



protexam

## DIAGNOSTIC BIOMARKER TESTS

*Ready-to-use tests  
with IVD registration*



# Bladder Cancer Check-Up and Status Management

# CONTENT



Bladder Cancer Check-Up (BCU) and Status Management (BSM) tests - why needed?



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# BLADDER CANCER CHECK-UP (BCU) AND STATUS MANAGEMENT (BSM) TESTS – WHY NEEDED?

<b>Test name</b>	<b>BCU or BSM (Bladder Check-Up or Management)</b>
<b>Function</b>	<ul style="list-style-type: none"><li>• Detection of primary bladder cancer.</li><li>• Monitoring for recurrence of bladder cancer.</li></ul>
<b>Accuracy (AUC)</b>	85 or 82 % +cytology
<b>Selected references</b>	<p><i>Mengual L, et al. Br J Cancer 2022, 127(11):2043.</i></p> <p><i>Krochmal M, et al. Sci Rep. 2019;9(1):7635.</i></p> <p><i>Frantzi M, et al. Clin Cancer Res, 2016, 22(16):4077.</i></p>

## To address the burden of bladder cancer (BC)

- The second leading cause of death among urogenital tumors
- A high recurrence rate of more than 50 % requiring monitoring
- 10% - 15% develop progression → poor prognosis
- Monitoring with expensive and invasive cystoscopies over many years

## BCU/ BSM test for non-invasive early detection, monitoring, and guiding therapy

- Early non-invasive detection of BC and monitoring provides an opportunity for timely initiation of appropriate treatment

# WHO ARE THE TESTS FOR?

The proteome test is recommended if **at least two of the following risk factors are present:**

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**Age > 55**

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**Medical history:** previous diagnosis and resection of BC or a previous suspicion of BC (prior negative cystoscopy); Multiple previous urinary tract infections, schistosomiasis, or previous treatment (radiotherapy, chemotherapy).

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**Physical symptoms:** blood in the urine (hematuria); painful urination; back pain.

