



protexam

DIAGNOSTIC BIOMARKER TESTS

*Ready-to-use tests
with IVD registration*



Prostate Cancer Check-Up and Status Management

CONTENT



Prostate Cancer Check-Up (PCU) and Status Management (PSM) tests - why needed?



Who are the tests for?



Application of PCU/ PSM test



Benefits for patients



Scientific evidence

PROSTATE CANCER CHECK-UP (PCU) AND STATUS MANAGEMENT (PSM) TESTS – WHY NEEDED?

Test name	PCU (Prostate Check-Up)	PSM (Prostate Status Management)
Function	Prostate cancer (PC) diagnosis after increased PSA-value	Diagnosis of significant PC
Accuracy (AUC)	81 %	82 %
Selected references	<p><i>Frantzi M, et al. Cancers (Basel). 2023;15(4):1166.</i></p>	<p><i>Frantzi M, et al. Br J Cancer 2019, 120(12):1120.</i></p> <p><i>Frantzi M, et al. World J Urol. 2022, 40(9):2195.</i></p> <p><i>Frantzi M, et al. medRxiv 2024.04.16.24305475.</i></p>

To address the burden of prostate cancer (PC)

- One of the most common types of cancer in men
- PSA screening is associated with unnecessary biopsy and overdiagnosis
- PCU test offers patients with elevated PSA levels a non-invasive approach to determine whether PC is present or absent.
- It is important to distinguish between indolent (does not require treatment) and significant tumor (requires treatment) to reduce unnecessary treatments. The PSM test enables non-invasive differentiation between indolent and significant tumor.

WHO ARE THE TESTS FOR?

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

Age > 55

Elevated PSA levels (>3 ng/ml)

Positive (PIRADS 4-5) or suspicious result (PIRADS 3) from multi-parametric magnetic resonance imaging (mpMRI)

Physical symptoms: Difficulty urinating or weakened urine stream, blood in urine or semen, bone pain, unexplained weight loss, erectile dysfunction

Family history

Previous suspicion of PC (prior negative biopsy)*

*Previous (including negative) biopsies are a risk factor, as there is increasing concern that prostate biopsy may lead to tumor seeding along the needle tract, in addition to potential complications such as morbidity and infection risk.

APPLICATION OF PCU AND PSM TESTS

Patients at risk
(≥ 2 risk factors)

PCU test

Negative

Positive

PSM test

Negative

Positive

biopsy

Treatment
according to
guidelines (active
surveillance)

Treatment
according to
guidelines (tumor
removal)

