

Early detection essential for cure



Urinary bladder cancer is an insidious disease showing a high rate of recurrence, often in association with more aggressive and invasive tumors. Regular follow-up of patients is thus essential. The activity tumor marker UBC™ here provides an efficient, cost-effective and non-invasive tool.

Monitor tumor cell activity with UBC™

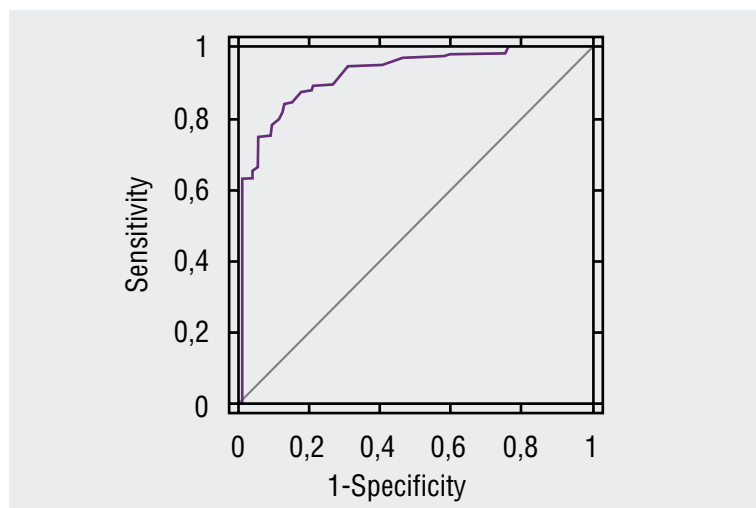
The activity tumor marker UBC™ (Urinary Bladder Cancer antigen) has proven to be a highly efficient, non-invasive tool in the management of urinary bladder cancer. UBC™ provides the physician with a reliable indicator of disease course, measured in terms of tumor cell activity instead of tumor burden. Using this valuable information in addition to the available clinical data gives a more complete picture of the

disease status. At initial presentation, urinary bladder tumors are most commonly superficial. The majority of patients however experience tumor recurrences, thus regular follow-up after completed therapy is extremely important. The UBC™ tumor marker, with its ability of early and distinct detection of increased tumor cell activity, here forms a reliable adjunctive tool.

UBC™ -A non-invasive adjunctive tool to cystoscopy

Cystoscopy is considered to be the golden standard for detection and follow-up of urinary bladder cancer. Although sensitive, cystoscopy is both an invasive and expensive technology that also causes discomfort for the patient. Thus, an adjunctive method to reduce the number of cystoscopies performed per patient is needed, particularly during follow-up. The urinary

tumor marker UBC™ has proven to fill these requirements, showing high sensitivity also for low stage and low grade tumors. By this, UBC™ is superior also to conventional cytology. The use of UBC™ in the management of urinary bladder cancer patients might reduce the necessary number of cystoscopies performed, especially during follow-up.



ROC (Receiver Operating Characteristics) analysis for UBC™ as diagnostic test for urinary bladder cancer. The area under the curve is 0.933, indicating UBC™ to be an excellent discriminative test.

Management of urinary bladder cancer patients

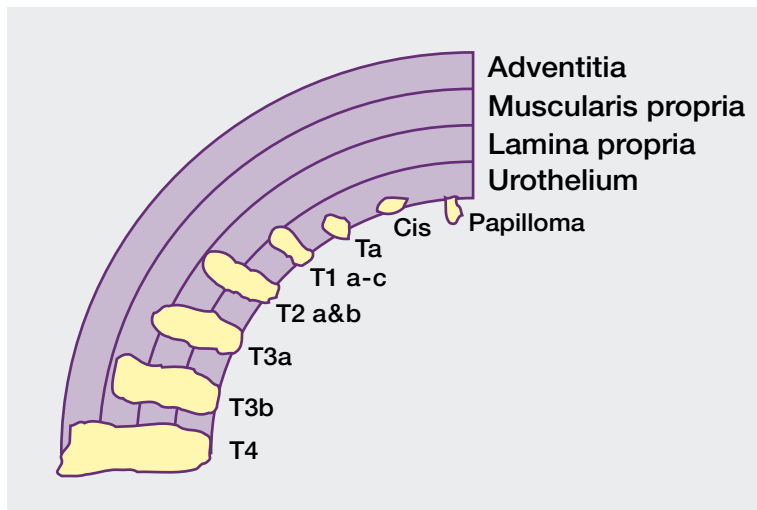
UBC™ is a quantitative test specifically designed for the analysis of urine samples. Changed UBC™ levels indicate changes in tumor cell activity, where elevated levels points to the presence of a tumor. The measured UBC™ concentrations have been reported to be associated with both stage and grade of the tumor, with