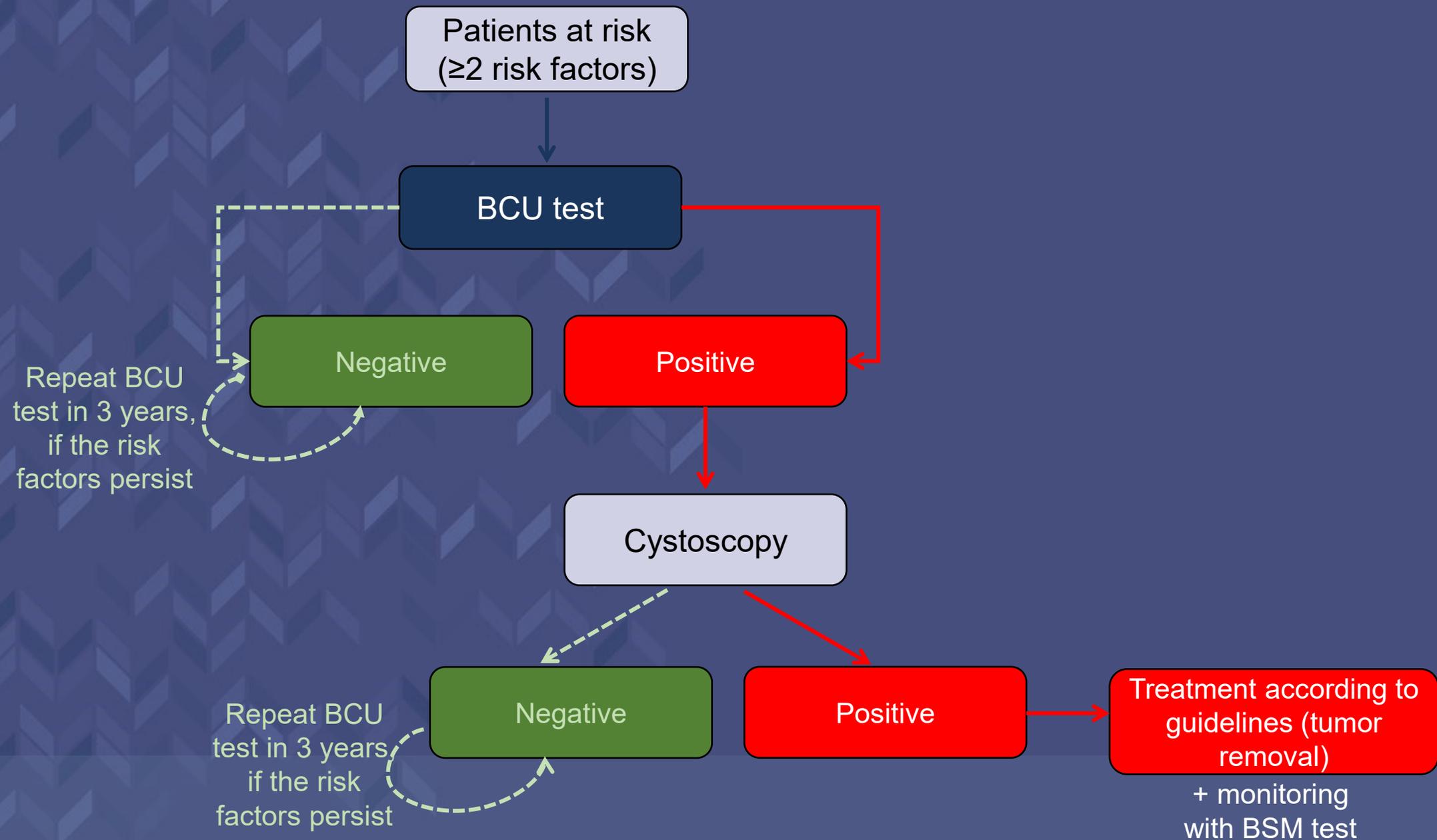
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**Occupational exposure:** working in industries such as dye manufacturing, rubber, textiles, leather, or chemicals.

