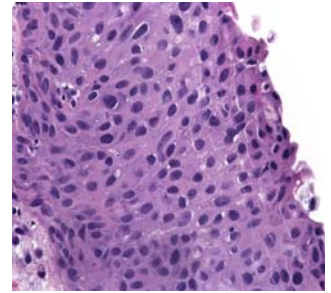


Urine UroVysion™ Test

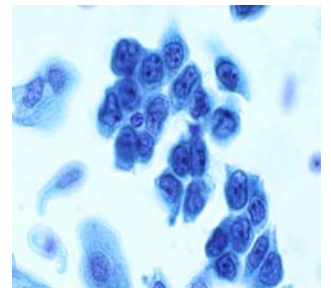
INTRODUCTION

- UroVysion kit is an FDA approved test designed to detect aneuploidy (gain) of chromosomes 3, 7, 17 and loss of the 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens from patients with hematuria suspected of having bladder cancer
- It is not affected by infection, hematuria, instrumentations or (BCG) immunotherapy



INDICATIONS

- Aid for initial diagnosis of bladder cancer
- Monitoring for tumor recurrence
- If positive portend an increase risk for tumor recurrence even when cystoscopy is negative

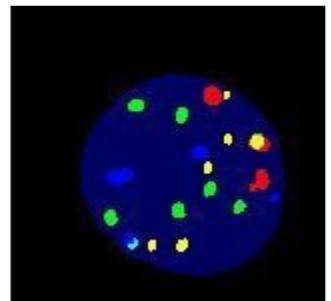


SPECIMEN REQUIREMENTS

- Urine (about 33ml) is collected in a capped plastic container prefilled with Carbowax. The test to be performed at the physician's office
- Ship or refrigerate the specimen immediately and ship within 24 hours
- Shipping on ice packs, but may be stored and shipped at temperatures up to 25C

SENSITIVITY AND SPECIFICITY

- Demonstrated high sensitivity for detecting high-grade and high-stage tumors (83 percent to 97 percent), including carcinoma *in situ* (about 100 percent)
- Overall sensitivity varied between 69 percent and 87 percent, with a sensitivity to detect low-grade (36 percent to 57 percent) and low-stage (62 percent to 65 percent) tumors
- High specificity across all grades and stages of tumors (>90 percent)



CLINICAL SIGNIFICANCE

- Excellent when combined with cystoscopy. Better at detection of high-grade urothelial carcinoma, such as carcinoma *in situ* (CIS), high-grade tumors which may be difficult to detect via cystoscopy.
- A negative FISH result does not rule out all bladder cancer or necessarily mean that an individual will not develop bladder cancer in the future

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Diagnosis at the Speed of Right