GOPATH LABORATORIES Global Pathology Services

Molecular Diagnosis Report

1000 Corporate Grove Dr., Buffalo Grove, IL 60089

Toll Free
855-467-2849

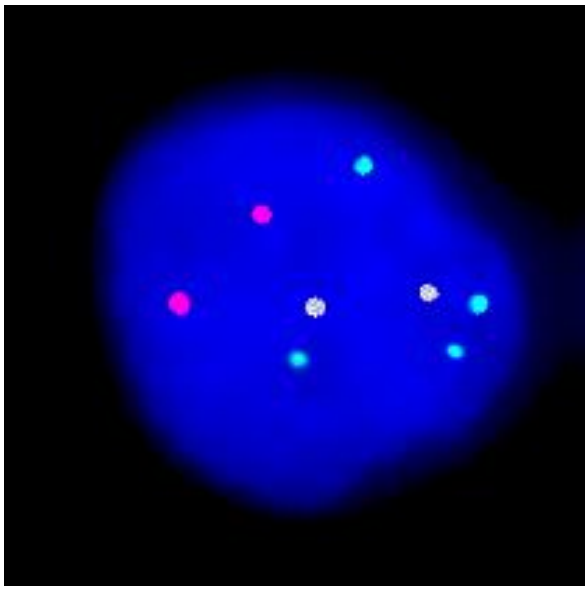
Test, Female	GF25-1023
DOB: 09/09/1999 **Age:** 25 **Gender:** Female **Collected:** 04/16/2025 **Received:** 04/22/2025 **Tissue:** Urine **Order ID:** 2700-A **Clinical Diagnosis:** Malignant neoplasm of overlapping sites of bladder **Test Ordered:** Urine FISH	**emasupport Account Do Not Use, MD** **SIOUXLAND UROLOGY ASSOC PC** , **Phone: Fax:**

URINE FISH ANALYSIS REPORT

FISH Result: Negative

Total Cells Read: 50

Total Abnormal Cells: 0



INTERPRETATION OF RESULT

UroVysion FISH is negative; cells are non-amplified. The criteria for positive UroVysion FISH is greater than or equal to 4 morphologically abnormal cells showing either a gain of multiple chromosomes for more than 1 of the following (CEP 3 red, CEP 7 green, or CEP 17 aqua) probes or a homozygous loss of 9p21 (no signals for LSI 9p21 gold).

ASSAY DESCRIPTION AND METHODOLOGY

UroVysion (Abbott Molecular) 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. Urovysion is intended as an aid for initial diagnosis of bladder cancer in patients with hematuria and subsequent monitoring of tumor recurrence in patients previously diagnosed with bladder cancer. Urothelial carcinoma cells will show various patterns of aneuploidy for chromosomes 3, 7, 17 and/or homozygous loss of the 9p21 locus. Specimens from patients positive for bladder cancer recurrence showed greater than or equal to 4 cells with multiple chromosomal gains or greater than or equal to 12 cells with loss of both copies of 9p21. External (amplified and non-amplified) and internal controls performed as expected. Because of sampling issue, normal UroVysion FISH cannot entirely exclude underlying malignancies. Rarely, the abnormal results can be nonspecific due to reactive changes. Clinical correlation is recommended.

ASSAY DISCLAIMERS

UroVysion (Vysis, Inc.) is FDA approved for use in conjunction with cystoscopy and is intended 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. UroVysion is a registered trademark of Vysis, Inc., a wholly owned subsidiary of Abbott Laboratories.

REFERENCES

1. Halling KC, King W, Sokolova A, et al. Assessing the value of reflex fluorescence in situ hybridization testing in the diagnosis of bladder cancer when routine urine cytological examination is equivocal. J Urol. 2000; 164: 1768-1775.

2. Sarosdy MF, Kahn PR, Ziffer MD, et al. Use of a multitarget fluorescence in situ hybridization assay to diagnose bladder cancer in patients with hematuria. J Urol. 2006 Jul; 176 (1): 44-47.

3. Jones S. DNA-based molecular cytology for bladder cancer surveillance. Urology 2006; 67 (Supplement 3A): 35-45.

4. Schlomer BJ, Ho R, Sagalowsky A, Ashfaq R, Lotan Y. Prospective validation of the clinical usefulness of reflex fluorescence in situ hybridization assay in patients with atypical cytology for the detection of urothelial carcinoma of the bladder. J Urol. 2010 Jan; 183 (1): 62-67.

Jim Luuu Admin, MD, PhD
Staff Pathologist
Electronically signed on 04/22/2025

Jim Lu, MD, PhD
Medical Director

Total ICD-9/10:C67.8

Total CPT: