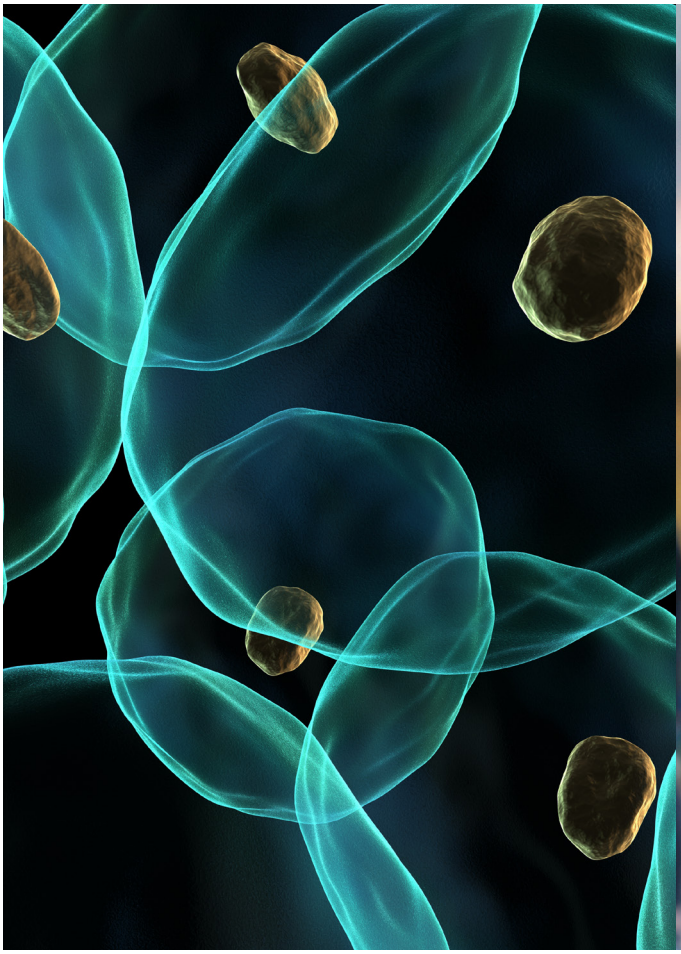
UBC® *Rapid*

For Bladder Cancer detection



UBC® *Rapid*

For Bladder Cancer detection

UBC® *Rapid* is a powerful diagnostic parameter in primary diagnosis and follow-up of bladder cancer, especially for papillary non-invasive high-grade tumors and carcinoma in situ (CIS).

UBC® *Rapid* performs better than urine cytology in many patients due to improved sensitivity and the combination of UBC® *Rapid* and cytology enables detection of additional tumors as opposed to cytology alone.

One clear advantage is that UBC® *Rapid* can be performed immediately and the result will be available during the patient visit.

Background

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.

9th

most commom cancer in the world

4 times

more likely that men gets bladder cancer than women

→ www.wcrf.org

CYTOKERATINS

In conditions of high cellular turnover, such as cancer, cytokeratins are released from the epithelial cells and can be detected in blood or urine. At present more than 20 different cytokeratins have been identified, of which cytokeratin 8, 18 and 19 are some of the most abundant in simple epithelial cells. The cytokeratin pattern is usually preserved during the transformation of normal cells into malignant cells.

DIAGNOSTIC

Cystoscopy is invasive and may cause pain and discomfort in patients and in cases with low grade tumors or carcinoma in situ, a diagnosis is not readily performed.
Urine cytology, a non-invasive urine test, is often used as an adjunct to cystoscopy. However, even if cytology has the advantage of high specificity its sensitivity varies considerably.
To overcome such shortcomings of the existing diagnostic methods for bladder cancer, urine tumor markers are available. One interesting possibility is the measuring of soluble cytokeratin 18 and 18 fragment in urine, since elevated amounts of these cytokeratin fragments are present in the urine of many individuals with bladder cancer, even at early stages of the disease.

"UBC® *Rapid* provides the physician with early signs of tumor recurrence during treatment monitoring".

Marie Torstensson
Marketing Manager, IDL Biotech AB

UBC® *Rapid*

UBC® *Rapid* is a point-of-care (POC) test that specifically measures soluble fragments of cytokeratin 8 and 18 in urine samples. UBC® *Rapid* shall be used for quantitative determination in combination with the POC-reader concile® Ω100. UBC® *Rapid* is also available as a qualitative version, UBC® *Rapid* VISUAL which should be read visually.

The outcome of bladder cancer depends on how advanced it is when it is diagnosed; aggessive non-muscle invasive bladder cancer, muscle invasive or confined to the bladder. Studies have demonstrated that the **UBC® *Rapid*** test can identify several primary bladder cancer tumors and is also an ideal marker for monitoring patients with existing bladder cancers and for detecting recurrences earlier [1,3-9]. **UBC® *Rapid*** can also identify malignancies missed by initial cytology/cystoscopy and with high sensitivity detect high risk tumors [3,7]. Due to the rapid format of **UBC® *Rapid*** test and ease of use it is an ideal urinary marker as an adjunctive test to standard methods to detect and monitor patients with bladder cancer.

High sensitivity for CIS

The performance of the **UBC® *Rapid*** POC test platform was further evaluated in a multicenter study [4]. Subanalysis of patients with carcinoma in situ demonstrated a very high diagnostic sensitivity (87%) for this aggressive form of bladder cancer that is also difficult to detect with cystoscopy. **UBC® *Rapid*** also showed a high diagnostic sensitivity for non-invasive high-grade tumours (71%). It was concluded that **UBC® *Rapid*** should be added in the diagnostics for carcinoma in situ and non-invasive high-grade tumors [6,9].

	CIS	NMI-LG	NMI-HG	MI-HG	CONTROL
Number	23	23	21	20	22
Sensitivity	87 %	30 %	71 %	60 %	
Specificity	91 %	91 %	91 %	91 %	91 %

THE FIRST QUANTITATIVE POC TEST PLATFORM – UBC® *Rapid*

The first clinical evaluation of **UBC® *Rapid*** on a POC test platform[5]. The study showed that quantitative results provide higher reproducibility and enable improved risk stratification compared with simple dichotomized POC test results. The accuracy of the POC test platform is at least equivalent to ELISA in 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. **UBC® *Rapid*** might be used as an adjunct to cystoscopy and cytology in laboratory independent settings.

WORKS IN HAEMATURIA

UBC® *Rapid* has the advantage of not being sensitive to blood contamination in the urine – haematuria, which is a common symptom of bladder cancer [2].

UBC® *Rapid*– For Bladder Cancer detection

TIME COUNTS

- Easy and rapid to perform
- Result within 10 minutes – during the patient visit.

FAST FACTS UBC® *Rapid*

- The only quantitative POC test platform for detection of bladder cancer, now also available as a qualitative test
- Works in haematuria
- UBC® also available as ELISA/IRMA

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Provides knowledge to decision.

Oncology
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TUBEX® *TF*

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