



# UROVYSION<sup>®</sup>

## FOR RESULTS BEYOND THE SCOPE

UroVysion brings **greater insights during bladder cancer patients' monitoring:**

- **Positive UroVysion results** may predict response to Bacillus Calmette-Guerin (BCG) therapy
- **Negative UroVysion results** confer high Negative Predictive Value (NPV)

UROVYSION HAS NO INTERFERENCE WITH BCG and 30 other possible urine constituents, microbial contaminants, preservatives and therapeutic agents.<sup>1</sup>

This gives you the confidence in the effectiveness of the treatment plans.

UroVysion can be used to allow early identification of patients with NMIBC\* who might be at high risk for tumor recurrence and progression so that alternative therapy may be offered while the potential for cure is high.<sup>2</sup>

\*NMIBC — non-muscle invasive bladder cancer



**SENSITIVITY**

**92.3%**<sup>1</sup>

**NEGATIVE  
PREDICTIVE VALUE**

**94.1%**<sup>1</sup>

1. UroVysion Package Insert 30-608385/R7.

2. Kamat AM, Dickstein RJ, et al. *J of Urology*, 2012 Mar;183:870-875. Bar charts reprinted with permission from Elsevier.

**For In Vitro Diagnostic Use Only**

#### 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.

#### Limitations:

The UroVysion Kit has been optimized for identifying and quantitating chromosomes 3, 7, and 17, and locus 9p21 in human urine specimens. The performance of the UroVysion Kit was validated using the procedures provided in the package insert only. Modifications to these procedures may alter the performance of the assay. UroVysion assay results may not be informative if the specimen quality and/or specimen slide preparation is inadequate, e.g., the presence of excessive granulocytes or massive bacteriuria. Technologists performing the UroVysion signal enumeration must be capable of visually distinguishing between the red and green signals.

(Limitations can't on reverse)

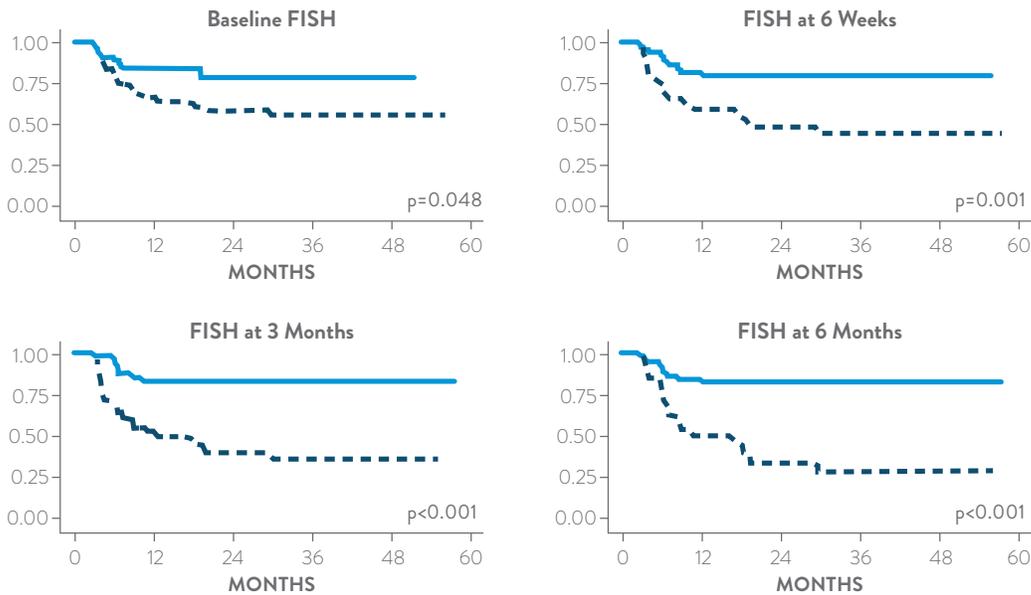
# UROVYSION PREDICTS TUMOR RECURRENCE AND PROGRESSION DURING BCG THERAPY

Knowing a tumor is likely to recur directly affects your treatment plan.

## PATIENTS WITH POSITIVE RESULTS ARE 3 TO 5 TIMES MORE LIKELY TO HAVE TUMOR RECURRENCE AND 5 TO 13 TIMES MORE LIKELY TO HAVE DISEASE PROGRESSION THAN THOSE WITH NEGATIVE RESULTS<sup>2</sup>

This is supported by the findings of an independent study, in which non-muscle invasive bladder cancer (NMIBC) patients were undergoing BCG therapy:

- A positive UroVysion result predicted tumor recurrence at all points
- The risk of recurrence increased with each positive result
- The change from a negative to a positive result was associated with a higher risk of recurrence



### The UroVysion Advantage

#### UROVYSION SEES BEYOND THE SCOPE

UroVysion is not affected by the inflamed lining of the bladder due to BCG therapy that makes cystoscopy more difficult.

2. Kamat AM, Dickstein RJ, et al. *J of Urology*, 2012 Mar;183:870-875. Bar charts reprinted with permission from Elsevier.

## Providing insight throughout the clinical pathway

For additional information please call your Abbott Molecular Sales Representative or visit the [urovysion-bladder-cancer-kit](http://urovysion-bladder-cancer-kit) and [urovysion-bladder-cancer-kit/additional-urovysion-information](http://urovysion-bladder-cancer-kit/additional-urovysion-information) pages at [molecular.abbott](http://molecular.abbott).

#### Limitations (con't)

Positive UroVysion results in the absence of other signs or symptoms of bladder cancer recurrence may be evidence of other urinary tract related cancers, e.g., urethra, renal, and/or prostate in males, and further patient follow-up is justified. In a study conducted on patients with hematuria, 3 patients whose initial bladder cystoscopy was negative, were subsequently diagnosed with renal cancer within 6 months of this initial visit. All 3 of these cases were positive by UroVysion. If UroVysion results are negative but standard clinical or diagnostic tests (e.g., cytology, cystoscopy) are positive, the standard procedures take precedence over the UroVysion test. Although the UroVysion kit was designed to detect genetic changes associated with most bladder cancers, there will be some bladder cancers whose genetic changes cannot be detected by the UroVysion test. Ta stage solitary tumors smaller than 5mm could not be detected by UroVysion FISH. UroVysion FISH results are dependent on the amount of tumor cells that are deposited on the slide.

#### Rx Only

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