



LINCOLN DIAGNOSTICS
PATHOLOGY/MOLECULAR/ONCOLOGY

UroVysion



Test for the detection of bladder cancer...



UroVysion — **FLUORESCENT *IN SITU* HYBRIDIZATION (FISH)
FOR THE DETECTION OF BLADDER CANCER**

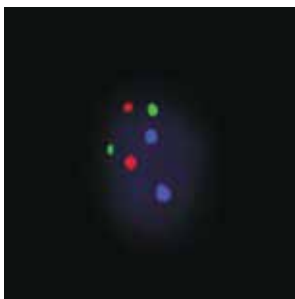
UroVysion - Fluorescent *in situ* hybridization (FISH) for the detection of bladder cancer

UroVysion

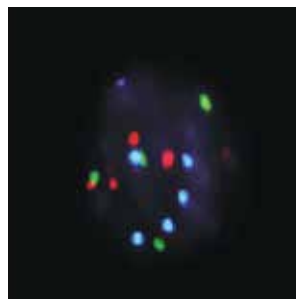
- Bladder cancer accounts for about 5% of all new cases in the US. Males are three to four times more likely to develop bladder cancer than females.
- Approximately 70% of all bladder cancers are non-muscle invasive, low-grade urothelial cell carcinomas (UCCs) at initial presentation and are conservatively managed.
- In about 5 to 20% of patients, bladder cancer can recur with a possibility of grade and stage progression to muscle invasive disease.
- Aneuploidy and structural chromosomal abnormalities (deletions and gains) are strongly associated with the stage and grade of bladder cancer.
- UroVysion™ is a highly sensitive and specific test used to diagnose urothelial carcinoma in urine. UroVysion has been approved by the FDA for both monitoring of patients with a history of bladder cancer and for detection in patients with hematuria.

Intended Use

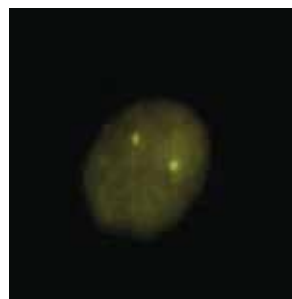
The **UroVysion Bladder Cancer Kit (UroVysion Kit)** is designed to detect aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens from persons with hematuria suspected of having bladder cancer. Results from the UroVysion Kit are intended for use, in conjunction with and not in lieu of current standard diagnostic procedures, as an aid for initial diagnosis of bladder carcinoma, in patients with hematuria and subsequent monitoring for tumor recurrence in patients previously diagnosed with bladder cancer.



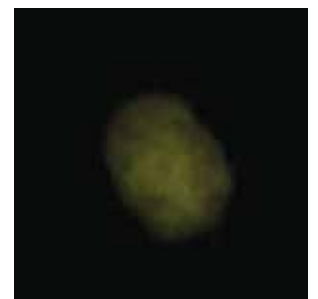
NORMAL



ABNORMAL
ANEUPLOIDY



NORMAL



ABNORMAL
LOSS OF GOLD 9p21

Methodology

Fluorescence in situ hybridization (FISH) is performed using the UroVysion™ Bladder Cancer Kit. The UroVysion assay is designed to detect aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens from persons with hematuria suspected of having bladder cancer.

Result Reported:

Negative: No evidence of numeric chromosomal aberrations associated with urothelial carcinoma.

Positive: Numeric chromosomal aberrations associated with urothelial carcinoma detected.

Interpretive Information

A positive result is consistent with a diagnosis of bladder cancer or bladder cancer recurrence, either in the bladder or in another site within the urinary system. A negative result is suggestive of the absence of bladder cancer but does not rule it out.

Results provided from this assay are intended for use, in conjunction with current standard diagnostic procedures, as an aid for initial diagnosis of bladder carcinoma in patients with hematuria, and subsequent monitoring for tumor recurrence in patients previously diagnosed with bladder cancer.

Summary and Explanation

An estimated 70,530 new cases of urinary bladder cancer will be diagnosed in the United States (52,810 men and 18,170 women) in 2010. Bladder cancer, the fourth most common cancer, is 3 times more common in men than in women in the United States. During the same period, approximately 14,680 deaths (10,410 men and 4,270 women) from bladder cancer are anticipated.¹ Bladder cancers are rarely diagnosed in individuals younger than forty.

Because the median age of diagnosis is 65, medical comorbidities are a frequent consideration in patient management. 90% of all bladder cancer cases are classified as transitional cell carcinomas (TCC), while the remaining 10% are predominantly squamous cell or adenocarcinomas.

