

IN PRACTICE...

SAMPLING

- ✓ Following the DRE, direct the patient to provide a first-catch urine 20 to 30 mL in a urine collection cup.
(Do not freeze the sample before transferring to the Progenesa™ PCA3 tube)
- ✓ Invert the sample 5 times to re-suspend the cells urine.
Using the disposable pipette provided in the blister pack then transfer 2.5 ml to the Progenesa™ PCA3 tube containing a specific transport medium within 4 hours of collection.

Our laboratory supplies Progenesa™ PCA3 tubes upon request:

+33.1.34.40.20.20

or

www.lab-cerba.com

(rubrique : analyses informations/ consommables)

STORAGE

Urine samples may be stored for:

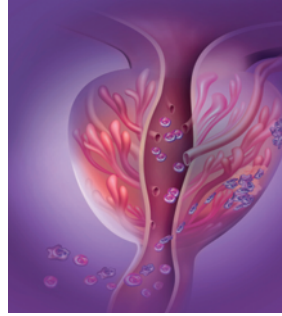
- ✓ 4 hours after collection without preservative at between +2°C et +8°C

Stability of urine in specific Progenesa™ PCA3 transport tube:

- ✓ 7 days at between +8°C and +30°C
- ✓ 14 days at between +2°C and +8°C
- ✓ 90 days at - 20 °C

RUN FREQUENCY : fortnightly

The first molecular biology test specific for prostate cancer: a guide for biopsy indication



Prostate cancer is the form of cancer most commonly diagnosed in men over the age of 50 years, with more than 60,000 new cases annually in France since 2005 (FRANCIM/InVS surveillance network). Diagnosis of prostate cancer is confirmed by positive prostate biopsy, an invasive procedure generally triggered by abnormalities detected on digital rectal examination (DRE) and/or increased serum levels of total PSA (prostate-specific antigen). While prostate biopsy remains the reference tool for diagnosis of this form of cancer, it can lead to complications, primarily bleeding and infection. The test involves examination of a very small proportion of the prostate tissue (< 1%), and its diagnostic sensitivity is related to the number of biopsy samples taken; there is a fairly high rate of false negatives. The limitations of biopsy thus compound those of DRE and of total PSA assay, and it is therefore important to have additional examinations available in order to avoid unnecessary biopsies.

WHAT IS PCA3?

PCA3 is a new molecular biology test performed on urine samples. Previously known as DD3, PCA3 is a gene first identified in 1999 that synthesises no known proteins but is expressed in the form of messenger RNA detectable with RT-PCR and specific for cancerous prostate cells. PCA3 is specific to the prostate overexpressed only by malignant tissue. Unlike PSA, the PCA3 score appears not to be correlated with diseases that increase the size of prostate gland such as benign prostatic hyperplasia (BPH). The PCA3 test may thus be used to determine the probability of presence of cancer cells in the prostate.

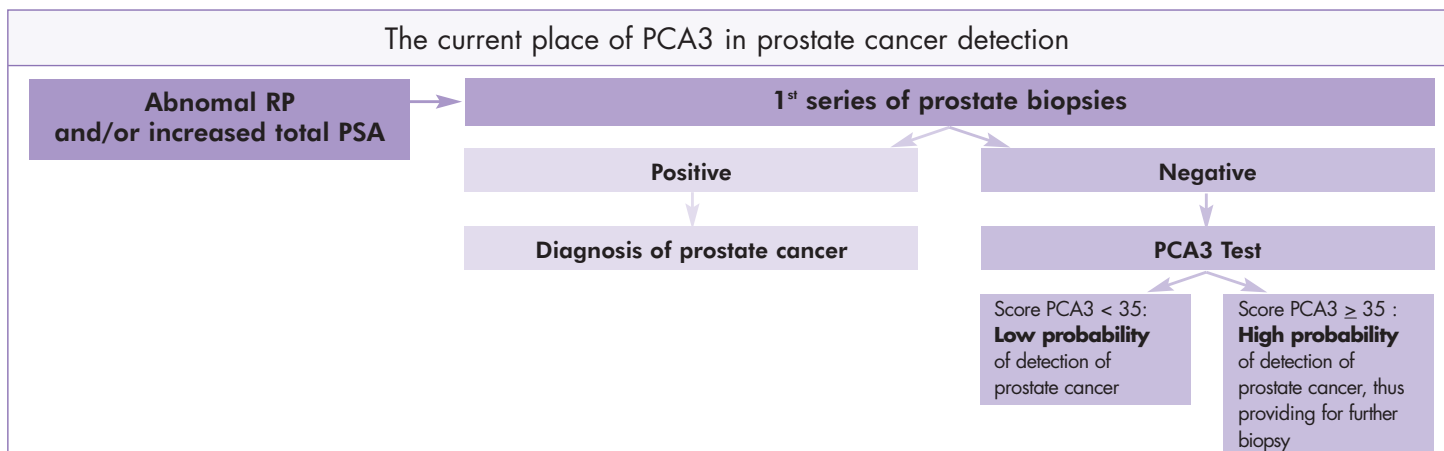
WHY REQUEST A PCA3 TEST?