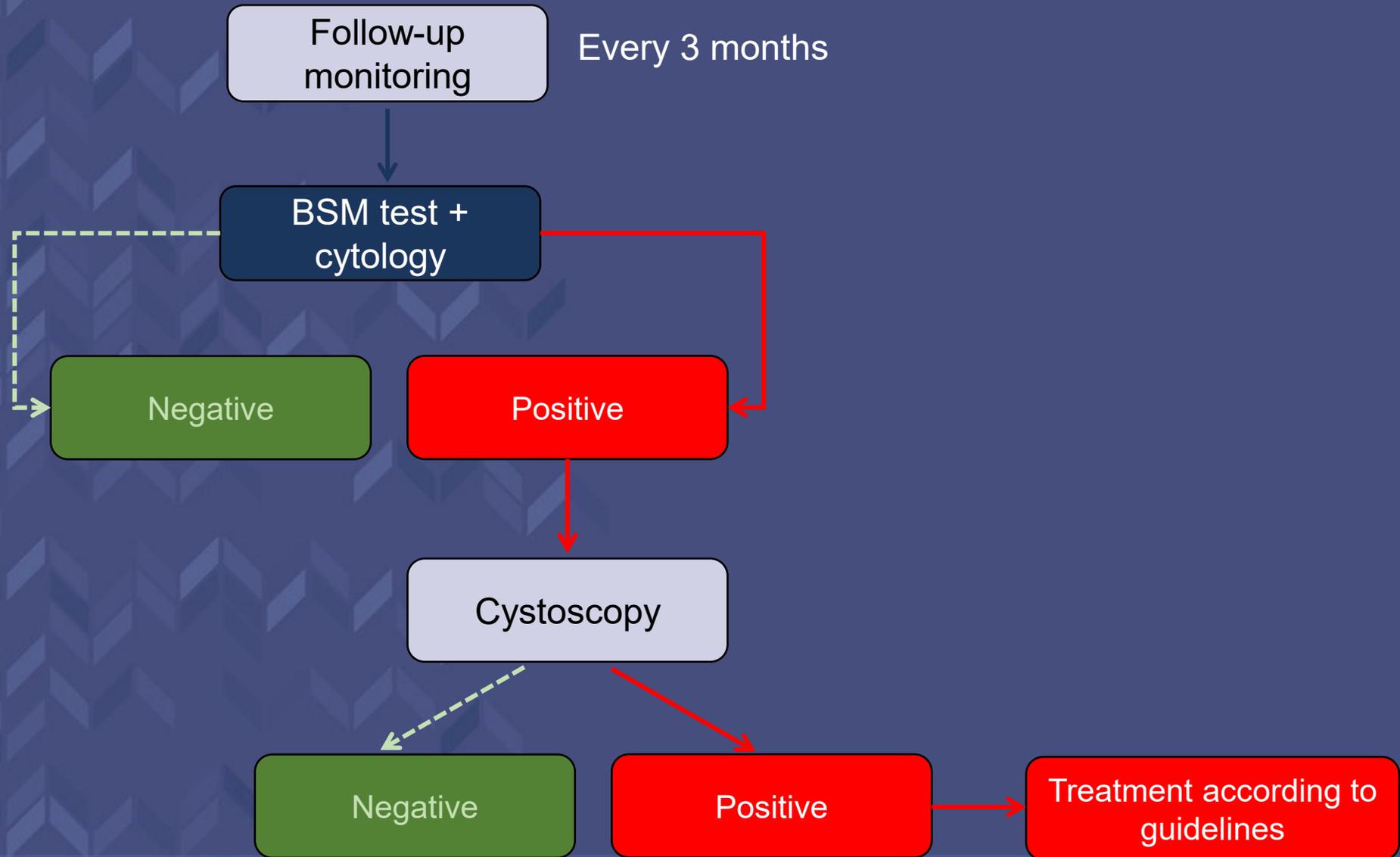
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**Family history**

# APPLICATION OF BCU TEST (DETECTION)



# APPLICATION OF BSM TEST (MONITORING)



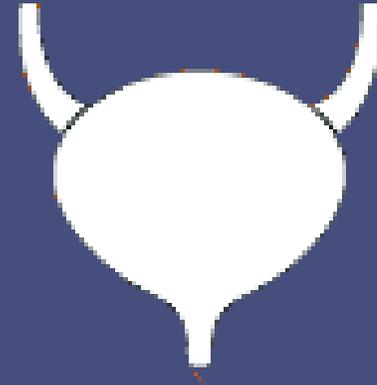
# BENEFITS FOR PATIENTS

## State of the art

- Invasive and uncomfortable for the patient - up to 80% of patients avoid surveillance because of this!
- Fails to detect upper urothelial carcinoma and urethral cancer in at least 30% of cases
- Complications: urinary tract infection, prostatitis, nephritis, urethral injury, sphincter injury, bladder injury, bleeding, temporary urinary incontinence