There are 4 clinically relevant subgroups of TCC, as defined by pathologic staging: carcinoma in situ (pTIS), non-invasive papillary TCC (pTa), minimally invasive TCC (pT1), and muscle invasive tumors (pT2-pT4). Each subgroup differs in the clinical outcome.

At presentation, 75% of tumors are "superficial" (i.e. pTa, pT1 or pTIS), of which 50 to 80% will have one or several recurrences, and 15 to 25% will progress to invasive tumors.

For this reason, patients with "superficial" bladder cancer are regularly monitored for tumor recurrence and progression with cystoscopy and sometimes urine cytology. Cystoscopy examination of the bladder, and often urine cytology, are also standard care for patients over 40 years of age and presenting with hematuria.

A number of studies, however, have demonstrated that urine cytology has a disappointingly low sensitivity for bladder cancer detection, and improved laboratory tests for bladder cancer detection are needed. Recent studies have demonstrated that FISH analysis for aneuploidy of specific chromosomes may be useful to aid in the detection of bladder cancer.

Lincoln Diagnostics Lab UroVysion FISH assay offers:

Turnaround time of 3-5 business days
Our highly qualified staff is accessible for consultation and assistance
Broad coverage by most private and public insurances

**TEST ORDERING
CODE**

88121

Specimen Requirements:

Urine Volume 33 mL; urine mixed with 17 mL preservative (PreserveCyt) in Urine Collection/Cytology kit Container

1. Use the large open cup in the kit to collect the urine specimen. Second void of the day is preferred.
2. Slowly pour the urine into the two smaller PreserveCyt containers to the maximum fill.
3. Tighten the lid until you hear a click in order to prevent leakage.

Specimen Stability:

1. Specimen without preservative - up to 24 hours post collection refrigerated at 2°C to 8°C.
2. Specimen with preservative (PreserveCyt) - up to 72 hours post collection refrigerated at 2°C to 8°C.

Rejection Criteria

1. Insufficient specimen quantity (less than 33ml).
2. Specimens collected in incorrect fixative, shown significant contamination with blood obscuring bacterial overgrowth and inadequate specimen cellularity.

Specimen Shipping Instructions

Specimens should be refrigerated at 2°C to 8°C and shipped with ice packs. Do not freeze.

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Report Sample



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Case Details

Doctor		Patient:	JOHN DOE	Specimen:	Urine
Acct#:	0000	DOB:	Dec.15,1950	Date of Report:	Apr.27, 2017
P:	000-000-0000	Age:	67	Date Collected:	Apr.23, 2017
F:	000-000-0000	Sex:	Male	Date Received:	Apr.23, 2017
Address:		Surgical #:	8	Source:	Urine
Patient ID:	000	Patient Address:		Clinical Info:	Hematuria

Molecular Pathology Report

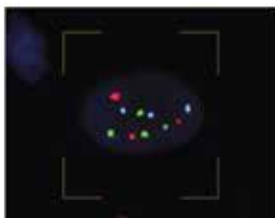
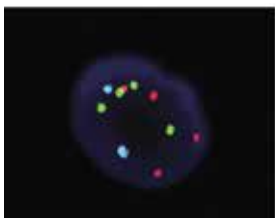
Urovysion FISH Specimen Source:	Urine
Clinical History:	Bladder Cancer
FISH Probes:	CEP 3, 7, 17 and LSI 9p21
Interphase Nuclei Scored:	251

Results

Results: Positive

Pattern	Target numbers	%	Comments
(1) Normal	78	52.0	
(2) 0_Gd	6	4.0	
(3) single_gain	17	11.3	
(4) Abnormal	49	32.7	
(8) Further_review	0	0	

Total: 150



FISH Interpretation

The Urovysion Bladder Cancer Kit is an FDA approved Fluorescence In Situ Hybridization (FISH) test used to detect aneuploidy of chromosomes 3,7 and 17 and loss of chromosome 9p21 locus in voided urine specimens from patients with hematuria suspected of having bladder cancer. Assessment of ploidy status was performed using an automated FISH signal scanning system BioView-Duet. A positive/abnormal result requires 4 or more cells to show gain for 2 or more chromosomes (3,7 and 17) in the same cell, or more to have zero 9p21 signals.

Results obtained using the UroVysion kit are intended for use in conjunction with other diagnostic tests, as an aid both in initial diagnosis of bladder cancer as well as for monitoring tumor recurrence in patients previously diagnosed with bladder cancer. The performance characteristics of this test have been verified at Lincoln Labs and the test is used for clinical purposes.

LABORATORY DIRECTOR



UroVysion



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