



UroVysion is a urine-based molecular test which can help guide physicians in making clinical decisions regarding patient care. UroVysion is intended to be used in combination with cytology and cystoscopy and may provide the most diagnostic benefit when standard of care is negative or unclear.



UROVYSION FOR DIAGNOSIS

UroVysion provides additional clinical value for bladder cancer diagnosis in conjunction with cytology and cystoscopy

| TEST | RESULT | UROVYSION CLINICAL VALUE | CONCLUSION |
|------------|----------------|--------------------------|--|
| CYSTOSCOPY | + | L | No need to run UroVysion when cytology and cystoscopy are both positive. (see UroVysion PI and comparison data between cystoscopy and UroVysion). ¹ If cystoscopy is positive you may not need cytology. ² |
| CYTOLOGY | + | | |
| CYSTOSCOPY | - | H | Cytology has poor sensitivity ³ and lower NPV ⁴ compared to UroVysion. Cytology has poor reproducibility and is notorious for both false positive and equivocal results. ¹ |
| CYTOLOGY | + | | |
| CYSTOSCOPY | + | L | No need to confirm bladder cancer diagnosis, as cystoscopy is standard of care, confirmed by histology and re-TURBT. ² |
| CYTOLOGY | - | | |
| CYSTOSCOPY | - | M | UroVysion can help to confirm diagnosis when cystoscopy and cytology are negative, and there is no visual evidence of cancer. ¹ |
| CYTOLOGY | - ⁴ | | |
| CYSTOSCOPY | Suspicious | HH | Suspicious cystoscopy diagnosis is confirmed by histology and re-TURBT. UroVysion can help aid the diagnosis of symptomatic patients (hematuria). ¹ |
| CYTOLOGY | - or atypical | | |

1. UroVysion Package Insert 30-608385/R7.

2. NCCN Bladder Cancer Guidelines V1.2018.

3. Halling, et al. *J of Urology*, November 2000, Vol. 164, Issue 5, Pages 1768-1775.

4. Dimashkiek, et al. *Cancer Cytopathology*, October 2013, 121(10): 591-597.

NPV – Negative Predictive Value

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 provides greater insights during monitoring of bladder cancer, especially in patients where cytology and cystoscopy are negative, equivocal or suspicious. UroVysion has a high negative predictive value providing confidence in the effectiveness of treatment plans and when used in patients undergoing Bacillus Calmette-Guerin (BCG) therapy, a UroVysion positive result indicates patients are 3-5 times more likely to have tumor recurrence.⁵

UROVYSION FOR MONITORING AND PREDICTION

UroVysion provides additional clinical value for bladder cancer monitoring in conjunction with cytology and cystoscopy

| TEST | RESULT | UROVYSION CLINICAL VALUE | CONCLUSION |
|------------|------------|--------------------------|--|
| CYSTOSCOPY | + | L | No need to run UroVysion (see UroVysion PI and comparison data). ¹ If cystoscopy is positive, cytology may not be necessary. ² |
| CYTOLOGY | + | | |
| CYSTOSCOPY | - | H | Cytology has poor sensitivity ⁴ and lower NPV ⁴ compared to UroVysion. Cytology has poor reproducibility and is notorious for both false positive and equivocal results. ⁵ |
| CYTOLOGY | + | | |
| CYSTOSCOPY | + | L | No need to confirm bladder cancer recurrence, as cystoscopy is standard of care, confirmed by histology and re-TURBT. FISH is often used in surveillance. ^{1,2} |
| CYTOLOGY | - | | |
| CYSTOSCOPY | - | M | UroVysion can help to predict recurrence in advance of cystoscopy and cytology. High NPV and potential anticipatory positives event provides utility as aid in monitoring, in particular during BCG Rx. ⁴ |
| CYTOLOGY | - | | |
| CYSTOSCOPY | Suspicious | HH | Suspicious cystoscopy is confirmed by histology and re-TURBT. UroVysion can help determine if a patient has recurred or is at increased risk for recurrence, in particular during BCG Rx. ⁴ |
| CYTOLOGY | - | | |

1. UroVysion Package Insert 30-608385/R7.

2. NCCN Bladder Cancer Guidelines V1.2018.

4. Dimashkiek, et al. *Cancer Cytopathology*, October 2013, 121(10): 591-597.

5. Kamat AM, et al. *J of Urology*, 2012; 187(3):862-867.

NPV – Negative Predictive Value

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 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

For In Vitro Diagnostic Use Only