

Prostate CancerTest™

Test Report

Patient Information

Requisition Number	
Patient Name	
ID Number	
Date of Birth	
Gender	<input checked="" type="checkbox"/> M
Patient Phone Number	
Patient E-mail	
Name of Lab	
Lab Phone Number	
Name of Physician	
Date of Collection	
Date of Report	

Test Report

Name:

Date of Birth:

ID:

Patient Clinical History

Most Recent PSA Test	Date	Result
	16/09/2016	8.08
Prostate Biopsy	Date	Pathology Result
DRE	Date	Result
Prostate Measurement	Date	Result
Family History of Prostate Cancer	Yes No	Relationship / Age of dx

Patient Test Result

Result: Negative (PCT Score: 48)

Summary Interpretation:

This individual has a PCT score 48 which is **below** the cut-off of **65** and correlates with **decreased probability** of a positive biopsy for prostatic adenocarcinoma.

Comment:

Continue testing annually with CellMax Prostate Cancer Test if PSA levels are within 4-10 ng/mL.

Electronic Signatures

This test was developed and its performance characteristics determined by CellMax. Clinical decisions regarding care and treatment of patients should not be solely based on this test. Not all disease will be accurately detected. How this information is used to guide patient care is the responsibility of the physician.

Lab Supervisor Leon Chen

Date

Pathologist Manana Kvezereli-Javey, MD, PhD

Date

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Test Report

Name:

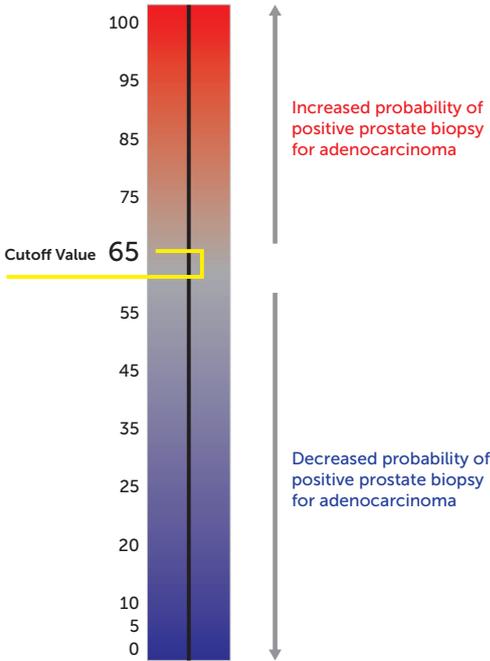
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About The Test

CellMax Life’s Prostate Cancer Test (PCT) is a blood-based test specifically designed for men with “gray zone” PSA levels between 4-10 ng/mL. Follow-up strategies for such individuals are not straightforward as there are no set guidelines provided by leading medical associations, yielding unnecessary invasive biopsies with numerous potential side effects. The test stratifies patients based on the PCT score derived from circulating tumor cell (CTC) count and other patient specific variables, and significantly reduces unnecessary biopsies.

Based on clinical studies, a low score (< 65) has been correlated with decreased probability of a positive prostate biopsy for prostatic adenocarcinoma, hence the result is reported as negative. A high score (> 65) has been correlated with increased probability of a positive prostate biopsy for prostatic adenocarcinoma, hence the result is reported as positive.



	Sensitivity	Specificity	Accuracy	Reduction of Unnecessary Biopsies
CellMax Prostate Cancer Test Performance Characteristics	80%	94%	90%	Up to 90%

Who Should Consider CellMax Prostate Cancer Test

- Men 45 years of age or older
- Recent PSA reading of 4-10 ng/mL
- Never been diagnosed with prostate cancer
- No history of urological procedure in the past 3 months

Advantages of CellMax Prostate Cancer Test

Test Characteristics

- Highly sensitive and specific
- Clinically proven in Taiwanese population
- Accurately distinguishes men with benign prostate disease from those with a high-risk prostate cancer
- High quality control
- Reduces the number of unnecessary biopsies by 90%

For Patients

- Convenient and a simple blood draw
- Non-invasive
- No preparation required
- No need for anesthesia
- Can spare unnecessary invasive procedures
- Additional consultation with MD available

