Abbott

UroVysion®

THE POWER OF DEFINITE RESULTS

When the standard of care gets ambiguous test results, it's hard to determine the best course of treatment.

Gayed et al.[1] combined data from two large prospective studies—Lotan et al.[2] and Schlomer et al.[3]—involving 263 patients and concluded that the decision to biopsy patients based on the UroVysion assay in patients with atypical cytology and equivocal or negative cystoscopy was associated with a significant decrease in bladder cancer associated costs.

THE VALUE OF UROVYSION

DECREASE IN BIOPSIES	DECREASE IN PATIENT COST*
EQUIVOCAL CYSTOSCOPY + ATYPICAL CYTOLOGY 68%	11%–53%
NEGATIVE CYSTOSCOPY + ATYPICAL CYTOLOGY 83%	26%–69%

* In-office (lower benefit) or operating room (higher benefit) procedure

1. Gayed BA, et al. *J of Urology*, 2013.
2. Lotan Y, et al. *J of Urology*, 179(6):2164-2169.
3. Schlomer BJ, et al. *J of Urology*, 2010;183(1):62-67.

For *In Vitro* Diagnostic Use Only

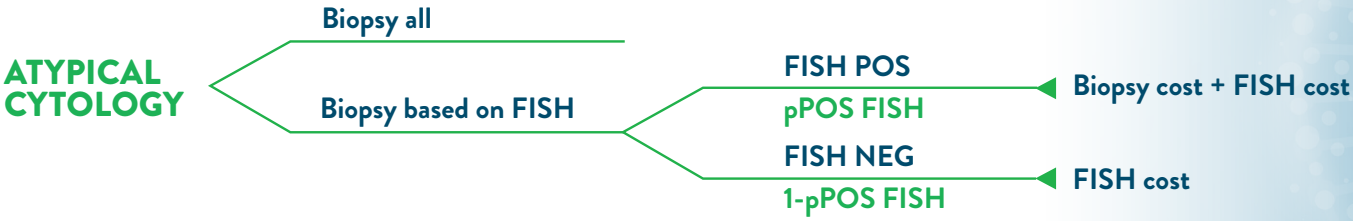
INTENDED USE:
The UroVysion Bladder Cancer Kit (UroVysion Kit) is designed to detect aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens from persons with hematuria suspected of having bladder cancer. Results from the UroVysion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

THE VALUE OF UROVYSION – THE POWER OF MOLECULAR INSIGHT

Model used to assess biopsy costs for equivocal/negative cytoscopy



PATIENT COSTS

Atypical Cytology with Equivocal Cystoscopy (62 patients)	Operating Room-based Biopsies	Biopsy Everyone	$3,267/patient	**$1,740/patient** or **53%**
		Biopsy based on FISH	**$1,527/patient**	
	Office-based Biopsies	Biopsy Everyone	$836/patient	**$95/patient** or **11%**
		Biopsy based on FISH	**$741/patient**	
Atypical Cytology with Negative Cystoscopy (201 patients)	Operating Room-based Biopsies	Biopsy Everyone	$3,267/patient	**$2,241/patient** or **69%**
		Biopsy based on FISH	**$1,026/patient**	
	Office-based Biopsies	Biopsy Everyone	$836/patient	**$216/patient** or **26%**
		Biopsy based on FISH	**$620/patient**	

UroVysion FISH results may reduce the risk and discomfort of unnecessary biopsies.

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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