Kidney

Protocol applies to all invasive carcinomas of renal tubular origin. It excludes Wilms tumors and tumors of urothelial origin.

Protocol revision date: January 2004
Based on AJCC/UICC TNM, 6th edition

Procedures

- **Incisional Biopsy (Needle or Wedge)**
- **Partial Nephrectomy**
- **Radical Nephrectomy**

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Surgical Pathology Cancer Case Summary (Checklist)

Protocol revision date: January 2004
Applies to invasive carcinomas only
Based on AJCC/UICC TNM, 6th edition

*KIDNEY: Biopsy

(Note: Use of checklist for biopsy specimens is optional)

*Patient name:
*Surgical pathology number:

Note: Check 1 response unless otherwise indicated.

***MACROSCOPIC**

***Specimen Type**
*___ Incisional biopsy, needle
*___ Incisional biopsy, wedge
*___ Other (specify): _____
*___ Not specified

***Laterality**
*___ Right
*___ Left
*___ Not specified

***MICROSCOPIC**

***Histologic Type**
*___ Cannot be determined
*___ Conventional (clear cell) renal carcinoma
*___ Papillary renal carcinoma
*___ Chromophobe renal carcinoma
*___ Collecting duct carcinoma
*___ Sarcomatoid carcinoma arising in renal cell carcinoma
(specify subtype): _____
*___ Renal cell carcinoma, unclassified
*___ Other (specify): _____
*___ Carcinoma, type cannot be determined

* Data elements ***with asterisks*** are ***not required*** for accreditation purposes for the Commission on Cancer. These elements may be clinically important, but are not yet validated or regularly used in patient management. Alternatively, the necessary data may not be available to the pathologist at the time of pathologic assessment of this specimen.

***Histologic Grade (Fuhrman Nuclear Grade)**
*___ Not applicable
*___ GX: Cannot be assessed
*___ G1: Nuclei round, uniform, approximately 10 µ; nucleoli inconspicuous or absent
*___ G2: Nuclei slightly irregular, approximately 15 µ; nucleoli evident
*___ G3: Nuclei very irregular, approximately 20 µ; nucleoli large and prominent
*___ G4: Nuclei bizarre and multilobated, 20 µ or greater, nucleoli prominent, chromatin clumped

***Additional Pathologic Findings (check all that apply)**
*___ None identified
*___ Inflammation (type): _____
*___ Glomerular disease (type): _____
*___ Interstitial disease (type): _____
*___ Other (specify): _____

***Comment(s)**

* Data elements ***with asterisks*** are ***not required*** for accreditation purposes for the Commission on Cancer. These elements may be clinically important, but are not yet validated or regularly used in patient management. Alternatively, the necessary data may not be available to the pathologist at the time of pathologic assessment of this specimen.

Surgical Pathology Cancer Case Summary (Checklist)

Protocol revision date: January 2004
Applies to invasive carcinomas only
Based on AJCC/UICC TNM, 6th edition

KIDNEY: Nephrectomy, Partial or Radical

Patient name:
Surgical pathology number:

Note: Check 1 response unless otherwise indicated.

MACROSCOPIC

Specimen Type
___ Partial nephrectomy
___ Radical nephrectomy
___ Other (specify): _____
___ Not specified

Laterality
___ Right
___ Left
___ Not specified

***Tumor Site (check all that apply)**
*___ Upper pole
*___ Middle
*___ Lower pole
*___ Other (specify): _____
*___ Not specified

Focality
___ Unifocal
___ Multifocal

Tumor Size (largest tumor if multiple)
Greatest dimension: ___ cm
*Additional dimensions: ___ x ___ cm
___ Cannot be determined (see Comment)

* Data elements ***with asterisks*** are ***not required*** for accreditation purposes for the Commission on Cancer. These elements may be clinically important, but are not yet validated or regularly used in patient management. Alternatively, the necessary data may not be available to the pathologist at the time of pathologic assessment of this specimen.