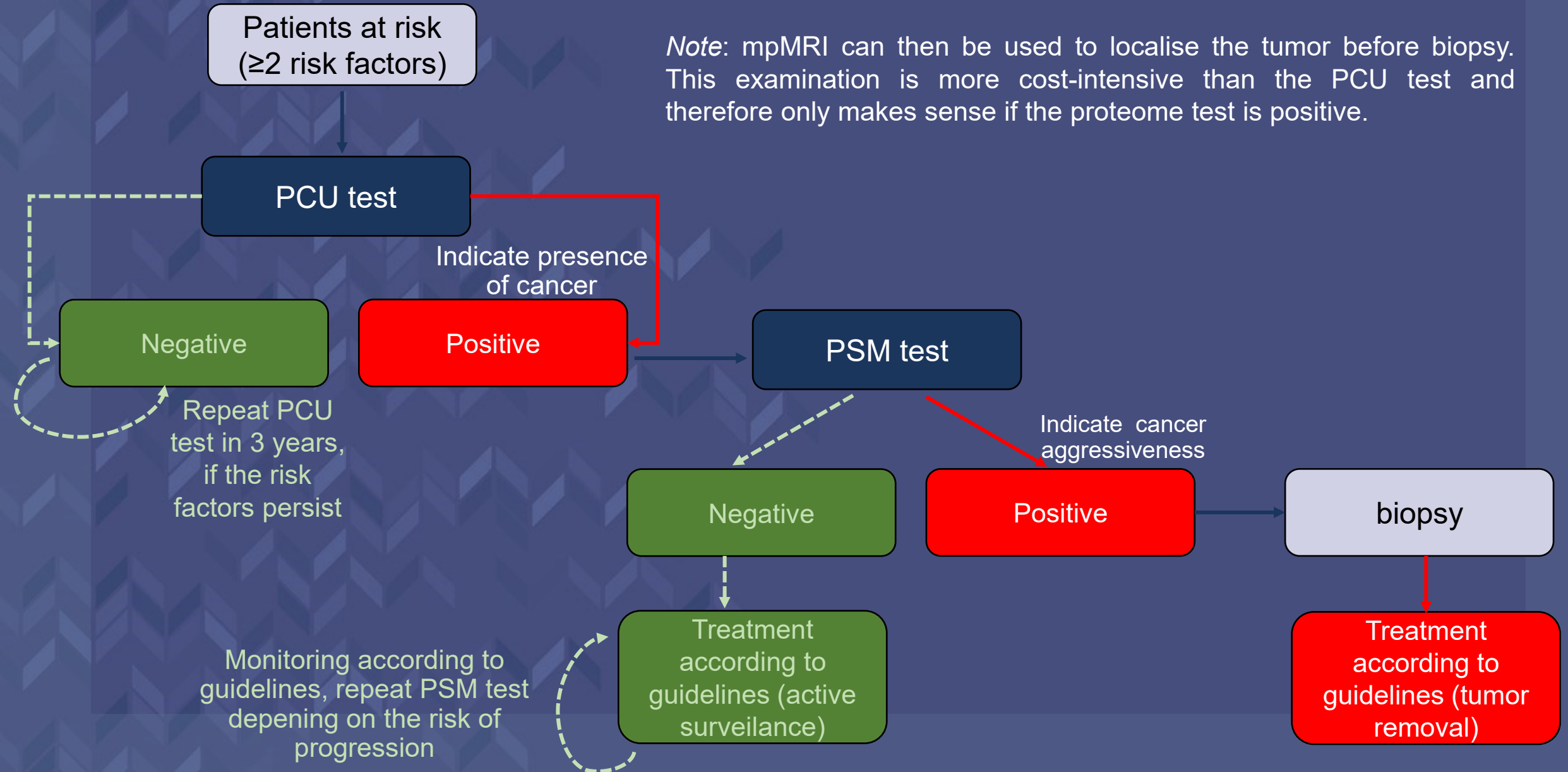
Indicate presence
of cancer

Indicate cancer
aggressiveness

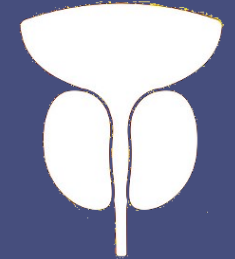
Repeat PCU
test in 3 years,
if the risk
factors persist

Monitoring according
to guidelines, repeat PSM test
depending on the risk of
progression

Note: mpMRI can then be used to localise the tumor before biopsy. This examination is more cost-intensive than the PCU test and therefore only makes sense if the proteome test is positive.



BENEFITS FOR PATIENTS



State of the art

- PSA, mpMRI: high level of uncertainty
- Biopsy: highly invasive
- 80% of men with an elevated PSA value (>3 ng/ml) do not have PC → unnecessary biopsies
- >50% of significant prostate tumors are not detected by the PSA test
- If available, mpMRI is recommended, may provide additional information
- Complications of biopsy: hematuria, rectal bleeding, pain in the hypogastrium, perineum or urethra, fever, nausea, vomiting, retention of urine or other adverse events

Proteomics test

- Non-invasive, no complications
- No need for prior digital rectal examination and/or prostate massage
- Reduction of unnecessary biopsies
- Identification of PC more accurately and earlier, enabling initiation of appropriate intervention

SCIENTIFIC EVIDENCE

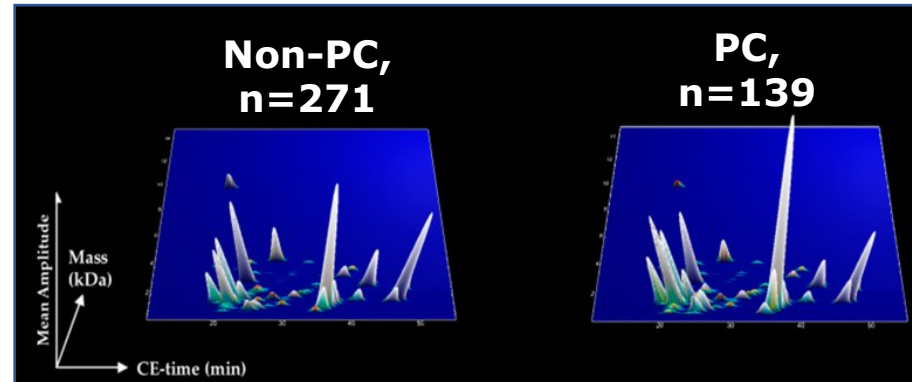
I) PCU test: Guiding biopsy in patients at risk

