

Elevated prostate-specific antigen (PSA) levels are important indicators of prostate pathologies. However, while PSA is organ-specific, it is not prostate cancer-specific.¹⁻³ An elevated PSA level does not distinguish prostate cancer from benign prostatic hyperplasia (BPH) and prostatitis.¹⁻³ Thus, biopsy is often recommended for men in the 3-10 ng/mL range, where a low specificity yields a negative biopsy rate of 70%-80%.²⁻³

In addition, elevated PSA levels may not independently identify all patients with prostate cancer.⁴ Up to 25% of men with PSA levels of 2.1-4.0 ng/mL may already have or will develop biopsy-detected prostate cancer.⁴

Clinical Application

- Prostate cancer gene 3 (PCA3) is strongly expressed in 95% of primary prostate cancer specimens and in prostate cancer metastasis.²
- The CaPDetect: PCA3 noninvasive molecular amplification assay detects and quantifies both PCA3 and PSA mRNA levels, providing a PCA3/PSA ratio score that can assist in determining whether a patient is at increased risk for developing prostate cancer.

PCA3 Sensitivity, Specificity, Informative Rate^{1-2,5}

Sensitivity	67%-82%
Specificity	76%-83%
Informative rate*	79%-98.2%

(*percentage of samples yielding sufficient RNA for analysis)

Innovation and Convenience

- A comprehensive menu of traditional methods as well as biomarkers and other emerging technologies to assist in risk assessment, diagnosis, and monitoring of urology patients
- Flexible test ordering and result reporting options, including Web-based services for convenient, timely access

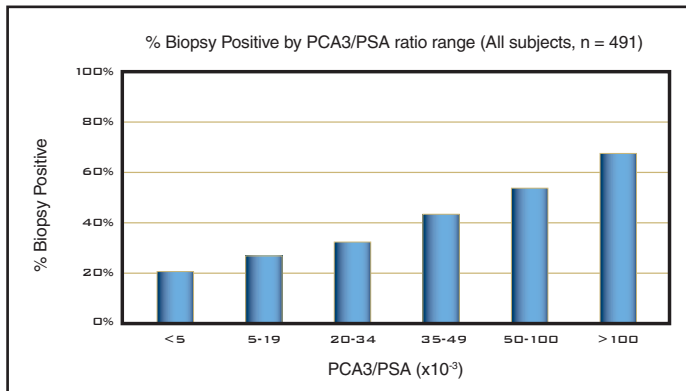
Confidence

- MD and PhD specialists on staff and available for consultation
- CarePath™ personalized, diagnosis-specific information for physicians and patients
- Summary statistics and utilization data for case management, as well as HEDIS and outcomes management initiatives
- A commitment to measuring quality and performance at every level of the testing process—from specimen pickup to result turnaround



CaPDETECT: PCA3 from DIANON Systems can aid in the detection of prostate cancer in patients with elevated serum PSA results and negative prostate biopsies.

Correlation of PCA3 Score with Probability of Positive Biopsy⁶



PCA3 Ratio	n	Bx pos	% Biopsy pos
<5	58	12	20.7%
5-19	170	46	27.1%
20-34	95	30	31.6%
35-49	47	20	42.6%
50-100	78	42	53.8%
>100	43	29	67.4%

Results

Quantitative ratio of PCA3/PSA mRNA yields a PCA3 Score

PCA3 score < 35 Patient at lower risk of positive biopsy

PCA3 score ≥ 35 Patient at higher risk of positive biopsy

References

- Groskopf J, Aubin SMJ, Deras IL, et al. APTIMA PCA3 molecular urine test: development of a method to aid in the diagnosis of prostate cancer. *Clin Chem.* 2006;52:1089-1095.
- Hessels D, Klein Gunnewiek JMT, van Oort I, et al. DD3PCA3-based molecular urine analysis for the diagnosis of prostate cancer. *European Urology.* 2003;44:8-16.
- Hessels D, Verhaegh GW, Schalken JA, Witjes JA. Applicability of biomarkers in the early diagnosis of prostate cancer. *Expert Rev Mol Diagn.* 2004;4(4):513-526.
- Thompson IM, Pauler DK, Goodman PJ et al. Prevalence of prostate cancer among men with a prostate-specific antigen level <4.0 ng per milliliter. *NEJM.* 2004;350:2239-2246.
- Tinzl M, Marberger M, Horvath S, Chypre C. DD3PCA3 RNA analysis in urine - a new perspective for detecting prostate cancer. *European Urology.* 2004;46:182-187.
- Marks LS, Deras IL, Mathis J, et al. Specificity of the PCA3 molecular urine test for prostate cancer. Program and abstracts of the American Urological Association 2006 Annual Meeting; May 20-25, 2006; Atlanta, Ga. Abstract 540.

Specimen collection and analysis

Digital Rectal Exam

3 strokes per lobe



Urine Specimen



Specimen Analysis



PCA3 and PSA mRNA concentrations measured in separate tubes from same specimen

Prostate Cancer Gene 3 (PCA3)

CPT 83913; 83891 (x2); 83902 (x2); 83898 (x2); 83896 (x2); 83912

Synonyms CaPDetect:PCA3

Specimen Urine

Volume 5 - 10 mL

Minimum Volume 2.0 mL

Container Gen-Probe APTIMA urine collection kit (Item N° 54189)

Collection Note: Patient should undergo an attentive digital rectal exam (3 strokes per lobe). Collect urine specimen containing cells released from the prostate gland.

Storage Instructions Freeze. Stability: Refrigerated up to 14 days; frozen up to 90 days.

Methodology This assay utilizes target capture, Transcription-Mediated Amplification (TMA), and Hybrid Protection Assay (HPA).

DIANON Systems

A LabCorp Company