Macroscopic Extent of Tumor (check all that apply)
___ Tumor limited to kidney
___ Tumor extension into perinephric tissues
___ Tumor extension beyond Gerota's fascia
___ Tumor extension into adrenal
___ Tumor extension into major veins

MICROSCOPIC

Histologic Type
___ Clear cell (conventional) renal carcinoma
___ Papillary renal cell carcinoma
___ Chromophobe renal cell carcinoma
___ Collecting duct carcinoma
___ Sarcomatoid carcinoma arising in renal cell carcinoma
Specify: subtype _____ ; ___% of sarcomatoid element
___ Renal cell carcinoma, unclassified
___ Other (specify): _____
___ Carcinoma, type cannot be determined

Histologic Grade (Fuhrman Nuclear Grade)
___ Not applicable
___ GX: Cannot be assessed
___ G1: Nuclei round, uniform, approximately 10 µ; nucleoli inconspicuous or absent
___ G2: Nuclei slightly irregular, approximately 15 µ; nucleoli evident
___ G3: Nuclei very irregular, approximately 20 µ; nucleoli large and prominent
___ G4: Nuclei bizarre and multilobated, 20 µ or greater, nucleoli prominent, chromatin clumped
___ Other (specify): _____

* Data elements ***with asterisks*** are ***not required*** for accreditation purposes for the Commission on Cancer. These elements may be clinically important, but are not yet validated or regularly used in patient management. Alternatively, the necessary data may not be available to the pathologist at the time of pathologic assessment of this specimen.

Pathologic Staging (pTNM)

Primary Tumor (pT)
___ pTX: Primary tumor cannot be assessed
___ pT0: No evidence of primary tumor
pT1: Tumor 7 cm or less in greatest dimension, limited to the kidney
___ pT1a: Tumor 4 cm or less in greatest dimension, limited to the kidney
___ pT1b: Tumor more than 4 cm but not more than 7 cm in greatest dimension, limited to the kidney
___ pT2: Tumor more than 7 cm in greatest dimension, limited to the kidney
pT3: Tumor extends into major veins or invades adrenal gland or perinephric tissues but not beyond Gerota's fascia
___ pT3a: Tumor directly invades adrenal gland or perirenal and/or renal sinus fat but not beyond Gerota's fascia
___ pT3b: Tumor grossly extends into the renal vein or its segmental (muscle-containing) branches, or vena cava below the diaphragm
___ pT3c: Tumor grossly extends into vena cava above diaphragm or invades the wall of the vena cava
___ pT4: Tumor invades beyond Gerota's fascia

Regional Lymph Nodes (pN)
___ pNX: Cannot be assessed
___ pN0: No regional lymph node metastasis
___ pN1: Metastasis in a single regional lymph node
___ pN2: Metastasis in more than 1 regional lymph node
Specify: Number examined: ___
Number involved: ___

Distant Metastasis (pM)
___ pMX: Cannot be assessed
___ pM1: Distant metastasis
*Specify site(s), if known: _____

Margins (check all that apply)
___ Cannot be assessed
___ Margins uninvolved by invasive carcinoma
___ Margin(s) involved by invasive carcinoma
- ___ Renal capsular margin (partial nephrectomy only)
- ___ Perinephric fat margin (partial nephrectomy only)
- ___ Renal vein margin
- ___ Gerota's fascial margin
- ___ Ureteral margin
- ___ Renal parenchymal margin (partial nephrectomy only)
- ___ Other (specify): _____

* Data elements ***with asterisks*** are ***not required*** for accreditation purposes for the Commission on Cancer. These elements may be clinically important, but are not yet validated or regularly used in patient management. Alternatively, the necessary data may not be available to the pathologist at the time of pathologic assessment of this specimen.

Adrenal Gland
___ Not present
___ Uninvolved by tumor
___ Direct invasion (T3a)
___ Metastasis (M1)

***Venous (Large Vessel) Invasion (V)**
(excluding renal vein and inferior vena cava)
*___ Absent
*___ Present
*___ Indeterminate

***Lymphatic (Small Vessel) Invasion (L)**
*___ Absent
*___ Present
*___ Indeterminate

***Additional Pathologic Findings (check all that apply)**
*___ None identified
*___ Inflammation (type): _____
*___ Glomerular disease (type): _____
*___ Interstitial disease (type): _____
*___ Other (specify): _____

***Comment(s)**

Background Documentation

Protocol revision date: January 2004

I. Incisional Biopsy
(Needle or Wedge)

A. Clinical Information

1. Patient identification
   a. Name
   b. Identification number
   c. Age (birth date)
   d. Sex
2. Responsible physician(s)
3. Date of procedure
4. Other clinical information
   a. Relevant history (eg, previous diagnoses and treatment, family history of renal tumors)
   b. Relevant findings (eg, imaging studies)
   c. Clinical diagnosis
   d. Procedure (eg, needle biopsy)
   e. Anatomic site(s) of specimen (eg, left kidney)

