Urinary marker for bladder cancer detection

Reference No: B71211

CHALLENGE
Urothelial carcinoma of the bladder (UCB) is the most common genitourinary cancer. Diagnosis of UCB currently relies on cystoscopy and urine cytology. Both examination methods have limitations. Urethrocystoscopy is expensive, invasive, and associated with postcystoscopy pain and/or risk of urinary infection. Cystoscopy has tendency to miss flat lesions, such as carcinoma in situ, while urine cytology is prone to missing well-differentiated low-grad lesions. After transurethral resection and adjuvant chemo- or immunotherapy, patients require regular follow-up cystoscopies due to the high recurrence rate, making TCC the most socioeconomically expensive tumor entity.

INNOVATION
The LIM and SH3 (LASP)-1 protein is a focal adhesion protein involved in numerous biological and pathological processes and has been linked to the oncogenesis of bladder cancer. The protein is detected in voided urine sediment of bladder cancer patients and is described as a promising new marker for bladder cancer that overcomes the limitations of the current diagnostic tests for UCB.

COMMERCIAL OPPORTUNITIES
- Convenient marker for detection and especially follow-up examination of UCB simply detectable in spontaneously voided urine
- Combinable with a second marker to further raise specificity/sensitivity

<table>
<thead>
<tr>
<th>Marker</th>
<th>Specificity</th>
<th>Sensitivity</th>
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</thead>
<tbody>
<tr>
<td>LASP1</td>
<td>83%* / 80%†</td>
<td>85%* / 59%‡</td>
</tr>
<tr>
<td>NMP22TM</td>
<td>49%</td>
<td>68%</td>
</tr>
<tr>
<td>BTStatTM</td>
<td>74%</td>
<td>71%</td>
</tr>
<tr>
<td>UroVysionTM</td>
<td>63%</td>
<td>76%</td>
</tr>
<tr>
<td>ImmunoCytTM</td>
<td>72%</td>
<td>73%</td>
</tr>
</tbody>
</table>

Cut off values for hematuria/leukocyturia contamination: excluding patients with * > 250 eryth./µl, > 15 leukoc./µl; † > 200 eryth./µl; > 25 leukoc./µl

DEVELOPMENT STATUS
In a cohort of 246 patients
- the diagnostic accuracy of LASP1 detection was confirmed,
- cut-off values were determined to handle erythrocyte/leukocyte contamination (although in follow up studies hematuria isn’t a major issue),
- a stabilization protocol for sample shipment was established

REFERENCES:
1. Ardelt et al., Urol Oncol. 2013; 31(8): 1591-1598