Clinical interpretation of the test: PCA3 score

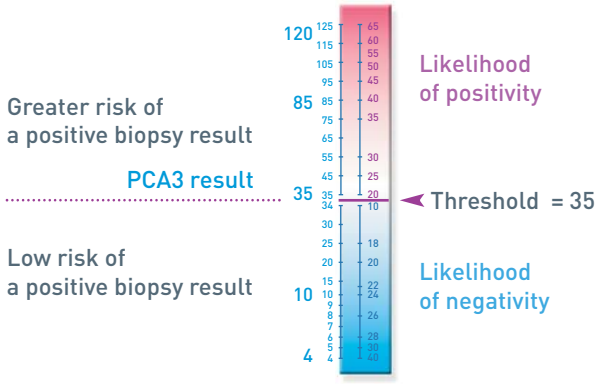
The PCA3 score reflects the risk of having a positive biopsy result in a patient.

The positive threshold used for the PCA3 test is a score of over 35.

A patient with a score of over 35 has a greater risk of having a positive biopsy result than patients with a negative score.

The PCA3 score is independent of the prostatic volume, unlike the serum PSA assay.

The interpretation of the score must be performed by taking the other clinical, biological and ultrasound elements into account (due to false positives or false negatives) .



References

1. Bussemakers M, van Bokhoven A, Verhaegh G, Smit F, Karthaus H, Schalken J. 1999. DD3: a new prostate-specific gene, highly over expressed in prostate cancer. Cancer Res; 59: 5975–5979.

2. de la Taille A, Irani J, Graefen M, Chun F, de Reijke T, Kil P, Gontero P, Mottaz A, Haese A. 2011. Clinical evaluation of the PCA3 assay in guiding initial biopsy decisions J Urol; 185: 2119-25.

3. Crawford ED et al., 2012. Diagnostic performance of PCA3 to detect prostate cancer in men with increased prostate specific antigen: a prospective study of 1,962 cases. J Urol ; 188: 1726-31.

4. Fradet Y, Saad F, Aprikian A, et al. 2004. uPM3, a new molecular urine test for thedetection of prostate cancer. Urology; 64: 311–316.

5. Hessels D, Gunnewiek J, van Oort I, et al. 2003. DD3PCA3-based molecular urine analysis for the diagnosis of prostate cancer. Eur Urol; 44:8–16.

6. Larré S, Ronsin C, Irani J. 2010. Immediate impact of ultrasound-guided prostate biopsies on PCA3 score. Eur Urol; 57: 1121-2.

7. Ploussard G et al., 2010. The prostate cancer gene 3 (PCA3) urine test in men with previous negative biopsies: does free-to-total prostate-specific antigen ratio influence the performance of the PCA3 score in predicting positive biopsies? BJU Int; 106 : 1143-7

In practice

Pre-analytical requirements

- Following digital rectal examination, collect 20 to 30 mL of first morning urine.
- Transfer 5 mL into 2 tubes containing transport medium.

Sample stability

- 5 days at 8°C - 30°C or 14 days a 2°C - 8°C.

Price

- Please contact the International Division.

To find out more about this subject

Find all the necessary details at:
www.biomnis.com/international › Test Menu
› Test guide or use the Biomnis mobile application

Biomnis group code: PCA3

Contact details

Biomnis
International Division
19 av. Tony Garnier ▪ 69007 LYON ▪ FRANCE
Tel.: +33 (0)4 72 80 57 42 ▪ Fax: +33 (0)4 72 80 76 56
www.biomnis.com

DS14UK - JANUARY 2014

Focus on...

