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. 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.

Set your sights higher

- Only urine-based molecular test approved by the FDA to aid bladder cancer surveillance and assist with diagnosis
- Clinically proven by more than 10 years of scientific data
- Greater sensitivity than cytology across all stages and grades
- 100% sensitivity in CIS tumors
- Delivers definitive results in atypical cytology cases with equivocal or negative cystoscopy
- Performs without interference in the presence of substances in urine samples such as BCG, Mitomycin C, and Thiota
- Delivers a 94.1% negative predictive value for detection of bladder cancer recurrence versus cystoscopy/histology in BCG-treated patients

Insist on UroVysion, the only urine-based molecular test approved by the FDA to aid in the diagnosis and monitoring of bladder cancer.

For additional information and full risk profile, visit www.AbbottMolecular.com or call 800-553.7042.

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. 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.
Bladder cancer presents many clinical challenges. Highly prevalent, it is also highly recurrent.

- Low-grade tumors have a 50% to 70% chance of recurrence\(^{1}\)
- T1 tumors have a 25% to 30% risk of progression to muscle-invasive disease\(^{1}\)
- Grade 2 or 3 tumors have an ~20% higher chance of progression to muscle-invasive disease than grade 1 tumors\(^{1}\)

Cystoscopy and cytology are the gold standard for diagnosis and surveillance of bladder cancer. Yet each has limited sensitivity, which can lead to uncertainty in diagnosis or monitoring.

UroVysion can help. The UroVysion Bladder Cancer Kit is a proven, widely utilized test that detects chromosomal abnormalities to add molecular precision to cystoscopy and cytology. It helps physicians detect abnormalities before a tumor is visible—a primary reason many urologists ask for UroVysion.


For bladder cancer surveillance and assistance with diagnosis, set your sights on UroVysion.

Providing insight throughout the clinical pathway

When to use UroVysion:
- As an aid in the initial diagnosis of bladder cancer in patients presenting with hematuria
- For monitoring recurrence in previously diagnosed patients

UroVysion is proven helpful:
- To clarify equivocal cystoscopy results
- When cytology is unclear

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:
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 the 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, e.g., the presence of excessive granulocytes or massive bacteriuria.

Caution:
United States Federal law restricts this device to sale and distribution to or on the order of a physician or to a clinical laboratory; and use is restricted to, by, or on the order of a physician.

For in Vitro Diagnostic Use

The only FDA-approved test of its kind

UroVysion detects aneuploidy for chromosomes 3, 7, and 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. It is the only urine-based molecular test approved by the FDA to aid in the diagnosis and monitoring of bladder cancer.

A simple test backed by definitive clinical proof

UroVysion is backed by more than 10 years of scientific data. More than an innovative test, it is routinely used by urologists worldwide.

For results you can trust, order UroVysion.
Evidence based and clinically advantageous

UroVysion has been studied in multicenter, blinded comparative studies involving hundreds of patients. Those and additional studies have established the following clinical benefits:

• In combination with cystoscopy, improves sensitivity to 98%—more than either cystoscopy (74%) or cytology (58%) alone.2
• 100% sensitivity in CIS tumors.2
• Shows significantly greater sensitivity than cytology for all grades and stages of bladder cancer.3
• May identify chromosomal abnormalities before a tumor is visible.4
• Provides definitive results for atypical cytology cases with equivocal or negative cystoscopy.5
• Aids in initial diagnosis of patients presenting with hematuria.2

In a comparison of cytology and FISH for the detection of urothelial cancer, FISH outperformed cytology across all tumor stages and grades. In this study, suspicious cytology results were considered positive and equivocal results were considered negative.2

Greater Sensitivity in Patients with Hematuria

In a large clinical trial of 497 patients presenting with hematuria but no history of bladder cancer, UroVysion was found to be significantly more sensitive than voided cytology for detecting bladder cancer for all grades and stages in patients evaluated for gross or microscopic hematuria.3

Greater Sensitivity Across Every Stage, Every Grade

In a comparison of cytology and FISH for the detection of urothelial cancer, FISH outperformed cytology across all tumor stages and grades. In this study, suspicious cytology results were considered positive and equivocal results were considered negative.2

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.
Bring clarity to bladder cancer monitoring

Positive UroVysion Predicts Recurrence During BCG Therapy

Non-muscle invasive bladder cancer (NMIBC) patients undergoing BCG therapy with positive UroVysion results were found to be 3 to 5 times more likely to have tumor recurrence vs. patients with negative UroVysion results.

- Positive UroVysion predicted tumor recurrence at all time points
- The risk of tumor recurrence increased with each additional positive UroVysion result
-Earlier conversion from negative to positive UroVysion result was associated with a higher risk of disease recurrence

![Graphical representation of UroVysion results over time](image)

High NPV for Patients Treated with BCG

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<th>Cystoscopy/Histology</th>
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<td>Total</td>
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In a comparison of UroVysion versus cystoscopy/histology for detection of bladder cancer recurrence in patients on BCG therapy within three months, UroVysion demonstrated a negative predictive value of 94.1%.7


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., 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.