

# Oncology

## UroVysion®

### Bladder Cancer Screen by Fluorescence *in situ* Hybridization

The UroVysion Bladder Cancer Kit is designed to detect aneuploidy for chromosomes 3, 7, 17, and loss or deletion of the 9p21 locus via fluorescence *in situ* hybridization (FISH).

The test is performed on urine specimens from individuals with hematuria or atypical cell morphology suspected of having bladder cancer, or on urine from patients previously diagnosed with bladder cancer.

UroVysion is a non-invasive method to aid in the initial diagnosis of bladder cancer and in the early detection of tumor recurrence in patients previously diagnosed with bladder cancer. Results of the UroVysion assay should be interpreted in conjunction with standard diagnostic procedures.

### Advantages of UroVysion

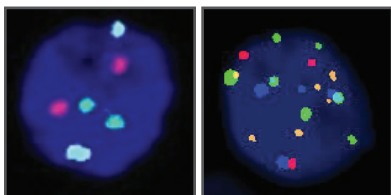
The Vysis® UroVysion Bladder Cancer Recurrence Kit enumerates specific chromosome regions to detect cancer-associated genetic changes.

UroVysion provides information that is complementary to results obtained by cystoscopy.

Direct analysis of cytogenetic changes reduces subjectivity in the interpretation of test results.

Less subjectivity affords more accurate monitoring of bladder cancer.

More accurate monitoring provides more information for therapeutic decisions.



Normal (left) and abnormal (right) interphase cells obtained after the Vysis UroVysion probe hybridization.

### UroVysion Kit

**The first molecular cytogenetic test** for monitoring the recurrence of bladder cancer. Utilizes DNA probes and Vysis' proprietary fluorescence DNA probe technology.

**Non-invasive** - Cells for analysis are harvested from voided urine. As few as four cells with certain genetic changes identified by the UroVysion Kit can be indicative of bladder cancer recurrence.

**Highly sensitive** for the detection of higher stage, higher grade bladder cancer tumors (100% sensitive for stage T2 and Tis tumors). The UroVysion Kit also detects lower stage, low grade tumors (94% sensitive for grade 3 tumors). High sensitivity means few false negatives.

**Highly specific** for cancer cells. In 275 patients (59 normal volunteers and 216 non-healthy subjects), the UroVysion Kit showed 94.5% specificity. In healthy volunteers (smokers and non-smokers over age 50), the specificity was 100%. High specificity means fewer false positive results.

**Results unaffected** by Bacillus Calmette-Guérin (BCG) intravesical therapy.

**Readily reimbursed** by private and public payers.

### Comparison of UroVysion to Conventional Urine Cytology Tests

UroVysion detects abnormalities in chromosome copy number that can occur independent of significant changes in cell morphology, making it more sensitive than conventional urine cytology. Both tests look for cancer cells that have been shed into the urine, but UroVysion identifies potential cancer cells by specific cytogenetic changes.

#### UroVysion helps identify the presence of the following:

*in situ* tumors that lie flat against the bladder wall

Transitional Cell Carcinomas (TCCs)

Suspected tumor sites in patients receiving BCG immunotherapy (Often, the inflammation caused by BCG immunotherapy may mask or make it difficult to visualize a tumor. UroVysion can help clinicians determine whether or not a site is cancerous.)

Other urinary tract related cancers beyond the view of the cystoscope, including ureter, urethra, renal or prostate, and indicates that additional follow up is warranted.



## Sensitivity

The following data tables from the clinical trials for the UroVysion Kit compare its sensitivity to urine cytology sensitivity for various stages and grades of bladder cancer (Tables 1 and 2):

Table 1 - Sensitivity ( % ) by Stage		
Stage	UroVysion Kit	Urine Cytology
TaG1	55%	20%
TaG2,3	83%	33%
T1	83%	67%
T2	100%	33%
Tis	100%	33%

Table 2 - Sensitivity ( % ) by Grade		
Grade	UroVysion Kit	Urine Cytology
1	55%	18%
2	78%	44%
3	94%	41%

## Specimen Requirements

50 mL. (min. 35 mL) of voided urine or bladder washings in the collection cup. Add PreservCyt® at a 2:1 ratio of urine. Specimen is stable for 48 hours at 2-8° C.

## CPT Codes

88367 x4

## Turnaround Time

5-7 days

## Test Code

FURO

For more information, contact your local representative or call MPLN client services at 800.932.2943.

## About MPLN

Since 1989, Molecular Pathology Laboratory Network, Inc. (MPLN) has offered an expanding selection of tests in molecular oncology, infectious diseases and human genetics to hospitals, medical laboratories and private physician groups nationwide.

Headquartered in Maryville, Tennessee, MPLN is a fully-licensed laboratory, certified by the Clinical Laboratory Improvement Amendment, accredited by the College of American Pathologists, and licensed in the states of Tennessee, Florida, New York and Maryland.

At MPLN, our philosophy is simple - we build strong professional relationships, deliver personalized service, and offer advanced diagnostic technology to support high-quality patient care.

## References

1. Phillips and Richardson (2006). Aneuploidy in bladder cancers: the utility of fluorescent in situ hybridization in clinical practice BJU Inter 98:33-37.
2. Sarosdy et al. (2006). Use of a multi-target fluorescence in situ hybridization assay to diagnose bladder cancer in patients with hematuria 176:44-47.

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