References


Van Rhijn et al., J Clin Oncol 21(10):1912-1921, 2003. “...patients with an FGFR3 mutation have a significantly better prognosis than those without the FGFR3 mutation.”

Kompier et al, J pathol 218:104-112, 2009. “Recurrences in this (FGFR3 mutant) patient group were of lower stage and grade than those of patients with wild-type primary tumor.”


Van Oers JM, et al. “FGFR3 mutations and a normal CK20 staining pattern define low-grade noninvasive urothelial bladder tumors.”


Disclaimer: This laboratory test was developed and its performance determined by multiple laboratories among them Predictive Biosciences and SunCoast Pathology Associates. This test has not been cleared or approved by the US FDA, although such approval is not required for clinical implementation. SunCoast Pathology Associates is CLIA certified to perform high complexity testing.
URO-GEN-DX™ is a proprietary test to detect genomic indicators for risk assessment for progression and prognosis of bladder cancer. The test uses fluorescence-in-situ hybridization (FISH) to examine specific genetic information in your chromosomes that has been correlated with increased progression of your disease.

The genomic information obtained by URO-GEN-DX™, in addition to the histopathology of your biopsy, and use of immunohistochemical studies for Ki67 and CK20, assists in the treatment and management of your cancer. This combination of tests complements the pathologic diagnosis, eliminates variability of assessment, and provides a new tool to aid in the management of bladder cancer.

By using FISH, URO-GEN-DX™ looks at specific chromosomes for p53 and PTEN (tumor suppressor genes), and FGFR-3 (an epithelial growth factor) give specific and personal genomic information.

The p53 gene is a tumor suppressor gene found on chromosome 17 and its product, the p53 protein, is responsible for the death of DNA damaged cells. In the absence of p53 activity, cells that cannot be repaired will continue to proliferate in their damaged state. The mutation or loss of p53 is associated with tumor recurrence and progression.

PTEN encodes a phosphatase that regulates a critical cell cycle involved in cell proliferation. When PTEN is deleted or otherwise inactivated, cell division continues unchecked, causing progression of cancer.

FGFR3 is an epithelial growth factor found in chromosome 4. Its presence, absence, or mutation has prognostic implications in tumor behavior.

Ki67 and CK20 are immunohistochemical tests also associated with tumor progression and are assessed using computer assisted image analysis. These tests improve traditional pathology results which are based on morphology alone.

<table>
<thead>
<tr>
<th>Marker Status</th>
<th>Prognosis</th>
<th>Pathologic Grade</th>
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</thead>
<tbody>
<tr>
<td>FGFR3 mutation, low Ki67, no loss of p53, PTEN or CK20</td>
<td>Favorable</td>
<td>Low Malignant Potential</td>
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<tr>
<td>FGFR3 mutation, high Ki67, loss of either p53 or PTEN, slight loss of CK20</td>
<td>Intermediate</td>
<td>Low Grade</td>
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<tr>
<td>FGFR3 mutation, high Ki67, loss of p53 or PTEN, and loss of CK20</td>
<td>Poor Prognosis</td>
<td>High Grade</td>
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