B. Macroscopic Examination

1. Specimen
   a. Unfixed/fixed (specify fixative)
   b. Number of pieces
   c. Dimensions
   d. Descriptive features
   e. Orientation, if designated by surgeon
   f. Results of intraoperative consultation
2. Tissue submitted for microscopic evaluation, as appropriate
   a. Entire specimen
   b. Selected sample
   c. Frozen section tissue fragment(s) (unless saved for special studies)
3. Special studies (specify) (eg, histochemistry, immunohistochemistry, morphometry, cytogenetic analysis)

C. Microscopic Evaluation

1. Tumor
   a. Histologic type (if possible) (Note **A**)
   b. Histologic grade (Note **B**)
   c. Venous/lymphatic vessel invasion, if possible to determine
   d. Extracapsular extension, if possible to determine
2. Additional pathologic findings, if present
3. Result/status of special studies (specify)
4. Comments
   a. Correlation with intraoperative consultation, as appropriate
   b. Correlation with other specimens, as appropriate
   c. Correlation with clinical information, as appropriate

II. Partial Nephrectomy

A. Clinical Information

1. Patient identification
   a. Name
   b. Identification number
   c. Age (birth date)
   d. Sex
2. Responsible physician(s)
3. Date of procedure
4. Other clinical information
   a. Relevant history (eg, previous diagnoses and treatment, family history of renal tumors)
   b. Relevant findings (eg, imaging studies)
   c. Clinical diagnosis
   d. Procedure (Note **C**)
   e. Operative findings
   f. Anatomic site(s) of specimen (eg, left partial kidney, upper pole)

B. Macroscopic Examination

1. Specimen
   a. Organs/tissues included
   b. Unfixed/fixed (specify fixative)
   c. Type of specimen (Note **C**)
   d. Kidney size (3 dimensions)
   e. Weight
   f. Orientation, if indicated by surgeon
   g. Weight of adrenal gland, if present
   h. Presence or absence of the following:
      (1) renal capsule
      (2) perirenal fat
   i. Other organs/tissue(s) (weigh or measure, as appropriate)
   j. Results of intraoperative consultation
2. Tumor(s)
   a. Number
   b. Location
   c. Size(s) (Note **D**)
   d. Descriptive characteristics (eg, solid/cystic, color, consistency, necrosis)
   e. Extent of invasion (Note **D**)
   f. Venous/lymphatic vessel invasion
3. Margins
   a. Renal capsule
   b. Renal vessels
   c. Ureter
   d. Cut surface of kidney, if heminephrectomy
4. Regional lymph nodes (Notes **D** and **E**)
   a. Number
   b. Location, if possible (Note **E**)
5. Tissues submitted for microscopic evaluation
   a. Tumor (1 section for each centimeter of tumor diameter and/or different gross appearances)

   b. Non-neoplastic kidney (1 section minimum)
   c. Sections to document tumor extent
      (1) calyces, renal pelvis
      (2) perirenal tissue, including hilus
      (3) major blood vessels
   d. All lymph nodes
   e. Margins (all)
   f. Adrenal gland (1 section minimum)
   g. Frozen section tissue fragment(s) (unless saved for special studies)
   h. Other tissue(s) (as appropriate)
6. Special studies (specify) (eg, histochemistry, immunohistochemistry, morphometry, DNA analysis [specify type], cytogenetic analysis)

C. Microscopic Evaluation

1. Tumor
   a. Histologic type (Note **A**)
   b. Histologic grade (Note **B**)
   c. Extent of invasion (Note **D**)
   d. Venous/lymphatic vessel invasion (Note **D**)
2. Margins
   a. Renal capsule
   b. Renal vessels
   c. Ureter
   d. Cut surface of kidney, if heminephrectomy
3. Regional lymph nodes
   a. Number
   b. Number with metastasis[#] (Note **D**) (specify location, if possible)
      [#] *Measure largest involved node*
4. Metastasis to other organ(s) or structure(s) (specify site)
5. Additional pathologic findings, if present
6. Other tissue(s)/organ(s) (eg, adrenal gland)
7. Results/status of special studies (specify)
8. Comments
   a. Correlation with intraoperative consultation, as appropriate
   b. Correlation with other specimens, as appropriate
   c. Correlation with clinical information, as appropriate

III. Radical Nephrectomy

A. Clinical Information

1. Patient identification
   a. Name
   b. Identification number
   c. Age (birth date)
   d. Sex
2. Responsible physician(s)
3. Date of procedure
4. Other clinical information
   a. Relevant history (eg, previous diagnoses and treatment, family history of renal tumors)
   b. Relevant findings (eg, imaging studies)

c. Clinical diagnosis
d. Procedure (eg, radical nephrectomy, with adrenalectomy, vena cava thrombectomy and lympadenectomy) (Note **F**)
e. Operative findings
f. Anatomic site(s) of specimen (eg, left kidney)