high levels indicating a worse prognosis. By following the patient with repeated and regular UBC™ assays, the physician can obtain critical information about tumor activity. This being particularly important during follow-up where a simple and non-invasive way of early detection of tumor recurrences thus is possible.

UBC™ - An activity tumor marker

The UBC™ test is a monoclonal assay that measures the reactivity against defined epitope structures on cytokeratins 8 and 18. The cytokeratins (intermediate filament proteins) are epithelial cell-specific. During the transformation

of normal cells into malignant cells, the cytokeratin expression patterns are usually maintained. Cytokeratins are present in the circulation as partially degraded single protein fragments, forming soluble protein complexes of different sizes.



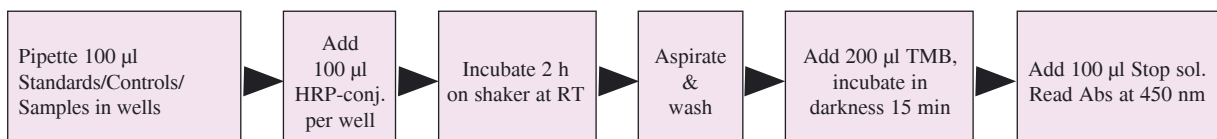
Schematic cross section drawing of the urinary bladder wall, showing both the tissue layers and the different stages of urinary bladder tumors classified according to the TNM-system.

UBC™ Technical Data

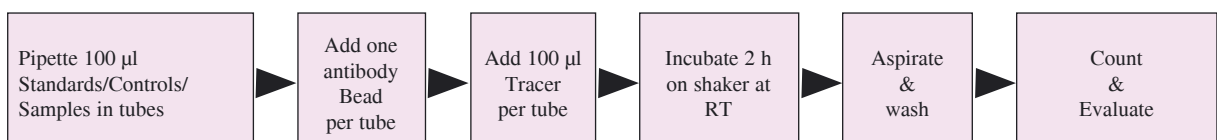
The UBC™ assay is available both as quantitative IRMA and ELISA tests. The specificity of the UBC™ assay was analyzed by immunohistochemistry, gel electrophoresis and immunoblotting.

The monoclonal antibodies used in the test are specific for UBC™, without detectable cross reactivity to other tumor-associated antigens that may be present in patient urine.

UBC™ Methodology



ELISA Assay procedure - Soluble fragments of cytokeratins 8 and 18 are reacted with a microplate well coated with monoclonal antibodies and simultaneously with HRP conjugated affinity purified antibodies.



IRMA Assay procedure - Soluble fragments of cytokeratins 8 and 18 are reacted with a bead coated with monoclonal antibodies simultaneously with a tracer (affinity purified antibodies).

UBC™

A tumor marker for Total Care Management

UBC™ is useful in the management of patients with urinary bladder cancer.

UBC™ is a reliable indicator of tumor cell activity.

UBC™ is a non-invasive and efficient tool, based on simple urine measurements and thus convenient for the patient.

UBC™ can serve as an reliable adjunctive tool during follow-up, thus reducing the number of cystoscopies performed.

UBC™ provides the physician with early signals on tumor recurrence during patient follow-up.

UBC™ has proven sensitive also in low stage and low grade urinary bladder tumors.

UBC™ supports therapeutical decisions to optimize patient management and improve the cost/benefit ratio.

UBC™ is a monoclonal immunoassay with reactivity against defined epitope structures on cytokeratins 8 and 18.