

# UroVysion Bladder Cancer



**UroVysion** has two primary indications; to aid in the initial diagnosis of bladder cancer and the early detection of tumor recurrence in patients previously diagnosed with bladder cancer. This test is FDA approved for patients with reoccurring hematuria.

Test Code: 10107

\*CPT Code: 87798 x12

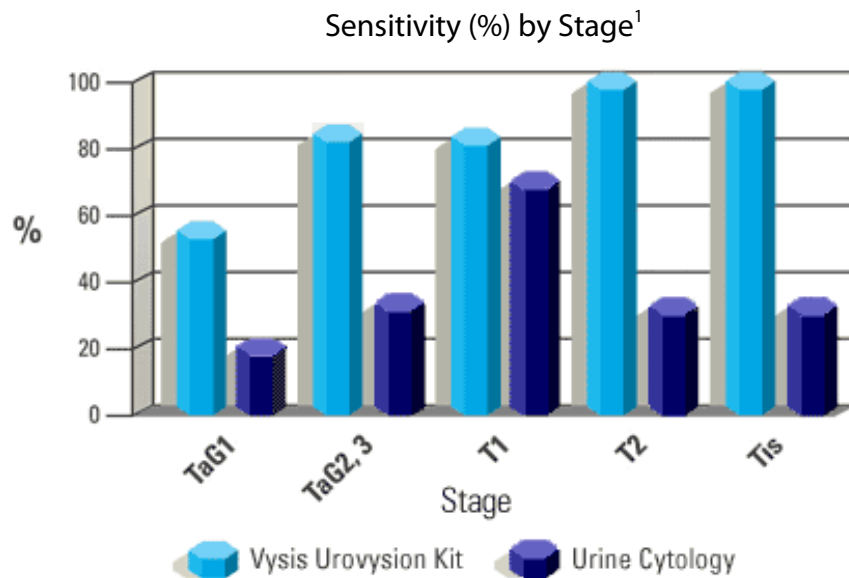
Specimen Requirements: Voided urine collected in UroVysion Kit

**Early detection of high grade disease is critical to increased survival.**

**Detects chromosomal abnormalities associated with the development and progression of Bladder Cancer.**

## Sensitivity

Vysis UroVysion is not only more sensitive than urine cytology by stage, but also more sensitive by grade.



## Specificity

The specificity of Vysis UroVysion is approximately **95%** among healthy and non-healthy subjects, which translates to fewer false positives.

\*The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.



### Risk Factors

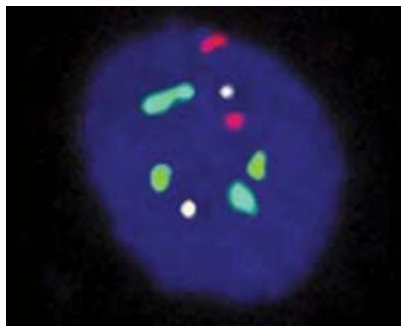
Smoking  
Urination Frequency or Urgency  
Painful Urination  
Abdominal Pain  
Anemia

Bone Pain or Tenderness  
Weight Loss  
Lethargy  
Urinary Incontinence

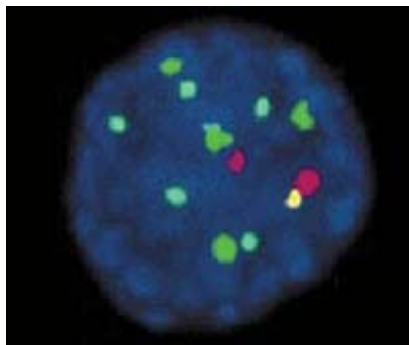
## Methodology

**UroVysion's molecular cytology combines the strength of urine cytology (morphology) with molecular (DNA-based) technology to enhance the detection of the presence of cancer.**

### Vysis UroVysion Images



Normal result observed in an interphase cell obtained from a sample after the Vysis UroVysion Bladder Cancer Recurrence Kit hybridization. Each probe signal, CEP 3 (red), CEP 7 (green), CEP 17 (aqua) and LSI p16 (gold) is present in two copies.



Aneusomic interphase cell obtained from a sample showing two copies of chromosome 3 (red), four copies of chromosome 7 (green), five copies of chromosome 17 (aqua) and one copy of p16 gene (gold) after the Vysis UroVysion Bladder Cancer Recurrence Kit hybridization

Fluorescence *in situ* hybridization (FISH) is a type of hybridization in which a DNA "probe" is labeled with fluorescent molecules so that it can be seen with a microscope. The word "*in situ*" means that the hybridization occurs "in place", in this case, within the nucleus of specimen cells that have been fixed to a microscope slide.

<sup>1</sup>Sarosdy, et al. Clinical Evaluation of a Multi-Target Fluorescent in Situ Hybridization Assay for Detection of Bladder Cancer, Journal of Urology. Nov 2002.