

## Confirm negative biopsies with **CONFIDENCE**

**PCA3** is a prostate-specific gene that is over-expressed in prostate tumors. Prostate cancer cells express 60 to 100 times more PCA3 RNA than normal cells.

### **Better information promotes CONFIDENT DECISIONS.**

Unlike PSA, PCA3 is not influenced by benign prostatic hyperplasia (BPH), prostatitis, medical procedures, or injury.

## PROGENSA PCA3 ASSAY

- ✓ The first urine-based molecular test that delivers confidence to **MAKE INFORMED REPEAT BIOPSY DECISIONS**
- ✓ Uses Transcription-Mediated Amplification (TMA) to quantify PCA3 and prostate-specific antigen (PSA) RNAs in patient samples
- ✓ **HIGHLY SPECIFIC** — indicates a cancer specificity lacking with PSA alone
- ✓ **EASY TO USE** — utilizes a **FIRST-CATCH** urine sample post-DRE

### **IMPROVE YOUR BIOPSY DECISIONS.**

Reduce the number of unnecessary repeat biopsies.

- ▶ Accurately classify a “true negative” patient with a high negative predictive value of **90%**.<sup>1</sup>
- ▶ Men with a PCA3 Score of <25 are **4.58** times less likely to have a positive repeat biopsy than men with a score of 25 or greater.<sup>1</sup>

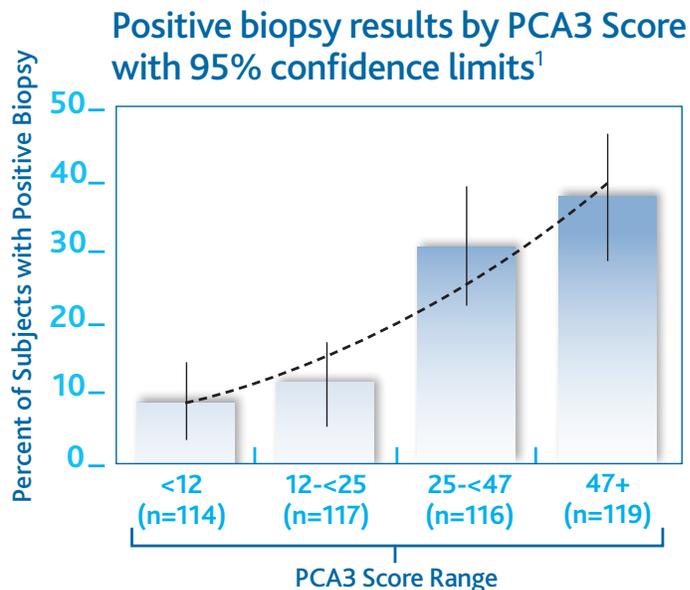


## Confirm negative biopsies with CONFIDENCE

- As the PCA3 Score increases, the likelihood for positive biopsy increases.
- As the PCA3 Score decreases, the likelihood for positive biopsy decreases.
- The greatest diagnostic utility occurs at a cutoff score of 25.

*The dashed line represents predicted probability of positive biopsy from a logistic regression model.*

*Ranges represent quartiles of the PCA3 Score distribution.*



### DRE instructions

Apply 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.**

### SAMPLE collection and preparation

1. Following a 3-stroke DRE (per above), collect 20-30 mL FIRST-CATCH urine in labeled urine cup.
2. Immediately invert specimen 4-5 times to re-suspend cells.
3. Transfer 2.5 mL of specimen into provided transport tube. Ensure total volume falls within fill lines.
  - If unable to transfer immediately, place in refrigerator at 2-8<sup>o</sup> C or on ice.
  - Specimen **MUST** be transferred into transport tube **within 4 hours of collection.**
4. Clearly label transport tube with patient name and date-of-birth.
5. Invert specimen again 5-6 times. Specimen is now ready for shipment.

**Specimen must arrive at Metamark laboratory within 5 days of collection.**

**ALL insurance coverage accepted.**

**Average patient cost with coverage = ~\$50.**

1. Gittleman, Marc C, 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. The Journal of Urology, Vol. 190, (2013): 64-69.