Quantum Pathology LLC
303 Bear Hill Rd, 2nd Floor
Waltham, MA 02451
Phone: 781.373.1689
Fax: 781.373.2078
CLIA#: 22D2081781

Medical Director: Lindsay B. Hardy, MD.

UroVysion FISH Report

Patient: **Johnson, Thomas F.** Age/Sex: 59/M DOB: 01/01/1960 Phone#: 888.555.1212 MRN: 12345	Physician: **Joseph Smith, M.D.** ABC Urology Associates, Inc 1000 Main Street Anytown, MA 12345 Referring Physician: Referring Physician Fax:	**Lab Case#: CY19-00001** Date Collected: 01/01/2019 Date Received: 01/01/2019 Date Reported: 01/08/2019 Accession#: QC19-00001

Clinical Information

ICD: C67.9

Diagnosis

Diagnosis: Abnormal Profile

Specimen: Urine, Voided

Abnormal cell

Interpretation

The UroVysion FISH study detected an abnormal profile. UroVysion FISH evaluates chromosomes 3, 7, 17, and 9p21 for aneuploid and deletion events associated with urothelial cell carcinoma. 135 cells were analyzed in this evaluation. Evidence of aneuploidy in at least 7 cells were found. These findings should be correlated with cytology and cystoscopy results. *

Gross Description

Source	Screening Type	Description
Urine, Voided	Manual-score quantified FISH	Received fresh with the patient's name labeled urine consists of 60 ml's of yellow clear fluid.

May Azar M.D.
Final Report Electronically signed on 01/08/2019 at 12:00 PM

FISH PROBES: D3Z1, D7Z1, LSI p16, D17Z1 Vysis UroVysion Lot#470582

Comments: 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.

This test was developed and its performance characteristics determined by Quantum Pathology, LLC. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing.