Clinical Information:

Source-Test: Urine/UroVysion Bladder Cancer FISH
Adequacy: Urothelial Cells - Cells are enough for evaluation.
Cell Counted: 120
Cell Analyzed: 120

Diagnosis:
Positive for aneuploid cells. 120 urothelial cells were evaluated. 62 amplification of chromosome 3, 7 and no 19p21 homozygous deletion were found and recorded.

Interpretation:
The positive UroVysion results correlate with a high sensitivity and specificity for bladder cancer.

Signed out:

Comments

Intended Use
The UroVysion Bladder Cancer FISH test is designed to detect polysomy for chromosomes 3, 7, 17, and homozygous loss of the 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens from persons with hematuria suspected of having Urothelial carcinoma. Due to its high specificity and increased sensitivity, the UroVysion test is useful for early detection of bladder cancer recurrence when used in conjunction with cystoscopy.

Summary and Explanation
Bladder cancer is the fifth most common cancer in the United States, with over 57,000 newly diagnosed cases and over 12,000 deaths annually. Bladder cancer is four times more likely to occur in men than in women. The median age at diagnosis is 65 years; bladder cancer is rare in individuals under 40. 90% of bladder cancer cases are classified as transitional cell carcinomas (TCC), while the remaining 10% are predominantly squamous cell or adenocarcinomas.

There are 4 clinically relevant subgroups of TCC, as defined by pathologic staging: carcinoma in situ (pTIS), non-invasive papillary TCC (pTa), minimally invasive TCC (pT1), and muscle invasive tumors (pT2-pT4). Each subgroup differs in clinical outcome. At presentation, 75% of tumors are “superficial” (i.e., pTa, pT1 or pTIS), of which 50 to 80% will have one or several recurrences, and 15 to 25% will progress to invasive tumors. For this reason, patients with “superficial” bladder cancer are regularly monitored for tumor recurrence and progression with cystoscopy and sometimes urine cytology. Cystoscopy examination of the bladder, and often urine cytology, are also standard care for patients > 40 years of age and presenting with hematuria.

A number of studies, however, have demonstrated that urine cytology has a disappointingly low sensitivity for bladder cancer detection and improved laboratory tests for bladder cancer detection are needed. Recent studies have demonstrated that FISH analysis for aneuploidy of specific chromosomes may be useful to aid in the detection of bladder cancer.
Principles of the Procedure

In situ hybridization is a technique that allows the visualization of specific nucleic acid sequences within a cellular preparation. Specifically, DNA fluorescence in situ hybridization (FISH) involves the precise annealing of a single stranded fluorescently labeled DNA probe to complementary target sequences. The hybridization of the probe with the cellular DNA site is visible by direct detection using fluorescence microscopy. The UroVysion probes are fluorescently labeled nucleic acid probes for use in in situ hybridization assays on urine specimens fixed on slides. The UroVysion Kit consists of a four-color, four-probe mixture of DNA probe sequences homologous to specific regions on chromosomes 3, 7, 9, and 17, which include Chromosome Enumeration Probe (CEP) 3 Spectrum Red, CEP 7 Spectrum Green, CEP 17 Spectrum Aqua and Locus Specific Identifier (LSI) 9p21 Spectrum Gold. The probes are pre-mixed and pre-denatured in hybridization buffer for ease of

Caution

The UroVysion FISH test is approved by the U.S. FDA for the detection of bladder cancer on voided urine. Although it is designed to detect changes associated with most bladder cancers, there will be some bladder cancers with genetic changes that cannot be detected by this test. This result should be interpreted within the context of the patient’s medical history and other diagnostic laboratory results.