarcoma (specify type)
Plasmacytoma
Lymphoma (specify type)
Granulocytic sarcoma or leukemic infiltrates
Adenocarcinoma of rete testis
Carcinomas and borderline tumors of ovarian type
Malignant mesothelioma

D. Scar

Testicular scars, particularly in patients presenting with metastatic disease and clinically inapparent testicular primaries, may represent regressed, "burnt-out" testicular germ cell tumors. Features that further favor such a diagnosis include associated intratubular calcifications, intratubular germ cell neoplasia unclassified (IGCNU), a lymphoplasmacytic infiltrate, hemosiderin-containing macrophages, and testicular atrophy. Scars with residual invasive tumors most likely represent partial regression of the tumor. In otherwise pure seminoma, such partial regression may have clinically important implications, since it is possible that some of these scars may represent regression of a non-seminomatous germ cell tumor component of the tumor.

E. Invasion of the Rete Testis, Hilar/Mediastinal Soft Tissue, Epididymis or Tunica Vaginalis

Tumors invading the tunica vaginalis (perforating the mesothelial lining) (Figure 1, Tumor A) are considered as stage pT2 by the American Joint Committee on Cancer (AJCC) TNM staging system. Invasion of rete testis or epididymis is not assigned a higher pT stage than that for a tumor limited to the testis. Rete testis invasion has been reported by some to be associated with higher risk of relapse in clinical stage I seminoma.[16] Hilar soft tissue invasion (Figure 1, Tumor B) is the predominant pathway of extratesticular extension for testicular tumors.[17] However, the issue of hilar soft tissue invasion has not been addressed by AJCC TNM, and its clinical significance also has not been studied well.

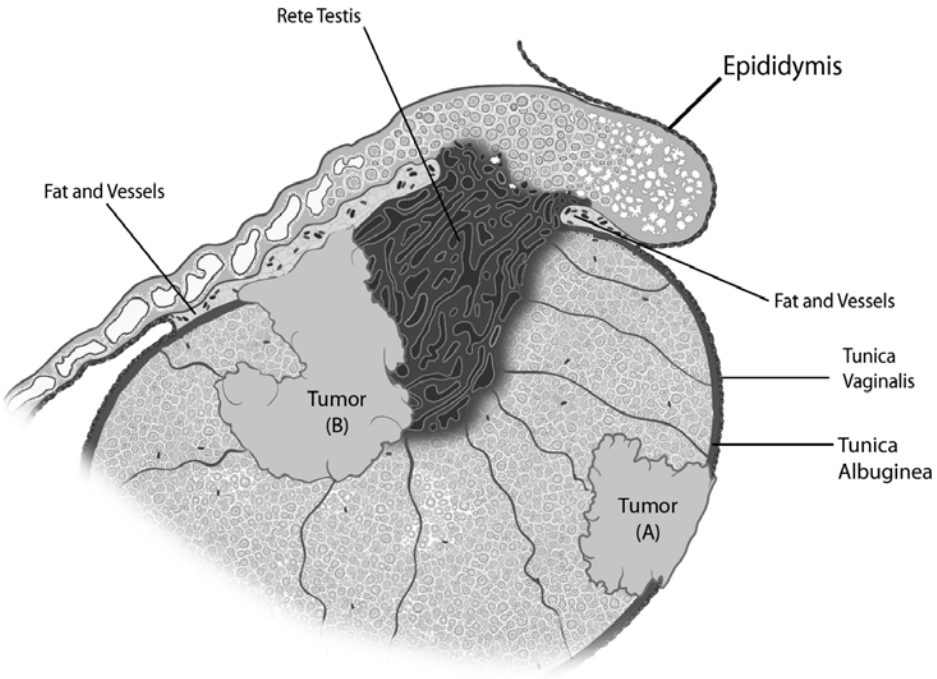

Figure 1. Diagrammatic representation of a tumor (Tumor A) invading tunica vaginalis, perforating through the mesothelium, and another tumor (Tumor B) partly involving the rete testis and invading the hilar soft tissue. Figure courtesy of Satish K. Tickoo, MD.

F. Venous/Lymphatic Vessel Invasion

In several studies, the presence of vascular space invasion (usually lymphatic but possibly also capillary or venous invasion) has been correlated with a significantly elevated risk for distant metastasis.[18-24] This observation, therefore, is most pertinent for patients who have clinical stage I disease, ie, those who have no evidence of spread beyond the testis by clinical examination (including radiographic and serum marker studies). Some clinicians manage the patients with clinical stage I disease who lack evidence of lymphatic or vascular invasion in their orchiectomy specimens (with possibly other favorable prognostic features, such as relatively small amounts of embryonal carcinoma) by close follow-up examinations rather than intervention.

The AJCC TNM staging system does not specifically address the issue of vascular invasion in the spermatic cord. While invasion of the cord is considered a pT3 stage, it would be logical to regard vascular invasion in the cord as pT2 stage, unless the tumor penetrates through the vessel wall into perivascular soft tissues of the cord.

G. Staging

The protocol recommends staging according to the American Joint Committee on Cancer (AJCC) and the International Union Against Cancer (UICC) TNM staging system.[25,26] Additional criteria for staging seminomas according to a modification of the Royal Marsden system are also recommended.[27] Some studies suggest that the staging of patients with seminoma by the TNM system is less meaningful therapeutically than staging by a modification of the Royal Marsden method.[25-27] Also, the data from a large Danish study of seminomas clinically limited to the testis do not support the conclusion

that local staging of the primary tumor, as performed in the TNM system, provides useful prognostic information; rather, the most valuable prognostic indicator was the size of the seminoma.[28] This protocol, therefore, encourages the use of the TNM system with optional use of the modified Royal Marsden staging system for patients with seminoma.

