For Urinary Bladder Cancer detection

Accurate tumor status in moments that matter.
Background urinary bladder cancer

Bladder cancer is a common cancer in men and women worldwide and transitional cell carcinoma (TCC) comprises up to 90% of all primary bladder tumors. The risk of developing bladder cancer is three to four times higher in men than in women and it increases with smoking, exposure of industrial chemicals and other carcinogens. At presentation more than 70% are non-muscle invasive bladder cancer, but the recurrence rate is high and therefore many patients progress to muscle invasive bladder cancer or metastatic disease.

The most common methods for detection of bladder cancer and for the assessment of recurrence are cystoscopy and urine cytology. Cystoscopy causes pain and discomfort in patients and in cases with small tumors or carcinoma in situ a diagnosis is not readily performed. Urine cytology, a non-invasive urine test, is the standard method for detection of bladder cancer and is recommended as an adjunct to cystoscopy. However, even if cytology has the advantage of high specificity its sensitivity for well-differentiated or low-grade tumors is low.

To overcome such shortcomings of the existing diagnostic methods for bladder cancer, urine tumor markers are available. One interesting possibility is the measuring of cytokeratin fragment in urine, since elevated amounts of cytokeratin fragments are present in the urine of many individuals with bladder cancer, even at early stages of the disease.

Cytokeratin filament

All eucaryotic cells have cytoplasmic cytoskeletal structures known as intermediate filaments. The cytoskeletal network is responsible for the mechanical integrity of the cell and it is critical during cellular processes like cell division, motility and cell to cell contacts. At present more than 20 different cytokeratins have been identified, of which cytokeratin 8, 18 and 19 are the most abundant in simple epithelial cells. The cytokeratins are epithelial cell specific and the cytokeratin pattern is usually preserved during the transformation of normal cells into malignant cells.

UBC®Rapid

UBC®Rapid is a powerful diagnostic parameter in primary diagnosis and follow-up of bladder cancer patients. In clinical tests, UBC®Rapid performs better than urine cytology due to improved sensitivity, in particular for low-grade tumours. Studies also show that the combination of UBC®Rapid and cytology leads to detection of additional tumours as opposed to cytology alone. One clear advantage is that a UBC®Rapid test can be performed immediately and the test result will be available during the patient visit. This platform has further been developed to also provide quantitative results of the UBC®Rapid test which facilitates risk prediction compared to other conventional non-quantitative dichotomized POC-testing.

<table>
<thead>
<tr>
<th>Product</th>
<th>Catalogue number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>UBC®Rapid</td>
<td>10-038</td>
<td>10 test, for qualitative measurement</td>
</tr>
<tr>
<td>UBC®Rapid</td>
<td>10-238</td>
<td>20 test, qualitative and quantitative measurement</td>
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The first quantitative POC test platform for urinary bladder cancer. **UBC’Rapid** is a powerful diagnostic parameter in primary diagnosis and follow-up of bladder cancer patients. Ritter et al.⁵ has performed a clinical evaluation of **UBC’Rapid** on a POC test platform, in bladder cancer, providing quantitative results. A quantitative result provides higher reproducibility and enables improved risk stratification compared with a simple dichotomized POC test results. The accuracy of the POC test platform is at least equivalent to **UBC’ELISA** in bladder cancer patients. **UBC’Rapid** might be used as an adjunct to cystoscopy and cytology in laboratory independent settings. In addition, it has been demonstrated by Lüdecke et al.⁴ that **UBC’Rapid** is not sensitive to blood contamination in the urine – haematuria, which is a common symptom of bladder cancer.

Comparison of **UBC’Rapid** (visual detection), **UBC’Rapid** (quantitative detection) **UBC’ELISA**, NMP22® BladderChek® and cytology.

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
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<tbody>
<tr>
<td><strong>UBC’Rapid visual</strong></td>
<td>37.7-67.2%</td>
<td>57.7-88.3%</td>
<td>41.4-59.0%</td>
<td>76.1-90.4%</td>
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<tr>
<td><strong>UBC’Rapid quantitative</strong></td>
<td>60.7%</td>
<td>70.1%</td>
<td>46.8%</td>
<td>79.3%</td>
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<tr>
<td><strong>UBC’ELISA</strong></td>
<td>48.3%</td>
<td>71.3%</td>
<td>42.7%</td>
<td>75.8%</td>
</tr>
<tr>
<td><strong>NMP22® BladderChek®</strong></td>
<td>16.4%</td>
<td>95.3%</td>
<td>62.5%</td>
<td>70.5%</td>
</tr>
<tr>
<td><strong>Cytology</strong></td>
<td>51.7%</td>
<td>78.1%</td>
<td>51.7%</td>
<td>78.1%</td>
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</table>

198 high risk patients (haematuria or irritative voiding syndromes) were included in the study; 61 patients clinically confirmed bladder cancer patients.

**UBC’Rapid** detects more patients with bladder cancer than NMP22® or cytology. Combining cytology with **UBC’Rapid** yielded a sensitivity of 88% for detection of bladder cancer in high risk patients.

At a glance

**UBC®Rapid** - For Urinary Bladder Cancer detection

- Specifically measures cytokeratins 8 and 18
- The only quantitative POC test platform for urine based detection of bladder cancer.
- Fast and Easy to perform – result within 10 minutes
- A non-invasive indicator of tumor cell activity measured in urine
- An alternative tool during patient follow-up that might reduce the number of cystoscopies
- Provides the physician with early signals of tumor recurrence during treatment monitoring
- Not sensitive to blood contamination in urine

References:


Diagnostic tools for reliable patient management.

**Oncology**
- TPS®
- UBC®
- TPAcyk®
- MonoTotal®

**Bacteriology**
- TUBEX® TF
- TUBEX® WASH BUFFER

IDL Biotech is certified according to ISO 9001:2008 and EN ISO 13485:2012