

MAKE REPEAT PROSTATE BIOPSY DECISIONS WITH CONFIDENCE

The ProgenSA[®] PCA3 test

is the first FDA-approved prostate cancer-specific test of its kind that gives you the information you need to determine if a repeat biopsy is necessary.^{1,2}

DECIDING WHETHER OR NOT TO DO A REPEAT PROSTATE BIOPSY CAN BE A **DIFFICULT DECISION.**

You want to confirm an initial prostate biopsy is a true negative, but you don't want to harm your patient.

When your patient has an initial negative prostate biopsy but continues to have elevated prostate-specific antigen (PSA) levels, you may want to do a repeat biopsy to determine if they have cancer.²

However, biopsies are costly and can cause your patients²:

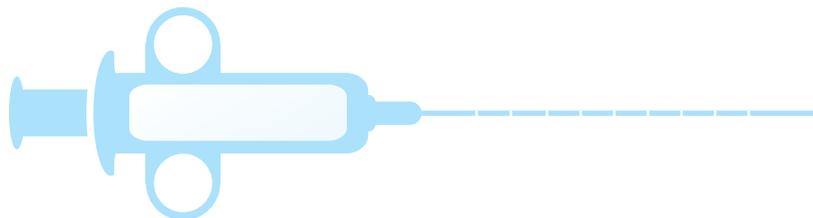
- Anxiety
- Discomfort
- Pain
- Complications

In fact, they can even lead to hospitalization.²

While most initial prostate biopsies are negative for cancer, the majority of repeat prostate biopsies are unnecessary.²

80%

Only 20 to 35% of initial negative biopsies indicate prostate cancer on repeat biopsy, **making as many as 80% of repeat biopsies unnecessary.²**



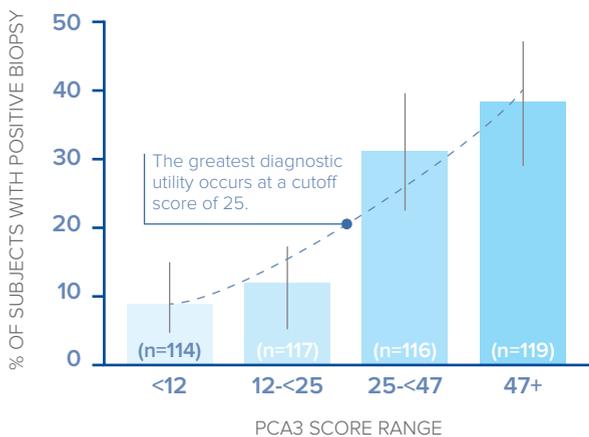
REDUCE
THE NUMBER OF UNNECESSARY
REPEAT BIOPSIES

with the Progenesa® PCA3 test,
the first FDA-approved urine-
based prostate cancer-specific
test of its kind.^{1,2}

CONFIDENTLY **AVOID AN UNNECESSARY REPEAT PROSTATE BIOPSY** WITH THE PROGENSA® PCA3 TEST.^{1,2}

The ProgenSA PCA3 test has a high negative predictive value of 90%, and has a scoring system that allows you to identify the risk of a positive prostate biopsy.^{1,2}

POSITIVE BIOPSY RESULTS BY PCA3 SCORE WITH 95% CONFIDENCE LIMITS.¹



- As the PCA3 Score increases, the likelihood for positive biopsy increases.
- As the PCA3 Score decreases, the likelihood for positive biopsy decreases.

The dashed line represents predicted probability of positive biopsy from a logistic regression model. Ranges represent quartiles of the PCA3 Score distribution.

DECIDE AT 25

Determining the need for repeat prostate biopsy¹

<25 | Repeat biopsy is unnecessary and prostate cancer is highly unlikely.



≥25 | Repeat biopsy may be necessary and patient may have prostate cancer.

This is a guideline only. Decisions should be made on a case-by-case basis.

MEN WITH A PCA3 SCORE **<25** are nearly **5 times more likely to have a negative repeat biopsy** than men with a score of **≥25**.²

THE PROGENSA PCA3 TEST IS EASY TO USE, UTILIZING A FIRST-CATCH URINE SAMPLE POST-DIGITAL RECTAL EXAM (DRE).¹

The ProgenSA PCA3 test can be performed in a few minutes right in your office.¹



PERFORM A DIGITAL RECTAL EXAM (DRE) by applying pressure on the prostate, enough to depress the surface approximately 1 cm from the base to the apex and from the lateral to the median line for each lobe. **Repeat this 3 times per lobe.**



COLLECT 20-30 ML OF FIRST-CATCH URINE in the labeled urine cup.