B. Macroscopic Examination

1. Specimen
   a. Organ(s)/tissue(s) included (Note **F**)
   b. Unfixed/fixed (specify fixative)
   c. Description of perirenal fat/Gerota's fascia
   d. Weight of adrenal gland, if present
   e. Kidney size (3 dimensions)
   f. Weight
   g. Length of ureter
   h. Other submitted tissues (weigh or measure, as appropriate) (eg, venous tumor thrombus, specimens from other organs)
   i. Results of intraoperative consultation
2. Tumor(s)
   a. Number
   b. Location
   c. Size(s) (Note **D**)
   d. Descriptive characteristics (eg, solid/cystic, color, consistency, necrosis)
   e. Extent of invasion (Note **D**)
   f. Hilar invasion
   g. Renal vein invasion
3. Margins
   a. Gerota's fascia
   b. Renal vessels
   c. Ureter
4. Regional lymph nodes (Notes **D** and **E**)
   a. Number
   b. Location, if possible
5. Separately submitted tissues (specify)
6. Tissue submitted for microscopic evaluation
   a. Tumor (1 section for each centimeter of tumor diameter and/or different gross appearances)
   b. Uninvolved kidney (1 section minimum)
   c. Sections to document tumor extent
      (1) calyces, renal pelvis
      (2) ureter
      (3) perirenal tissues, including hilus and Gerota's fascia
      (4) renal vessels, including separately submitted tumor thrombus
   d. All lymph nodes
   e. Margins, as appropriate
   f. Adrenal gland (1 section minimum)
   g. Frozen section tissue fragment(s) (unless saved for special studies)
   h. Other tissue(s), as appropriate
7. Special studies (specify)

C. Microscopic Evaluation

1. Tumor
   a. Histologic type (Note **A**)
   b. Histologic grade (Note **B**)
   c. Extent of invasion (Note **D**)
   d. Venous/lymphatic vessel invasion
2. Margins
   a. Gerota's fascia
   b. Renal vessels
   c. Ureter
   d. Other(s), as appropriate
3. Regional lymph nodes
   a. Number (Note **D**)
   b. Number with metastasis[#] (specify location, if possible) (Note **D**)
      [#] *Measure largest involved node*
4. Metastasis to other organs(s) or structure(s) (specify site)
5. Additional pathologic findings, if present
6. Other tissue(s)/organs
7. Results/status of special studies (specify)
8. Comments
   a. Correlation with intraoperative consultation, as appropriate
   b. Correlation with other specimens, as appropriate
   c. Correlation with clinical information, as appropriate

Explanatory Notes

A. Histologic Type

The histopathologic classification most recently published by the American Joint Committee on Cancer (AJCC) and the International Union Against Cancer (UICC) is recommended and shown below.[1-3] However, the protocol does not preclude the use of other published classifications[4-11] which appear in the Armed Forces Institute of Pathology (AFIP) *Atlas of Tumor Pathology,* 3rd series, Fascicle 11, "Tumors of the Kidney, Bladder and Related Urinary Structures," as shown below.[4]

AJCC/UICC Histologic Classification of Renal Carcinoma

Conventional (clear cell) renal carcinoma
Papillary renal carcinoma
Chromophobe renal carcinoma
Collecting duct carcinoma
Renal cell carcinoma, unclassified

AFIP Histologic Classification of Renal Cell Carcinoma

Clear cell (hypernephroid) renal cell carcinoma
Granular renal cell carcinoma[#]
Papillary renal cell carcinoma
Chromophobe renal cell carcinoma
Collecting duct-type renal cell carcinoma
Sarcomatoid renal cell carcinoma[#,##]
Mixed-type renal cell carcinoma

Renal cell carcinoma, undifferentiated

[#] These histologic types of renal cell carcinoma are not included in the AJCC/UICC classification shown above because it is argued that they may not represent unique forms of differentiation. Abundant granular cytoplasm may occur in any of the following tumor types: oncocytoma, chromophobe renal cell carcinoma, papillary renal cell carcinoma, collecting duct carcinoma, and epithelioid angiomyolipoma.

