

AVOID A POTENTIALLY UNNECESSARY REPEAT PROSTATE BIOPSY

The ProgenSA[®] PCA3 test

is the first FDA-approved prostate cancer-specific test
of its kind that helps you and your doctor
decide if a repeat biopsy is truly needed.^{1,2}

YOUR BIOPSY WAS NEGATIVE. BUT WHAT'S NEXT?

If you recently had a negative prostate biopsy but continue to have high prostate-specific antigen (PSA) levels, we understand that you probably have a lot of questions, especially about what to do next. And we're here to answer them.

If I still have high PSA levels after a negative prostate biopsy, does that mean I have prostate cancer?

It's important to note that **just because you continue to have high PSA levels, it doesn't mean you have prostate cancer.** 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, including¹⁻³:



BENIGN PROSTATIC HYPERPLASIA (BPH)

(an enlarged prostate)



PROSTATITIS (inflammation/infection of the prostate)



MEDICAL PROCEDURE



PROSTATE INJURY

A HIGH PSA LEVEL ISN'T ENOUGH

to determine if you should have a repeat biopsy.¹⁻³

THE PROGENSA® PCA3 TEST CAN HELP YOUR DOCTOR **DECIDE IF A REPEAT BIOPSY IS NECESSARY**.^{1,2}

What is the ProgenSA PCA3 test?

The ProgenSA PCA3 test is the **first FDA-approved prostate cancer-specific test of its kind**. It measures a gene called prostate cancer gene 3 (PCA3). Your PCA3 levels, along with your PSA levels, are used to calculate a PCA3 Score. This score can help you and your doctor **decide if a repeat biopsy is truly needed**.^{1,2}

What is PCA3?

PCA3 is a gene that is over-expressed in prostate cancer cells. It is a **better indicator of prostate cancer than PSA**. This is because PSA levels can be high in both men with prostate cancer and men with non-cancerous prostate conditions. Unlike PSA, **PCA3 is specific to prostate cancer** only.^{1,2,4}

How and where is the ProgenSA PCA3 test performed?

The test is performed **right in your doctor's office**. A urine sample is collected after your doctor performs a digital rectal exam (DRE).¹ Typically, results are delivered to your doctor in about 1 to 2 weeks.



HOW DOES THE PROGENSA PCA3 TEST HELP DETERMINE
IF ANOTHER PROSTATE BIOPSY IS NECESSARY?

The ProgenSA PCA3 test scoring system helps your doctor **decide more confidently whether a repeat biopsy is necessary than just looking at your PSA level.**¹

The higher the PCA3 Score, the more likely the biopsy will be positive. And the lower the PCA3 Score, the more likely the biopsy will be negative.¹

LESS THAN 25

Repeat biopsy is unnecessary and prostate cancer is highly unlikely.

25

PCA3 SCORE¹

25 OR HIGHER

Repeat biopsy may be necessary and there's a possibility of prostate cancer.

In a clinical study, **90% of men with a PCA3 score of less than 25 had a**

NEGATIVE
REPEAT BIOPSY FOR
PROSTATE CANCER.^{1,2*}

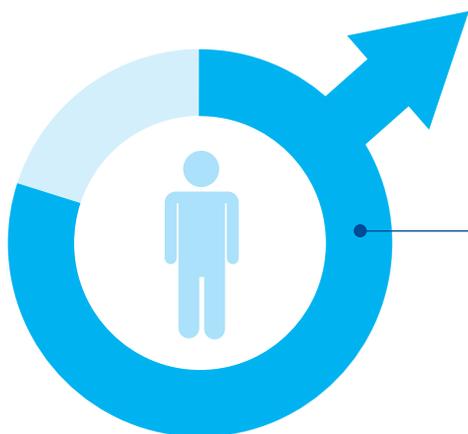
*Study included men with at least 1 previous negative biopsy.

Should I get another prostate biopsy to confirm my initial negative result?

While a repeat biopsy can help to confirm an initial negative result, the decision to undergo the procedure should be carefully considered. Biopsies can cause complications and **even lead to hospitalization.**²

THE MAJORITY OF REPEAT BIOPSIES TURN OUT TO BE UNNECESSARY.²

Only **20 to 35%** of men with an initial negative biopsy have a repeat biopsy that indicates prostate cancer.²



This means **as many as 8 out of 10 men will have an unnecessary repeat biopsy.**²

The ProgenSA® PCA3 test can help you and your doctor evaluate whether or not a repeat biopsy is really needed to confirm your initial negative biopsy. And as a result, may help you

AVOID AN UNNECESSARY BIOPSY.^{1,2}

THE PROGENSA® PCA3 TEST IS

CLINICALLY PROVEN to help you and your doctor decide if you really need a repeat prostate biopsy^{1,2}

COLLECTED right in your doctor's office^{1,2}

COVERED by major insurance providers, including Medicare

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.** Hessels 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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