INVERT SPECIMEN 5 TIMES to re-suspend cells.



TRANSFER 2.5 ML OF SPECIMEN into transport tube labeled with patient name and date of birth. If unable to transfer immediately, place in refrigerator at 2-8^o C or on ice. **Specimen MUST be transferred into transport tube within 4 hours of collection.**

ENSURE TOTAL VOLUME FALLS WITHIN FILL LINES.



INVERT SPECIMEN AGAIN 5 TIMES. Specimen is now ready for shipment.

Due to specimen stability concerns, the lab cannot accept anything after 5 days since being collected.

■■■■■■■■ THE PROGENSA PCA3 TEST IS
**COVERED BY MAJOR INSURANCE
PROVIDERS, INCLUDING MEDICARE.**

A HIGH PSA LEVEL ALONE ISN'T ENOUGH TO DEFINITELY CONFIRM THE NEED FOR A REPEAT BIOPSY.^{1,2}

While higher-than-normal levels of PSA are found in men with prostate cancer, they can also be a sign of other non-cancerous conditions.^{1,3}

Elevated PSA levels can be associated with:

BENIGN PROSTATIC HYPERPLASIA (BPH)

PROSTATITIS

MEDICAL PROCEDURE

PROSTATE INJURY

PROSTATE CANCER

Because PSA can be indicative of many non-cancerous conditions, it only holds a positive predictive value (PPV) for prostate cancer of 20 to 30%.* Therefore, additional information is needed to decide if a repeat prostate biopsy is necessary.^{3,4}

PCA3 is specific for prostate cancer, while PSA is not.²

Unlike PSA, prostate cancer gene 3 (PCA3) is not influenced by non-cancerous conditions, making it much more specific for prostate cancer.^{1,2,5}



PCA3 IS **highly over-expressed** in **95% of prostate cancers**.^{2,5}



PROSTATE CANCER CELLS **express 60 to 100 times more PCA3 RNA than normal cells**.⁵

*Based on a PSA level of 4 to 10 ng/mL (often classified as higher-than-normal).³

WITH THE PROGENSA® PCA3 TEST, YOU CAN CONFIDENTLY

DETERMINE the risk or likelihood of a positive prostate biopsy^{1,2}

DECIDE if a repeat prostate biopsy is necessary^{1,2}

DISCUSS whether a repeat biopsy is needed with your patients

Intended Use: The ProgenSA PCA3 assay is an *in vitro* nucleic acid amplification test. The assay measures the concentration of prostate cancer gene 3 (PCA3) and prostate-specific antigen (PSA) RNA molecules and calculates the ratio of PCA3 RNA molecules to PSA RNA molecules (PCA3 score) in post-digital rectal exam (DRE) first-catch male urine specimens. The ProgenSA PCA3 assay is indicated for use in conjunction with other patient information to aid in the decision for repeat biopsy in men 50 years of age or older who have had one or more previous negative prostate biopsies and for whom a repeat biopsy would be recommended by a urologist based on current standard of care, before consideration of ProgenSA PCA3 assay results. A PCA3 score <25 is associated with a decreased likelihood of a positive biopsy. Prostatic biopsy is required for diagnosis of cancer.

WARNING: The ProgenSA PCA3 assay should not be used for men with atypical small acinar proliferation (ASAP) on their most recent biopsy. Men with ASAP on their most recent biopsy should be treated in accordance with current medical guidelines.

WARNING: The clinical study only included men who were recommended by urologists for repeat biopsy. Therefore, the performance of the ProgenSA PCA3 assay has not been established in men for whom a repeat biopsy was not already recommended.

References: **1.** ProgenSA® PCA3 Assay [package insert]. San Diego, CA: Hologic, Inc; 2014. **2.** Gittelman MC, Hertzman B, Bailen J, et al. PCA3 molecular urine test as a predictor of repeat prostate biopsy outcome in men with previous negative biopsies: a prospective multicenter clinical study. *J Urol.* 2013;190(1):64-69. **3.** Raja J, Ramachandran N, Patel U. Current status of transrectal ultrasound-guided prostate biopsy in the diagnosis of prostate cancer. *Clin Radiol.* 2006;61:142-153. **4.** Seitz C, Palermo S, Djavan B. Prostate biopsy. *Minerva Urol Nefrol.* 2003;55:205-218. **5.** Hessesels D, Klein Gunnewiek JMT, van Oort I, et al. DD3PCA3-based molecular urine analysis for the diagnosis of prostate cancer. *Eur Urol.* 2003;44(1):8-15.

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