

DOCTOR
FISCH, HARRY
HARRY FISCH, M.D.
ACCT #: [REDACTED]
P: [REDACTED] F: [REDACTED]

PATIENT
EPSTEIN, JEFFREY
DOB: 01/20/1953 Age: 62Y Sex: M
Address: 9 EAST 71ST STREET
NEW YORK, NY 10021

SAMPLE
Specimen ID: 303053951
Date Reported: 10/30/2015 5:55 PM
Date Collected: 10/27/2015 4:44 PM
Date Received: 10/27/2015 11:42 PM
Source: URINE

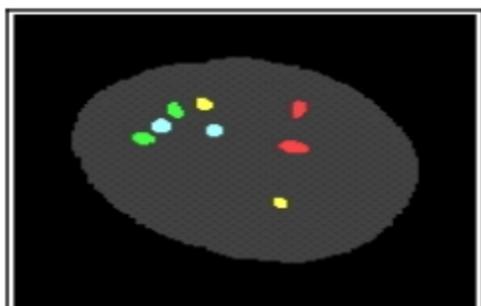
AUTOMATED UROVYSION™ - FLUORESCENCE IN SITU HYBRIDIZATION (FISH)

INTERPRETATION

Negative for aneuploid cells.

RESULTS

No. of Cells	Description
0	Aneuploid cells with extra signals, representing at least double aneuploidy of chromosomes 3, 7, and/or 17
0	Cells with loss of both gold (9p21) signals
102	Total cells scored



Two green, two red, two aqua, and two gold signals (x 1,000)

INTERPRETIVE INFORMATION

The UroVysion™ Bladder Cancer Kit (Vysis, Inc.) detects aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus via 4-color interphase FISH. It is FDA approved for use as an aid both in initial diagnosis of bladder cancer and for monitoring tumor recurrence on voided urine specimens in patients with transitional carcinoma of the bladder.

Assessment of ploidy status was performed using an automated Fluorescence In Situ Hybridization (FISH) signal enumeration system (Metafer Slide Scanning System, MetaSystems Group Inc., Watertown, MA). A maximum of 5000 cells are scanned. A positive/abnormal result requires 4 or more cells to show gain for 2 or more chromosomes (3, 7, and/or 17) in the same cell, or 12 or more cells to have zero 9p21 signals.

A comparison of positive FISH results to cystoscopy/histology for detection of recurrent bladder cancer shows concordance in approximately 75% of cases, with the greatest correlation (up to 100%) in tumors of high grade and/or stage. The absence of detectable aneuploid cells does not exclude a bladder malignancy, nor does a negative result from a suboptimal specimen without the appropriate number of evaluable cells. Correlation with cytology and/or cystoscopic findings, as well as the patient's history and other laboratory tests is suggested.

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REFERENCES

1. Bubendorf L, Grilli B, Sauter G, Mihatsch MJ, Gasser TC, Dalquen P. Multicolor FISH for enhanced detection of bladder cancer in voided urine specimens and bladder washings. *Am J Clin Pathol.* 116(1):79-86, 2001.
2. Kruger S, Mess F, Bohle A, Feller AC. Numerical aberrations of chromosome 17 and the 9p21 locus are independent predictors of tumor recurrence in non-invasive transitional cell carcinoma of the urinary bladder. *Int J Oncol.* 23(1):41-48, 2003.
3. Varella-Garcia M, Akduman B, Sunpaweravong P, Di Maria MV, Crawford ED. The UroVysion™ fluorescence in situ hybridization assay is an effective tool for monitoring recurrence of bladder cancer. *Urol Oncol.* 22(1):16-19, 2004.
4. Vysis UroVysion™ Bladder Cancer Recurrence Kit Package Insert. Product Number 30-161070 and 36-161070, Vysis, Inc. 2004.

The performance characteristics of this test were determined by BioReference Laboratories. It has been cleared by the U.S. Food and Drug Administration. These results may be used for clinical, investigational or for research purposes, and should be interpreted with other relevant clinicopathologic data.