II) PSM test: Guiding intervention in patients at active surveillance

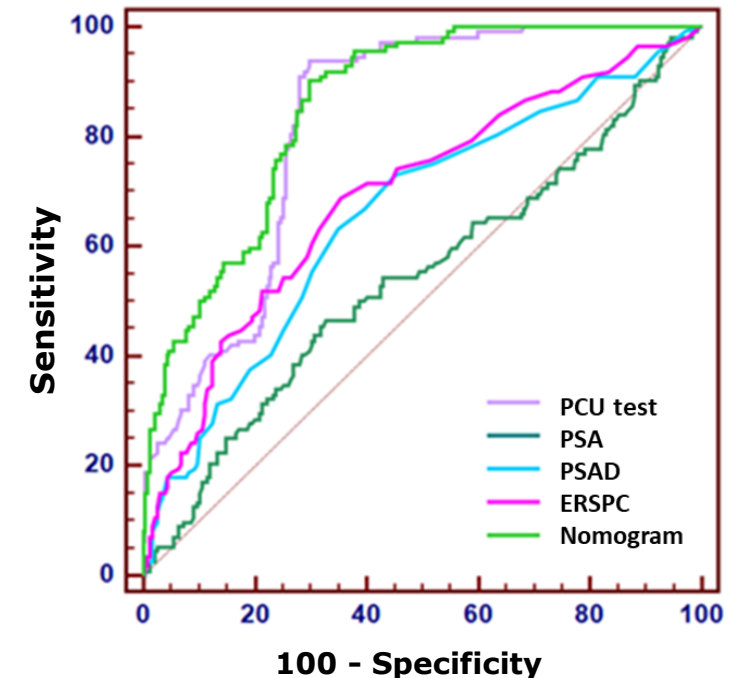
Frantzi M, et al. *Cancers (Basel)*. 2023;15(4):1166.

I) PCU test: Guiding biopsy in patients at risk

- Urinary peptide signature reflects differences between patients with and without PC



- Evidence from large multicentric study: 970 patients
- **Performance is significantly superior to clinical standards**



SCIENTIFIC EVIDENCE

I) PCU test: Guiding biopsy in patients at risk

II) PSM test: Guiding intervention in patients at active surveillance

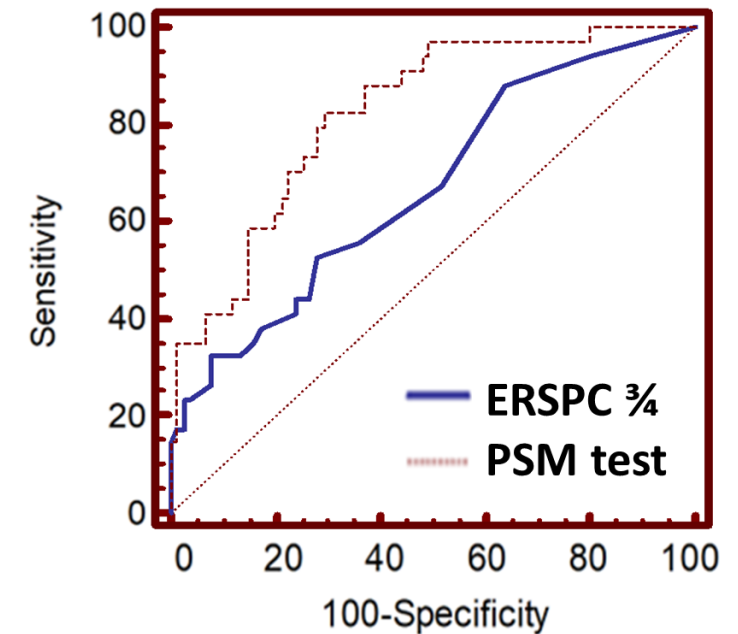
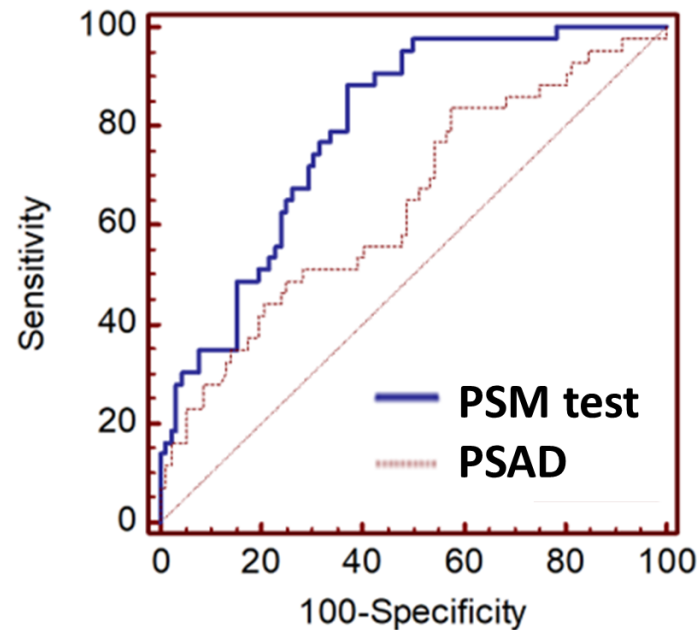
Frantzi M, et al. medRxiv
2024.04.16.24305475.

Frantzi M, et al. World J Urol.
2022, 40(9):2195.

Frantzi M, et al. Br J Cancer
2019, 120(12):1120.

II) PSM test: Guiding intervention at active surveillance

- Multicentric clinical studies, n>1000 patients
- Three independent validation studies
- Performance significantly superior to clinical standards: PSA, PSAD, ERSPC



"EXPLORING
THE FUTURE:
DO YOU HAVE
QUESTIONS?"



www.mosaiques.de
www.mosaiques-group.com



xken

www.xken-health.com



www.power-of-proteomics.com
www.CDPP.dev



protexam

www.protexam.com

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