

# PCA3

## General:

The PCA3 gene test - carried out on urine samples taken after digital rectal examination - can identify men who are more likely to have a positive biopsy for cancer, as compared to the predictive value of the PSA test alone. The test measures messenger RNA, which transfers DNA instructions from the PCA3 gene. PCA3 is a gene that is only expressed in the prostate and over-expressed by a factor of perhaps 60- to 100 times in cancerous tissue of the prostate (PCA3 score). At the cellular level, PCA3 determination can separate benign from malignant prostate cells with an accuracy approaching 100%

Overexpression of PCA3 by cancer cells has allowed diagnostic use of gene levels in tissues or fluids containing prostate cellular material. In clinical studies to date, urinary PCA3 scores (PCA3-mRNA/PSA-mRNA) are consistently superior to serum PSA levels in diagnosis of prostate cancer. An unsuspect score shows that the sample contains prostate cells without over-expression of the PCA3-gene.

For a PCA3-score of <35 the present literature describes a risk of only 16% for a detection of a prostate-CA in a (further) biopsy. The higher the PCA3 score (cut-off >35%), the more likely it is that the patient will prove to have prostate cancer on biopsy.

The risk for a prostate-CA with a PCA3-score >35 is 2.5-times higher compared to PCA3-scores <35. The present literature describes a significantly higher probability of >40% for a detection of a prostate-CA in a (further) biopsy. This test will help oncologists to select which men, with a marginally raised PSA, should go on to prostate biopsy.

**Indication:** Screening of prostate gland carcinoma, course monitoring after prostate gland resection, radiotherapy, monitoring of hormonal therapy, borderline PSA values

**Preanalytics:** Urine collection is the most critical step; the assay evaluates mRNA, a very labile sample that is destroyed in approximately 20 minutes in the absence of inhibiting agents. Approximately 2 ml of the urine sample is filled into a **PCA3-transport tube** with lysis buffer that contains ribonuclease inhibitors. Mix urine before transfer. After transfer in the PCA3-transport tube, the analyte is stabil up to one week. Then specimen has to be transported as quick as possible to the laboratory in cooling gel packs, **do not freeze** ! Special PCA3-transport tubes are required and can be ordered at the laboratory.

**Material:** urine (please contact FML prior to sending)

1. The patient should drink at least 500 ml (=0.5 liters) before sample urine collection.

2. Before sample urine collection perform **digital rectal examination**:

Apply significant pressure on prostate and press from the base to apex and from the side to the middle. This should be done **for each part three times as applied pressure** and not as massage!!

3. After digital rectal examination collect **20-30 ml first stream urine** from patient (no middle stream urine!). If the patient cannot stop urinating after collecting 20 – 30 ml, keep another container beside collection place. **At least 2.5 ml urine** is necessary for PCA3 assays!

4. Store the urine sample at 2-8°C or on ice (do not freeze!!! the sample!) and bring the sample to the laboratory latest **within 4 hours!!** Please instruct driver to keep the sample directly on an ice pack.

5. The sample will then be transferred into special transport vials within the laboratory.

TAT: 2 weeks\*

Method: PCR

Units: PCA3 score

Ref.- range: score of  $\leq 35$ : elevated probability of finding tumor cells in the prostate biopsy  
Lower score: low probability of finding tumor cells in a biopsy of the prostate

For complete list of laboratory test offered at Freiburg Medical Laboratory, please visit  
<http://www.fml-dubai.com/parameter-listings/>