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UroVysion®

FOR RESULTS YOU CAN TRUST

UroVysion Bladder Cancer Kit (UroVysion Kit) is the **only FDA approved and CE marked urine-based test that uses DNA probes** to identify chromosomal abnormalities associated with bladder cancer.

The UroVysion Kit is designed to detect aneuploidy for chromosomes 3, 7, 17 and loss of the 9p21 locus via fluorescence in situ hybridization (FISH).[1]

- **9p21 deletion** is a common genetic alteration in pTa tumors[3]
- **Loss of 9p21** is thought to occur early in the development of papillary and flat urothelial neoplasia[2]
- **Homozygous loss of 9p21 probe was detected in 3-8%** of bladder cancer cases tested in UroVysion clinical trials[3]

Cystoscopy and cytology are the standard of care for diagnosis and surveillance of bladder cancer, but may lead to uncertain results.

CYSTOSCOPY OR CYTOLOGY ALONE	UROVYSION CAN...
Relies on visible morphological tumor changes	**Detect abnormalities and molecular changes *before* a tumor is visible**
Has limited sensitivity in detecting bladder cancer	**Have greater sensitivity than cytology alone as shown in studies[3]**
May have difficulty detecting CIS tumors in the bladder lining	**Is 100% sensitive in detecting CIS tumors as shown in studies[4]**
Therapeutic agents (such as Bacillus Calmette-Guerin [BCG]) may mask results	**No interference from BCG and 30 other possible urine constituents, microbial contaminants, preservatives and therapeutic agents[1]**
A BCG-inflamed bladder lining often impairs detection with cystoscopy	**Even during BCG therapy, UroVysion detects early stage of chromosomal abnormalities that have not progressed to a visible tumor**
Unable to predict if tumors will recur during BCG therapy	**Predict tumors recurring during BCG therapy as shown in studies[5]**
Cystoscopy has a false negative rate of 10%-30%[6]	**Delivers high Negative Predictive Value (NPV) in both diagnosis (95.3%) and during BCG treatment (94.1%) [1]**

1. UroVysion Package Insert 30-608385/R7.
2. Baudenderf, Acta Cytologica, 2011 and he references Knowles MA, Scand. *J of Urology*, Nephrol Suppl, 2008.
3. Abbott Data on File.
4. Halling KC, et al. *J of Urology*, November 2000, Vol. 164, Issue 5, Pages 1768-1775.
5. Kamat AM, Dickstein RJ, et al. *J of Urology*, 2012 Mar 183: 870-875.
6. Lotan Y, et al. *J of Urology*, June 2008. Vol.179, 2164-2169.

For *In Vitro* Diagnostic Use Only

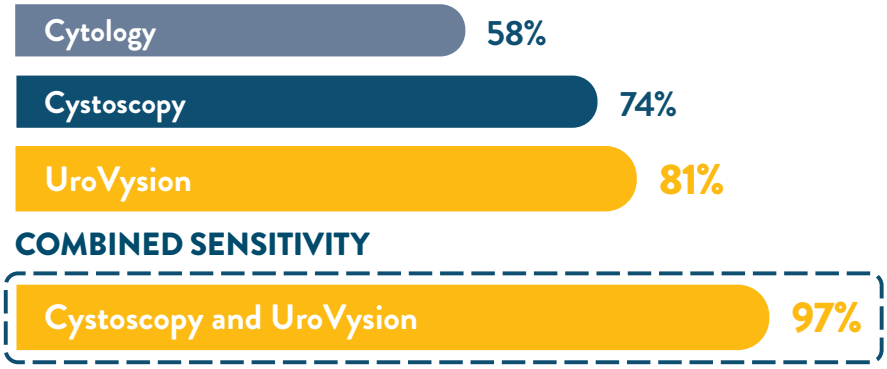
INTENDED USE:
The UroVysion Bladder Cancer Kit (UroVysion Kit) is designed to detect aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens from persons with hematuria suspected of having bladder cancer. Results from the UroVysion 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 con't on reverse)

INCREASE THE SENSITIVITY OF BLADDER CANCER DETECTION WITH UROVYSION

Combining UroVysion with cystoscopy makes detection significantly more sensitive.[4]



In addition UroVysion demonstrates 100% sensitivity for carcinoma in situ (CIS)

(Sensitivity for cystoscopy alone and UroVysion plus cystoscopy was computed from primary data presented in Table 1 of Halling KC, et al. *J of Urology*, November 2000, Vol. 164, Issue 5, Page 1770)

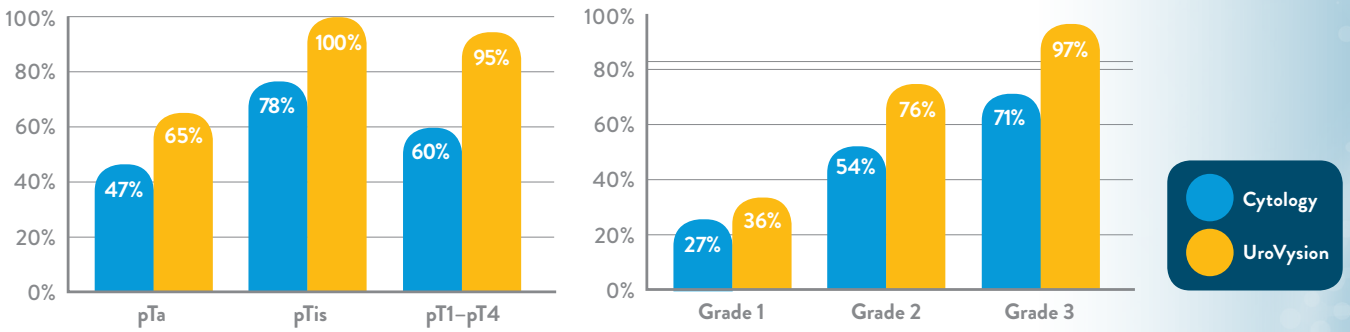
The UroVysion Advantage

USE UROVYSION TO PROVIDE EARLIER INSIGHT

For more confident and timely treatment decisions.

UROVYSION OUTPERFORMED CONVENTIONAL CYTOLOGY IN ALL STAGES AND GRADES FOR DETECTING MALIGNANCY

Greater sensitivity across every stage, every grade[4,7]



In a comparison trial, FISH outperformed cytology for detecting urothelial cancer across all tumor stages and grades. This study considered suspicious cytology results as positive and equivocal results as negative.[4]

4. Halling KC, et al. *J of Urology*, November 2000, Vol. 164, Issue 5, Pages 1768-1775.
7. Sarosdy MF, Kahn PR, Ziffer MD, et al. *J of Urology*, 2006 Jul 176 (1): 44-47.

For additional information please call your Abbott Molecular Sales Representative or visit the urovysion-bladder-cancer-kit and urovysion-bladder-cancer-kit/additional-urovysion-information pages at **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 then 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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