AJCC/UICC TNM and Stage Groupings

By AJCC/UICC convention, the designation "T" refers to a primary tumor that has not been previously treated. The symbol "p" refers to the pathologic classification of the TNM, as opposed to the clinical classification, and is based on gross and microscopic examination. pT entails a resection of the primary tumor or biopsy adequate to evaluate the highest pT category, pN entails removal of nodes adequate to validate lymph node metastasis, and pM implies microscopic examination of distant lesions. Clinical classification (cTNM) is usually carried out by the referring physician before treatment during initial evaluation of the patient or when pathologic classification is not possible.

Pathologic staging is usually performed after surgical resection of the primary tumor. Pathologic staging depends on pathologic documentation of the anatomic extent of disease, whether or not the primary tumor has been completely removed. If a biopsied tumor is not resected for any reason (eg, when technically unfeasible) and if the highest T and N categories or the M1 category of the tumor can be confirmed microscopically, the criteria for pathologic classification and staging have been satisfied without total removal of the primary cancer.

Anatomic Stage/Prognostic Groups

Group	T	N	M	S
Stage 0	pTis	N0	M0	S0
Stage I	pT1-4	N0	M0	SX
Stage IA	pT1	N0	M0	S0
Stage IB	pT2	N0	M0	S0
	pT3	N0	M0	S0
	pT4	N0	M0	S0
Stage IS	Any pT/TX	N0	M0	S1-3 (post-orchiectomy)
Stage II	Any pT/TX	N1,N2,N3	M0	SX
Stage IIA	Any pT/TX	N1	M0	S0
	Any pT/TX	N1	M0	S1
Stage IIB	Any pT/TX	N2	M0	S0
	Any pT/TX	N2	M0	S1
Stage IIC	Any pT/TX	N3	M0	S0
	Any pT/TX	N3	M0	S1
Stage III	Any pT/TX	Any N	M1	SX
Stage IIIA	Any pT/TX	Any N	M1a	S0
	Any pT/TX	Any N	M1a	S1
Stage IIIB	Any pT/TX	N1,N2,N3	M0	S2
	Any pT/TX	Any N	M1a	S2
Stage IIIC	Any pT/TX	N1,N2,N3	M0	S3
	Any pT/TX	Any N	M1a	S3
	Any T	Any N	M1b	Any S

TNM Descriptors
For identification of special cases of TNM or pTNM classifications, the “m” suffix and “y,” “r,” and “a” prefixes are used. Although they do not affect the stage grouping, they indicate cases needing separate analysis.

The “m” suffix indicates the presence of multiple primary tumors in a single site and is recorded in parentheses: pT(m)NM.

The “y” prefix indicates those cases in which classification is performed during or following initial multimodality therapy (ie, neoadjuvant chemotherapy, radiation therapy, or both chemotherapy and radiation therapy). The cTNM or pTNM category is identified by a “y” prefix. The ycTNM or ypTNM categorizes the extent of tumor actually present at the time of that examination. The “y” categorization is not an estimate of tumor prior to multimodality therapy (ie, before initiation of neoadjuvant therapy).

The “r” prefix indicates a recurrent tumor when staged after a documented disease-free interval, and is identified by the “r” prefix: rTNM.

The “a” prefix designates the stage determined at autopsy: aTNM.

Additional Descriptors

Residual Tumor (R)
Tumor remaining in a patient after therapy with curative intent (eg, surgical resection for cure) is categorized by a system known as R classification, shown below.

RX Presence of residual tumor cannot be assessed
R0 No residual tumor
R1 Microscopic residual tumor
R2 Macroscopic residual tumor

For the surgeon, the R classification may be useful to indicate the known or assumed status of the completeness of a surgical excision. For the pathologist, the R classification is relevant to the status of the margins of a surgical resection specimen. That is, tumor involving the resection margin on pathologic examination may be assumed to correspond to residual tumor in the patient and may be classified as macroscopic or microscopic according to the findings at the specimen margin(s).

Modified Royal Marsden Staging System

Stage I	Tumor confined to the testis	
Stage II	Infradiaphragmatic nodal involvement	
	IIA	greatest dimension of involved nodes less than 2 cm
	IIB	greatest dimension of involved nodes 2 cm or more but less than 5 cm
	IIC	greatest dimension of involved nodes 5 cm or more but less than 10 cm
	IID	greatest dimension of involved nodes 10 cm or more
Stage III	Supraclavicular or mediastinal involvement	
Stage IV	Extranodal metastases	

H. Additional Pathologic Findings

Important findings include Leydig cell-hyperplasia, which may be correlated with b-hCG elevation; scarring, the presence of hemosiderin-laden macrophages, and intratubular calcification, which may indicate regression of a tumor; testicular atrophy; and abnormal testicular development (eg, dysgenesis or androgen-insensitivity syndrome).[29,30]

I. Metastatic Tumor

Often the most important distinction in patients with metastatic testicular germ cell tumor following initial chemotherapy is the differentiation of metastatic residual teratoma from nonteratomatous types of germ cell tumor. Pure teratomatous metastasis is generally treated by surgical excision alone, whereas patients who have other residual germ cell tumor components are usually treated with additional chemotherapy.

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