MAYO CLINIC LABORATORIES

Test Definition: FUROC

UroVysion for Detection of Bladder Cancer, Urine

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, 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

Acceptable: 70% ethanol, PreservCyt, CytoLyt, ThinPrep UroCyte (UroCyte PreservCyt Solution)

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

Specimen Minimum Volume

See Specimen Required

Reject Due To

Unfixed specimens 48 hours after collection	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Ambient		
	Refrigerated (preferred)		

Clinical & 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 fluorescence in situ hybridization (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 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 tumors and does not provide information on tumor stage.

Biopsy may help clarify the diagnosis and tumor stage.

Clinical Reference

1. Halling KC, Kipp BR. Bladder cancer detection using FISH (UroVysion assay). Adv Anat Pathol. 2008:15(5):279-286. doi:10.1097/PAP.0b013e3181832320
2. Gayed BA, Seideman C, Lotan Y. Cost-effectiveness of fluorescence in situ hybridization in patients with atypical cytology for the detection of urothelial carcinoma. J Urol. 2013;190(4):1181-1186. doi:10.1016/j.juro.2013.03.117

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 4',6-diamidino-2'-phenylindole dihydrochloride (DAPI) stain. Fluorescence microscopy with unique band filters is then used to scan the slide for atypical cells (eg, 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 multitarget, multicolor fluorescence in situ hybridization assay for the detection of urothelial carcinoma in urine. J Mol Diagn. 2000;2(3):116-123. doi:10.1016/S1525-1578(10)60625-3)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

7 to 10 days

Specimen Retention Time

Processed samples: Normal: 1 year; Abnormal: Indefinitely

Performing Laboratory Location

Rochester

Fees & 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 account representative. 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 US Food and Drug Administration.

CPT Code Information

88120

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LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
FUROC	UroVysion (R) for Bladder Cancer	82251-0

Result ID	Test Result Name	Result LOINC® Value
54674	Result Summary	50397-9
54675	Result	82251-0
54676	Interpretation	69047-9
54677	Reason for Referral	42349-1
54678	Specimen	31208-2
54679	Source	31208-2
54680	Released By	18771-6