TEST CHANGE

Bladder Cancer by FISH

3016627, BC REQUEST

Specimen Requirements:	
Patient Preparation:	
Collect:	Second-morning, clean-catch voided urine specimen collected in PreservCyt collection vial included in UroCyte Urine Collection Kit (ARUP Supply #41440). Collection kit is available online through eSupply using ARUP Connector contact Client Services at 800-522-2787. For specific instructions refer to Specimen Collection & Handling.
Specimen Preparation:	Specimens must be transported in PreservCyt fixative. Acceptable source is~~sources are~~ voided urine.~~, bladder washings, ureteral washings, or urethral washings.~~ (Min: 35 mL)
Transport Temperature:	Ambient or refrigerated
Unacceptable Conditions:	Unfixed specimens not in PreservCyt fixative. Frozen specimens. Specimens submitted in expired collection vials.
Remarks:	Submit source information with the specimen.
Stability:	Ambient: 1 week from collection; Refrigerated: 1 week from collection; Frozen: Unacceptable
Methodology:	Qualitative Fluorescence in situ Hybridization (FISH)/Computer Assisted Analysis/Microscopy
Performed:	Mon-Fri
Reported:	4-14 days
Note:	
CPT Codes:	88121
New York DOH Approval Status:	Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.

Interpretive Data:

NEGATIVE results indicate a lack of evidence for the presence of numeric chromosomal abnormalities commonly associated with urothelial carcinoma within the cells collected in this specimen. Negative results in the presence of other symptoms/signs of urothelial carcinoma may suggest the possibility of a false negative test. In this circumstance, additional clinical studies to

exclude urothelial carcinoma should be pursued, as clinically indicated. Although this test was designed to detect genetic abnormality associated with most urothelial cancers, there will be some urothelial cancers whose genetic changes cannot be detected by this test.

POSITIVE results indicate the presence of one or more numeric chromosomal abnormalities commonly associated with urothelial carcinoma within the cells collected in this specimen. Positive results in the absence of clinical documentation of urothelial carcinoma within the bladder suggest the possibility of urothelial carcinoma or other urologic malignancy from another site (including ureter, kidney, urethra, and prostate). In this circumstance, further clinical evaluation to exclude these as a source of the abnormal cells is justified.

The UroVysion Bladder Cancer Kit~~Oxford Gene Technology, Inc.~~ probes were used to detect aneuploidy for chromosomes 3, 7, 17, and/or loss of 9p21 locus~~and 17~~ via fluorescence in situ hybridization (FISH). Results from this test are intended for use~~,~~ in conjunction with, and not in lieu of, current standard diagnostic procedures, as an aid for initial diagnosis of urothelial carcinoma and for monitoring for tumor recurrence in conjunction with cystoscopy in patients with previously diagnosed bladder cancer.

Reference Interval:

Negative: No evidence of numeric chromosomal aberrations associated with urothelial carcinoma identified.
Positive: Numeric chromosomal aberrations associated with urothelial carcinoma identified.