Overview

Useful For
Monitoring for tumor recurrence in patients with a history of urothelial carcinoma involving the bladder or upper urinary tract

Assessing patients with hematuria for urothelial carcinoma

Special Instructions

- Pathology/Cytology Information

Method Name
Fluorescence In Situ Hybridization (FISH) Using DNA Probes

NY State Available
Yes

Specimen

Specimen Type
Varies

Necessary Information
1. Specimen source is required on request form (ie voided, catheterized, bladder washing).

2. Provide fixative, source, reason for referral (Evaluate for urothelial carcinoma or Hematuria.) and status of diagnosis (known previous diagnosis or suspected/unknown).

Specimen Required

Specimen Type: Urine

Sources: Voided urine, catheterized urine, bladder washings, stoma collections, ureteral brushings or washings, and renal pelvic brushings or washings

Supplies: FISH for Urothelial Carcinoma Urine Collection Kit (T509)

Container/Tube:

Preferred: FISH for Urothelial Carcinoma in Urocyte Urine Collection Kit (T509)

Acceptable: 70% ethanol, PreservCyt, CytoLyt

Specimen Volume: 30 mL

Collection Instructions:

1. Follow instructions included with Urocyte Urine Collection Kit.

2. If kit is not used, submit a random urine specimen with an equal volume of 70% ethanol, PreservCyt, or CytoLyt.
Forms
1. Pathology/Cytology Information (T707) in Special Instructions

2. If not ordering electronically, complete, print, and send an Oncology Test Request (T729) with the specimen.

Specimen Minimum Volume
30 mL is recommended, however, will not reject if <30 mL

Reject Due To
No specimen should be rejected.

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varies</td>
<td>Refrigerated (preferred)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Clinical and Interpretive

Clinical Information
Cystoscopy and urine cytology have been the primary methods for detecting urothelial carcinoma (UC). Unfortunately urine cytology has relatively poor sensitivity for the detection of recurrent UC. This is problematic because patients who have undetected recurrent tumors may have tumor progression that places them at increased risk of developing metastatic UC.

The UroVysion assay is a FISH assay for the detection of recurrent UC. The UroVysion probe set contains probes to the centromeres of chromosomes 3, 7, and 17, and a locus-specific probe to the 9p21 band (site of the P16 tumor suppressor gene). The UroVysion assay detects cells with chromosomal abnormalities that are consistent with a diagnosis of UC. Studies have shown that the assay has higher sensitivity than urine cytology but similar specificity for the detection of recurrent UC. The UroVysion assay also demonstrates higher specificity than the BTA-stat assay for recurrent UC.

Reference Values
An interpretive report will be provided.

Interpretation
Lower Tract Samples:

Abnormal: any specimen satisfying 1 of the following criteria:

- Four or more cells with gains of 2 or more chromosomes

- Ten or more cells with a gain of a single chromosome or 10 or more cells with tetrasomic signal patterns (ie, 4 copies for each of the 4 probes)

- Homozygous deletion of the 9p21 locus in 20% or more of the cells analyzed
For cases that are abnormal, the percentage of abnormal cells and type of chromosomal abnormality (ie, polysomy, trisomy, tetrasomy, or homozygous 9p21 deletion) are indicated in the test report.

Negative:
- Fewer than 4 cells with gains of 2 or more chromosomes
- Fewer than 10 cells with gain of a single chromosome or tetrasomy
- Less than 20% of cells with homozygous 9p21 deletion

Upper Tract Samples:
Abnormal: any upper tract specimen satisfying 1 of the following criteria:
- Four or more hypertetrasomy cells with at least 5 copies of 2 or more chromosomes
- Ten or more cells with a gain of a single chromosome or 10% or more cells with tetrasomic or near-tetrasomic signal patterns (ie, 4 copies for each of the 4 probes)
- Homozygous deletion of the 9p21 locus in 20% or more of the cells analyzed

Negative:
- Fewer than 4 cells with hypertetrasomy with at least 5 copies of 2 or more chromosomes
- Fewer than 10% of cells with tetrasomy
- Less than 20% of cells with homozygous 9p21 deletion

Cautions
Significant cell populations with chromosomal gains or homozygous 9p21 deletion indicate that the patient has a genitourinary malignancy, which is most frequently bladder cancer, or (much less likely) a metastatic involvement of the genitourinary tract. However, the patient may have another genitourinary malignancy (eg, renal pelvic or ureteral transitional cell carcinoma, prostatic carcinoma with urethral invasion, renal cell carcinoma, or metastatic cancer involving the genitourinary tract).

This assay is intended for detecting tumor and does not provide information on tumor stage.

Biopsy may help clarify the diagnosis and tumor stage.

Clinical Reference


Performance

Method Description
Urinary cells are harvested, fixed, and placed on a slide. The UroVysion probe set, which contains fluorescently labeled DNA probes specific to the centromeres of chromosomes 3, 7, 17, and to the 9p21 locus is hybridized to the cells on the slide. The slide is washed and counterstained with DAPI stain. Fluorescence microscopy with unique band filters is then used to scan the slide for atypical cells (e.g., cells with nuclear enlargement or irregularity). These cells are assessed for gains of chromosomes (3, 7, 17) or homozygous 9p21 deletion. If the number of cells with chromosomal gains (polysomy or trisomy) or homozygous 9p21 deletion observed on scanning is sufficient to consider the test result positive, the percentage of transitional cells with polysomy, trisomy, or homozygous 9p21 deletion is determined. (Halling KC, King W, Sokolova IA, et al: A comparison of cytology and fluorescence in situ hybridization for the detection of urothelial carcinoma. J Urol 2000;164:1768-1775; Sokolova IA, Halling KC, Jenkins RB, et al: The development of a multi-target, multi-color fluorescence in situ hybridization assay for the detection of urothelial carcinoma in urine. J Mol Diagn 2000;2:116-123)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday; 6 a.m.-8 p.m.
Saturday; 10 a.m.-6:30 p.m.
Sunday; 1 p.m.-9:30 p.m.

Analytic Time
4 days

Maximum Laboratory Time
7 days

Specimen Retention Time
Call Lab

Performing Laboratory Location
Rochester

Fees and Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification
This test has been modified from the manufacturer’s instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
88120

LOINC® Information
# Test Definition: FUROC

**UroVysion (R) for Bladder Cancer**

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FUROC</td>
<td>UroVysion (R) for Bladder Cancer</td>
<td>82251-0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>54674</td>
<td>Result Summary</td>
<td>50397-9</td>
</tr>
<tr>
<td>54675</td>
<td>Result</td>
<td>82251-0</td>
</tr>
<tr>
<td>54676</td>
<td>Interpretation</td>
<td>69047-9</td>
</tr>
<tr>
<td>54677</td>
<td>Reason for Referral</td>
<td>42349-1</td>
</tr>
<tr>
<td>54678</td>
<td>Specimen</td>
<td>31208-2</td>
</tr>
<tr>
<td>54679</td>
<td>Source</td>
<td>31208-2</td>
</tr>
<tr>
<td>54680</td>
<td>Released By</td>
<td>18771-6</td>
</tr>
</tbody>
</table>