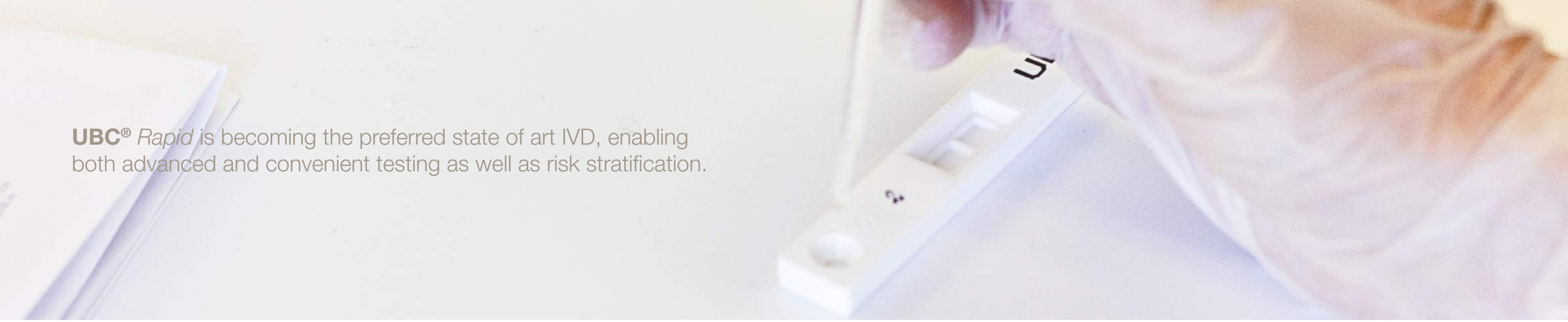
UBC® *Rapid*

For Bladder Cancer detection

Accurate tumor status in moments that matter.

iDL Biotech



UBC® *Rapid* is becoming the preferred state of art IVD, enabling both advanced and convenient testing as well as risk stratification.

UBC® *Rapid*

For Bladder Cancer detection

UBC® *Rapid* is a powerful diagnostic parameter in primary diagnosis and follow-up of bladder cancer, especially for non-invasive high-grade tumours and tumours in situ (CIS). **UBC®** *Rapid* performs better than urine cytology 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 a test can be performed immediately and the result will be available during the patient visit.

Background 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 may cause 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 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 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.

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 and 18 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.

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 a POC-reader.

UBC® *Rapid* 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 (Lüdecke et al 2012)[4].

High sensitivity for CIS

The performance of the **UBC®** *Rapid* POC test platform was further evaluated in a multicenter study (Ecke et al 2015)[6]. Subanalysis of patients with cancer 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 cancer in situ and non-invasive high-grade tumors. (Ecke et al, 2017)[7]

The first quantitative POC test platform for Bladder Cancer — **UBC®** *Rapid*.

Ritter et al [5] performed the first clinical evaluation of **UBC®** *Rapid* on a POC test platform. The study showed that quantitative results provide higher reproducibility and enable improved risk stratification compared with simple dichotomized POC test results, see table below. The accuracy of the POC test platform is at least equivalent to ELISA in bladder cancer patients (see table below). **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.

Comparison of **UBC®** *Rapid* (qualitative determination), **UBC®** *Rapid* (quantitative determination) **UBC®** *ELISA*, NMP22® BladderChek® and cytology.

	Sensitivity	Specificity	PPV	NPV
UBC® *Rapid* **Quantitative determination**	60.7 %	70.1 %	46.8 %	79,3 %
UBC®ELISA	48,3 %	71,3 %	42,7 %	75,8 %
NMP22® BladderChek®	16,4 %	95,3 %	62,5 %	70,5 %
Cytology	51,7 %	78,1 %	51,7 %	78,1 %

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

At a glance

UBC®*Rapid* - For Bladder Cancer detection

- The only quantitative POC test platform for urine based detection of bladder cancer.
- Easy and rapid to perform – result within 10 minutes
- Works in haematuria
- **UBC**® also available as ELISA/IRMA

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Diagnostic tools for reliable patient management.

Oncology

TPS® UBC® TPAcyk™ MonoTotal®

Bacteriology

TUBEX® *TF* TUBEX® WASH BUFFER

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IDL Biotech AB (publ), P.O Box 11151, SE-161 11 Bromma, Sweden
Phone: +46 8 799 67 50, Fax: +46 8 799 93 20
idlbiotech@idl.se, www.idl.se

iDL Biotech

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