

UroVysion FISH for Urothelial Carcinoma

Urothelial carcinoma shows a high recurrence rate; therefore, ongoing, lifelong surveillance is necessary. Bladder cancer can be identified by enumerating morphologically abnormal cells with aneuploidy of chromosomes 3, 7, 17, or by the loss of both chromosomal 9p21 segments.

Molecular testing can be used in conjunction with other standard procedures for diagnosis or to monitor patients for recurrence of urothelial carcinoma. Compared with cystoscopy, molecular testing is noninvasive. The UroVysion FISH test is designed to detect chromosomal abnormalities associated with urothelial cell carcinoma in voided urine specimens.

Disease Overview

Incidence

The following are the estimated numbers of new urinary system cancer cases in the United States per year¹:

- Urinary bladder cancer: ~81,400
- Kidney and renal pelvis: ~73,750
- Ureter and other urinary organs : ~3,970

Symptoms

Two primary symptoms associated with urothelial carcinoma are²:

- Hematuria
- Irritative voiding

Screening/Diagnosis Issues

Individuals complaining of mild hematuria are traditionally tested for the presence of neoplastic lesions with the following tests:

- Cytology²
 - More sensitive to high-grade lesions
 - May miss low-grade papillary tumors
- Cystoscopy³
 - Can detect low-grade papillary tumors

Genetics

Variants

- Amplification of chromosomes 3, 7, 17
- Deletion of the 9p21 locus

Tests to Consider

UroVysion FISH 2001181

Method: Fluorescence in situ Hybridization/Computer Assisted Analysis/Microscopy

- May aid in diagnosis of urothelial carcinoma in individuals with hematuria
- Use to monitor for tumor recurrence in patients previously diagnosed with urothelial carcinoma
- Use to detect amplification of chromosomes 3, 7, 17, and deletion of the 9p21 locus

Related Tests

Cytology, Non-Gynecologic 2000623

Method: Microscopy

Bladder Tumor Associated Antigen 2000183

Method: Qualitative Immunoassay

- Aids in management of patients with bladder cancer in conjunction with cystoscopy
- Qualitative assay detects bladder tumor-associated antigen in urine of patients diagnosed with bladder cancer

Test Interpretation

Sensitivity/Specificity

- Clinical sensitivity: 68-81%
- Clinical specificity: 79-96%

Results

Result	Laboratory Finding
Positive	Detection of ≥ 1 of the following numeric chromosomal abnormalities commonly associated with urothelial carcinoma ^a : <ul style="list-style-type: none">• ≥ 4 cells show gains for ≥ 2 chromosomes (3, 7, or 17) in the same cell• ≥ 12 cells have no 9p21 signals
Negative	Lack of evidence for the presence of numeric chromosomal abnormalities commonly associated with urothelial carcinoma within the cells collected in specimen

^aIn the absence of clinical documentation of urothelial carcinoma within the bladder, a positive result suggests the possibility of urothelial carcinoma or other urologic malignancy in the ureter, urethra, kidney, or prostate. Further clinical evaluation to exclude these tissues as a source of abnormal cells is recommended.

Source: Abbott, 2014⁴

Limitations

- Some urothelial cancers will not be detected
- Negative results in the presence of other symptoms/signs of urothelial carcinoma may suggest possibility of false-negative test result
- Gene variants or defects other than amplification of chromosomes 3, 7, or 17, and deletion (loss) of 9p21 locus are not detected

References

1. American Cancer Society. [Cancer Statistics Center](#). [Accessed: Apr 2020]
2. Chang SS, Boorjian SA, Chou R, et al. [Diagnosis and treatment of non-muscle invasive bladder cancer: AUA/SUO guideline](#). J Urol. 2016;196(4):1021-1029.
3. National Comprehensive Cancer Network. [NCCN Clinical Practice Guidelines in Oncology, bladder cancer](#), version 3.2020. [Published: Jan 2020; Accessed: Mar 2020]
4. Abbott Molecular. [UroVysion Bladder Cancer Kit](#) [package insert]. [Updated: Aug 2014; Accessed: Apr 2020]

Related Information

[Bladder Cancer](#)

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