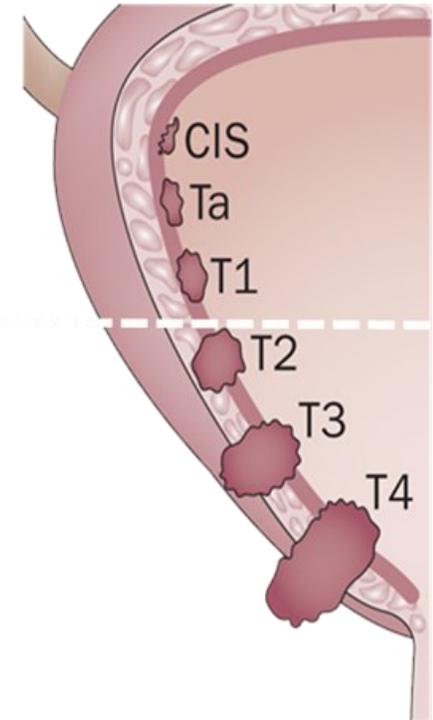
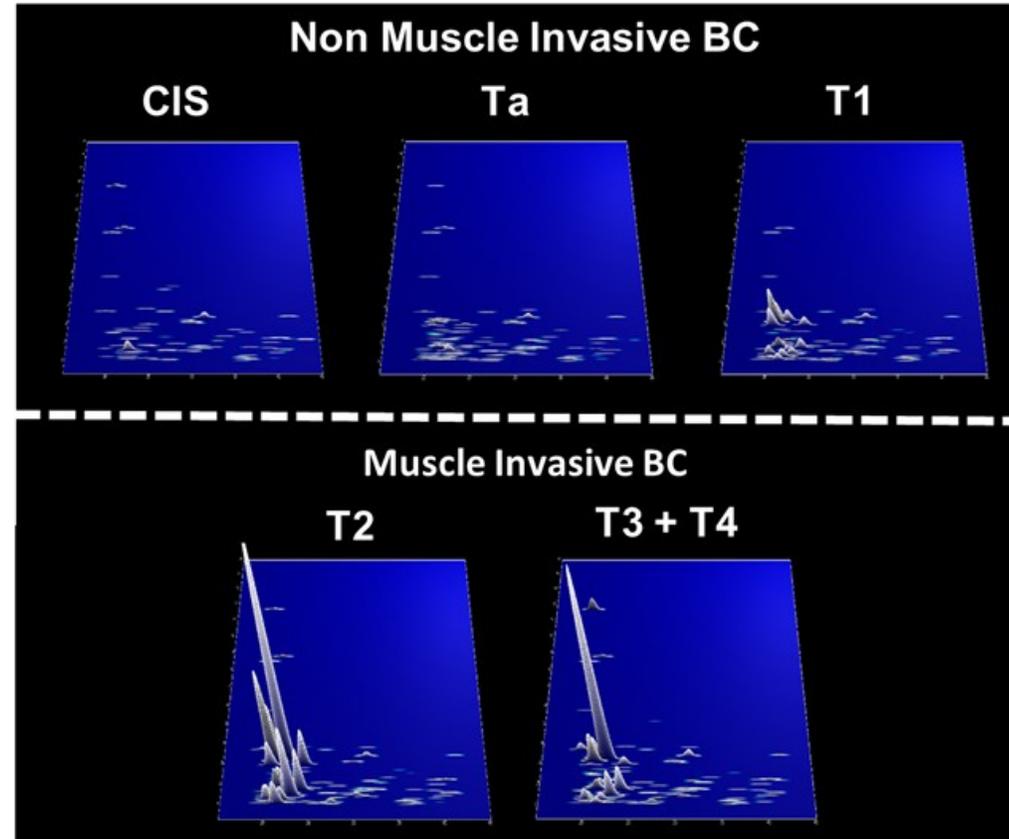
## Proteomics test

- Non-invasive, no complications
- Significantly reduces the number of cystoscopies (for diagnosis: 70% to 80%, and to 60% for monitoring) → better compliance with BC diagnostics and follow-up monitoring
- The BSM test detects carcinomas in the upper urothelial tract and in the urethra at an early stage - in 30% of cases and in severe cases!



# SCIENTIFIC EVIDENCE

Latosinska A, Frantzi M, et al.  
*Proteomics Clin Appl.* 2018  
Mar;12(2).



