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MOLECULAR DIAGNOSTICS

UROVYSION

FOR RESULTS YOU CAN TRUST

UroVysion Bladder Cancer Kit (UroVysion Kit) is a 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]

- Deletion of 9p21 is also common and occurs early in the development of both papillary and flat urothelial neoplasia[2]
- 9p21 deletions were found in 21% of urothelial bladder carcinomas[3]
- Deletions of 9p21 is indicative of aggressive disease and non-inflamed microenvironment[3]

CYSTOSCOPY OR CYTOLOGY ALONE:

A BCG-inflamed bladder lining often impairs detection with cystoscopy

Limited ability to identify molecular or microscopic changes before tumors become visible

UROVYSION CAN:

Even during BCG therapy, UroVysion detects early stage of chromosomal abnormalities that have not progressed to a visible tumor

Identify patients at risk for recurrence during BCG therapy as shown in study[4]

Intended Use[1]

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 of the Procedure on reverse)**

INCREASE THE SENSITIVITY OF BLADDER CANCER DETECTION WITH UROVYSION

Combining UroVysion with cystoscopy makes detection significantly more sensitive.[5]

COMBINED SENSITIVITY

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)

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ORDERING INFORMATION

LIST NUMBER	PRODUCT NAME	QUANTITY
02J27-025	UroVysion Bladder Cancer Kit	20 assays
02J27-095	UroVysion Bladder Cancer Kit	100 assays
02J27-011	ProbeChek Control Slides for UroVysion Bladder Cancer Kit	3 slides

Limitations of the Procedure[1]

1. The UroVysion Kit has been optimized for identifying and quantitating chromosomes 3, 7, and 17, and locus 9p21 in human urine specimens.
2. The performance of the UroVysion Kit was validated using the procedures provided in this package insert only. Modifications to these procedures may alter the performance of the assay.
3. The clinical interpretation of any test results should be evaluated within the context of the patient's medical history and other diagnostic laboratory test results.
4. UroVysion assay results may not be informative if the specimen quality and/or specimen slide preparation is inadequate, eg, the presence of excessive granulocytes or massive bacteruria.
5. Technologists performing the UroVysion signal enumeration must be capable of visually distinguishing between the red and green signals.
6. Positive UroVysion results in the absence of other signs or symptoms of bladder cancer recurrence may be evidence of other urinary tract related cancers, eg, ureter, urethra, renal, and/or prostate in males, and further patient follow-up is justified.
   In a study* conducted on patients with hematuria (see Symptomatic Patients: Performance vs Standard of Care for details on this clinical study) 3 patients, whose initial bladder cystoscopy was negative, were subsequently diagnosed with renal cancer within 6 months of this initial study visit. All 3 of these cases were positive by UroVysion.
7. If UroVysion results are negative but standard clinical or diagnostic tests (eg, 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.
8. Ta stage solitary tumors smaller than 5 mm could not be detected by UroVysion FISH.[6] UroVysion FISH results are dependent on the amount of tumor cells that are deposited on the slide.

REFERENCES

1. UroVysion Package Insert 30-608385/R9. **2.** Bubendorf, Lukas, Acta Cytologica, 2011 and he references Knowles MA, Scand. *J of Urology*, Nephrol Suppl, 2008. **3.** Gorbokon N, et al. *J Pathol Clin Res.* 2025 Jan;11(1):e70012 **4.** Kamat AM, Dickstein RJ, et al. *J of Urology*, 2012 Mar 187:870-875. **5.** Halling KC, et al. *J of Urology*, November 2000, Vol. 164, Issue 5, Pages 1768-1775. **6.** Riesz, P., G. Lotz, et al. (2007). "Detection of bladder cancer from the urine using fluorescence in situ hybridization technique." *Pathol Oncol Res.* 13(3):187-94.

*See page 13 of UroVysion Package Insert for more information.

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For *in vitro* diagnostic use. Rx Only.

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