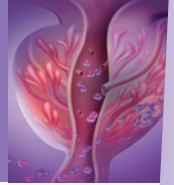
It is a **non-invasive test used to guide the decision about whether biopsy is required**. There has been a steady rise in prostate biopsies in France as individualised screening tests have become more frequent, resulting in an increase in the urological management of patients undergoing an initial series of negative biopsies. Given the limitations associated with the currently available examinations, an assay that can help determine whether biopsy is indicated is clearly advantageous.

PCA3 provides a non-invasive test that may be used:

- ✓ in addition to PSA
- ✓ in patients with negative initial biopsy results
- ✓ on account of its specificity for prostate cancer
- ✓ as a guide to whether further biopsy is required in the short term

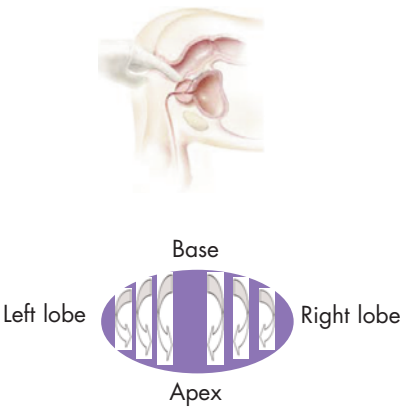


The current place of PCA3 in prostate cancer detection





URINE SAMPLE COLLECTION PROCEDURE

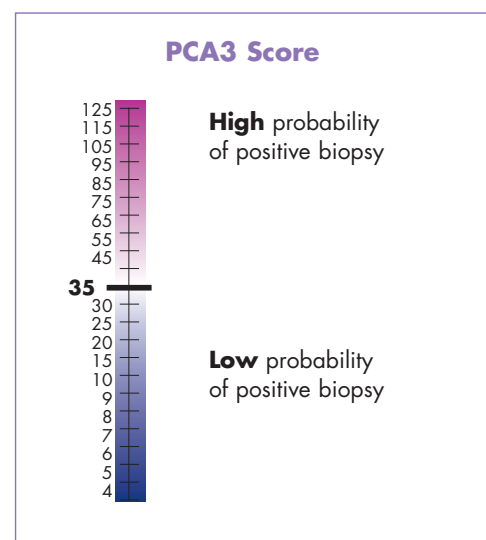
The PCA3 score is obtained with urine samples collected after DRE applying sufficient pressure on each lobe to force expulsion of prostate cells into the urethra.

Urine sample collection procedure		
<p>1 Digital rectal examination</p> <ul style="list-style-type: none"> ✓ Perform no more than 3 stokes to each lobe 	<p>2 First-catch urine collection</p>  <ul style="list-style-type: none"> ✓ DO NOT FREEZE before transferring to the ProgenSA™ PCA3 tube ✓ Homogenise by inverting (x5) prior to transfer 	<p>3 Transfer of urine</p> <ul style="list-style-type: none"> ✓ in a ProgenSA™ PCA 3 tube within 4 hours of collection. Pending transfer, urine samples may be stored at between +2°C and +8°C.  <p>2.5 mL (taking care to fill up to the marks indicated).</p> <p>Stability of urine in specific ProgenSA™ PCA3 transport tube:</p> <ul style="list-style-type: none"> ✓ 7 days at between +8°C and +30°C ✓ 14 days at between +2°C and +8°C ✓ 90 days at -20°C

INTERPRETING THE RESULTS

- ✓ PCA3 mRNA along with the mRNA of PSA is measured quantitatively.
- ✓ The result is presented in the form of a **PCA3 score** which is based on the following ratio: **(mRNA PCA3 / mRNA PSA) x 1000**
- ✓ A **threshold of 35** is taken as the dividing line, ensuring the best compromise between sensitivity and specificity, separating normal subjects or those with benign prostate hypertrophy from subjects with prostate cancer.
- ✓ The PCA3 score is represented on a risk continuum line: higher PCA3 score correlate with higher probability of a positive prostate biopsy.

The PCA3 score is independent of total serum PSA and prostate size. The PCA3 score is correlated with the Gleason prostatectomy score and studies are currently underway to evaluate the prognostic information provided by PCA3 scores.



For more information visit: www.pca3.org

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