- **Urinary peptidomics molecular signatures reflect BC progression (each peak represent a single peptide).**

# SCIENTIFIC EVIDENCE

## BCU test:

- Negative predictive value (NPV): 91%
- Positive predictive value (PPV): 61%
- Sensitivity 89%, Specificity 67%

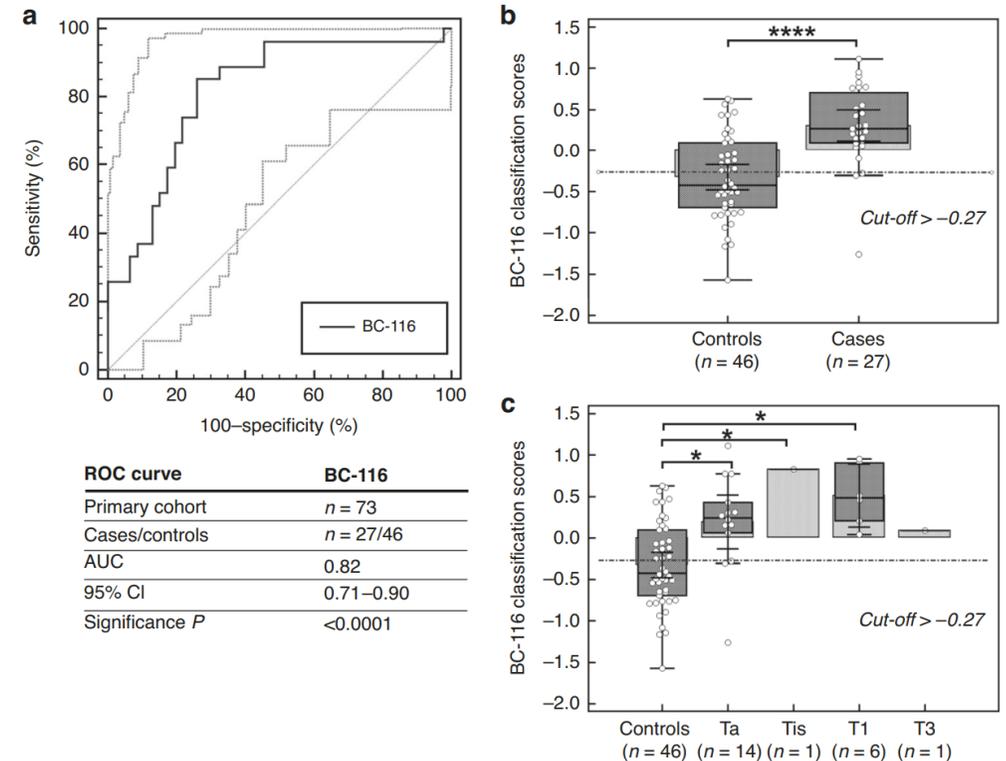
## BSM test + cytology:

- Negative predictive value (NPV): 95%
- Positive predictive value (PPV): 32%
- Sensitivity 86%, Specificity 61%

For patients with suspected cancer and generally for patients at risk of cancer, the NPV is most important. NPV means that negative result of the proteome test is really negative, so that no cancer is overlooked.

**Evidence from multiple, multi-centric and prospective studies including more than 2000 patients**

## Performance characteristics of the urinary biomarkers in the primary cohort



Mengual L, Frantzi M, et al. *Br J Cancer*. 2022;127(11):2043-2051.

Krochmal M, et al. *Sci Rep*. 2019;9(1):7635.

Frantzi M, et al. *Clin Cancer Res*. 2016;22(16):4077-86.

"EXPLORING  
THE FUTURE:  
DO YOU HAVE  
QUESTIONS?"



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**Dr. Maria Frantzi**  
**protexam GmbH**  
**Rotenburger Str. 20**  
**D-30659 Hannover, GERMANY**  
**Phone: +49 (0)511 55 47 44 29**  
**Fax: +49 (0)511 55 47 44 31**  
**e-mail: [med@protexam.com](mailto:med@protexam.com)**