Progensa™ urine test for PCA3

Clinical significance in the decision-making process for prostate biopsies.

biomnis
SPECIALISED MEDICAL PATHOLOGY

Detecting prostate cancer

- **Prostate cancer is the most common cancer in men aged over 50** and is the second cause of cancer-related mortality in men.
- **Early diagnosis** (or screening) via a digital rectal examination and evaluation of the PSA (Prostate Specific Antigen) level is offered in men aged between 50 and 75. Men with risk factors (a family history); the age is lower at 45 years old.
- **If the digital rectal examination and/or PSA level are found to be abnormal,** an ultrasound-guided transrectal prostate biopsy is necessary to detect the presence or otherwise of prostate cancer.
  - **If the biopsy is positive** = positive diagnosis. The treatment given depends on the age, life expectancy and aggressivity of the cancer (surgery, radiotherapy, hormone treatment or monitoring).
  - **If the biopsy is negative** = monitor PSA levels and take new biopsy samples in function to the patient's age and/or the changes in the PSA level (rate of change in PSA levels or the "PSA velocity").
  - **If the biopsy is negative** = monitor PSA levels and take new biopsy samples in function to the patient's age and/or the changes in the PSA level (rate of change in PSA levels or the "PSA velocity").

PSA dosage limitations: Sensitivity and Specificity

The PSA antigen is specific for the prostate but not specific for prostate cancer: benign prostatic hyperplasia (or prostatic adenoma) as well as infections or inflammation can also cause an increase in this marker.

- **We observe approximately 15% of prostate cancers** in patients with a normal PSA level, i.e. ‹4.0 ng/mL..
- **The PSA test has a poor level of sensitivity and a lack of specificity** notably within the grey area of maximum uncertainty, which lies between 4 and 10 ng/L (numerous false negatives, false positives and unnecessary biopsies).
- **This lack of specificity leads to the performance of prostate biopsies** which can eventually be found to be negative and are considered as unnecessary as a result (estimated at between 45-65% of cases).
- **Other inconveniences of this lack of specificity** are the over-diagnosis and over-treatment of prostate cancers whereby the disease progression potential is very poor or non-existent.
- **No** PSA level threshold allows us to obtain both considerable sensitivity and specificity.
- **Every positive PSA test leads to one or several biopsies being collected:**
  - Raised costs for the health care system.
  - Uncomfortable for the patients and a cause of worry and apprehension.
  - Risk of infections and/or risk of haemorrhage.

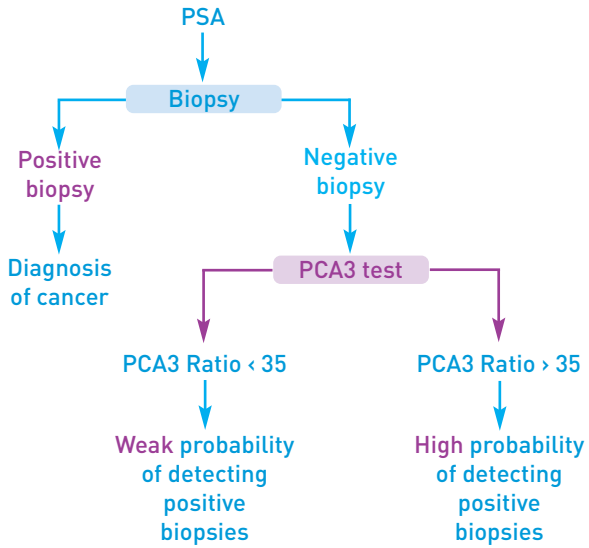
The clinical significance of the PROGENSA™ PCA3 assay

- A tool for the diagnosis of prostate cancer
- A prognostic tool in patients with abnormal PSA levels and a normal biopsy result.
- Offers assistance to clinicians when making a decision whether or not to take a new biopsy from the patient.

The DD3 gene... DD3PCA3... PCA3

- In 1999, a "pseudo-gene" named DD3 and subsequently renamed PCA3 (prostate cancer gene 3) was discovered. Its expression is restricted to the prostate with a very weak expression in health prostate cells.
- Over-expression of PCA3 in cancerous prostate cells (~60 to 100 times greater).

Indication of the PROGENSA™ PCA3 assay



How to perform the PROGENSA™ PCA3 assay

1. Perform a digital rectal examination putting sufficient pressure on the prostate with 3 passages per prostatic lobe in order to release as many prostate cells as possible in the urine.
2. Collect the first morning urine sample (25 - 30 mL) and transfer 5 mL of this first jet into the transport medium used for the PCA3 test (medium: PROGENSA PCA3 Urine Specimen Transport Kit) and send it to the laboratory.