[##] Sarcomatoid morphology may be manifested by any renal cell carcinoma (conventional, papillary, chromophobe, collecting duct or unclassified subtypes), as well as urothelial carcinoma of the renal pelvis, and may represent a progression in tumor grade. Recent studies have shown that percentage of sarcomatoid component in a renal cell carcinoma may be prognostically important.[12]

B. Histologic Grade

The following grading scheme for renal cell carcinoma developed by Fuhrman et al is recommended and shown below.[13] However, the protocol does not preclude the use of other grading schemes.[14-18] The system of grading should be specified in the pathologist's report.

Grade X	Cannot be assessed
Grade 1	Nuclei round, uniform, approximately 10 µm in diameter; nucleoli inconspicuous or absent
Grade 2	Nuclei slightly irregular, approximately 15 µm in diameter; nucleoli evident
Grade 3	Nuclei very irregular, approximately 20 µm in diameter; nucleoli large and prominent
Grade 4	Nuclei bizarre and multilobated, 20 µm or greater in diameter, nucleoli prominent, chromatin clumped.

C. Operative Procedures

A partial nephrectomy may vary from a simple enucleation of the tumor to a partial nephrectomy including variable portions of the calyceal or renal pelvic collecting system. The perirenal fat immediately overlying the resected portion of kidney but not to the level of Gerota's fascia is usually included.

D. TNM and Stage Groupings

The TNM staging system of the AJCC and UICC for renal cell carcinoma is recommended and shown below.[19,20]

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.

Primary Tumor (T)

TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
T1	Tumor 7 cm or less in greatest dimension, limited to the kidney
T1a	Tumor 4 cm or less in greatest dimension, limited to the kidney
T1b	Tumor more than 4 cm but not more than 7 cm in greatest dimension, limited to the kidney
T2	Tumor more than 7 cm in greatest dimension, limited to the kidney
T3	Tumor extends into major veins or invades adrenal gland or perinephric tissues but not beyond Gerota's fascia
T3a	Tumor directly invades adrenal gland or perirenal and/or renal sinus fat but not beyond Gerota's fascia
T3b	Tumor grossly extends into the renal vein or its segmental (muscle-containing) branches, or vena cava below the diaphragm
T3c	Tumor grossly extends into vena cava above diaphragm or invades the wall of the vena cava
T4	Tumor invades beyond Gerota's fascia

Note: Direct invasion of the adrenal gland, which is categorized as local extension, must be differentiated from metastatic tumor in the adrenal, which is categorized M1 (see below for Distant Metastasis).

Regional Lymph Nodes (N)[#] (see Note **E**)

NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in a single lymph node
N2	Metastasis in more than 1 regional lymph node

[#] Laterality does not affect the N classification.

Distant Metastasis (M)

MX	Distant metastasis cannot be assessed
M0	No distant metastasis
M1	Distant metastasis

Stage Groupings

Stage I	T1	N0	M0
Stage II	T2	N0	M0
Stage III	T1	N1	M0
	T2	N1	M0
	T3	N0	M0

	T3	N1	M0
	T3a	N0	M0
	T3a	N1	M0
	T3b	N0	M0
	T3b	N1	M0
	T3c	N0	M0
	T3c	N1	M0
Stage IV	T4	N0	M0
	T4	N1	M0
	Any T	N2	M0
	Any T	Any N	M1

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).

Vessel Invasion
By AJCC/UICC convention, vessel invasion (lymphatic or venous) does not affect the T category indicating local extent of tumor unless specifically included in the definition of a T category. In all other cases, lymphatic and venous invasion by tumor are coded separately as follows.

Lymphatic Vessel Invasion (L)
LX Lymphatic vessel invasion cannot be assessed
L0 No lymphatic vessel invasion
L1 Lymphatic vessel invasion

Venous Invasion (V)
VX Venous invasion cannot be assessed
V0 No venous invasion
V1 Microscopic venous invasion
V2 Macroscopic venous invasion

E. Lymph Nodes
Regional lymphadenectomy is not generally performed even with a radical nephrectomy. A few lymph nodes may be found in a nephrectomy specimen in the renal hilus around the major renal vessels. Other regional lymph nodes (eg, paracaval, para-aortic, and retroperitoneal) may be submitted separately.

F. Radical Nephrectomy
A standard radical nephrectomy specimen consists of the entire kidney, including the calyces, pelvis and a variable length of ureter. The adrenal gland is usually removed en bloc with the kidney. The entire perirenal fatty tissue is removed to the level of Gerota's fascia, a membranous structure that is similar to the consistency of the renal capsule, which encases the kidney and perirenal fat. Variable lengths of the major renal vessels at the hilus are submitted. Some lymph nodes may be present in the renal hilus.

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