For Physicians

- Easy to order
- Interpretation is provided
- Dissolves uncertainty who to biopsy
- Additional questions can be answered by US MD or local PhD-level Clinical Director



Facts: Prostate Cancer

Early diagnosis and active surveillance can yield a better outcome

- Prostate cancer is the fifth most commonly diagnosed cancer in Taiwan
- Prostate cancer has seventh highest cancer-related mortality rate in Taiwan
- Prostate cancer occurs more frequently in men over age 50; 70% occurring in men over 65
- Prostate cancer at early stages is asymptomatic
- Nearly 30% prostate cancer is diagnosed at late stage
- Prostate cancer has almost 100% survival rate if diagnosed early
- Five-year survival rate for advanced stage metastatic prostate cancer is about 30%

Common Prostate Cancer Symptoms

Most prostate cancer signs and symptoms are manifested

- Difficulty initiating urination
- Difficulty emptying the bladder
- Painful or burning sensations while urinating
- Weak or interrupted urine flow
- Frequent and sudden urge to urinate, mostly nocturnal
- Blood in the urine or semen

More generalized symptoms include:

- General malaise
- Dizziness
- Pain in the lower back and pelvic area
- Weakness or numbness in the legs or feet



Factors Contributing to Increased Prostate Cancer Risk

Some risk factors are modifiable

- Advanced age
- Ethnicity
- Family history of prostate cancer
- Inherited mutations (e.g. *BRCA1/BRCA2* genes)
- Diet rich in red-meat and high-fat
- Obesity
- Smoking tobacco
- Conditions such as prostatitis (inflammation of the prostate), and benign prostatic hyperplasia (BPH)

Modifiable Risk Factors

Make lifestyle changes to improve your health

- Reducing alcohol intake
- Quit smoking
- Increasing exercise
- Weight loss
- Healthy diet rich in fruits and vegetables
- Rectal examination and PSA test



Prostate Cancer Screening and Early Detection Recommendations

Routine testing and surveillance can help men stay cancer-free. However, current prostate cancer screening and surveillance recommendations have numerous pitfalls.

- It is recommended for men >45-50 years of age to make an informed decision on screening for prostate cancer
- Standard of care includes blood test for Prostate Specific Antigen (PSA) and Digital Rectal Exam (DRE)
- Individuals with increased PSA (with or without positive DRE) may be recommended prostate biopsy

Facts about Digital Rectal Exam (DRE) test

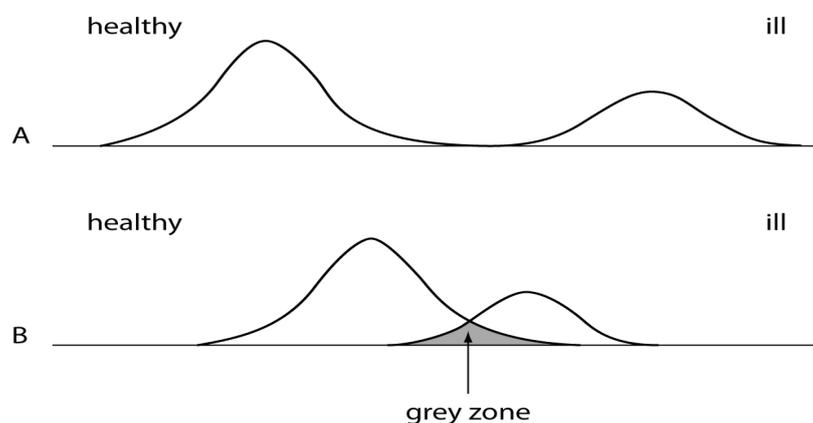
The main reason why DRE is still administered today is its low cost and feasibility in doctor's office

- Manual examination of prostate gland through rectum administered by a physician
- Limited sensitivity test for early cancer detection, since it can only evaluate the peripheral zone and apex of the prostate gland

Facts about Prostate-specific antigen (PSA) blood test

PSA test is a good start towards prostate cancer screening; however it needs to be supplemented by ancillary testing such as CellMax Prostate Cancer Test for certain individuals

- PSA is a protein secreted by the prostatic epithelium and is not specific for prostate cancer
- PSA level increases above its reference range (0-4ng/ml) in the patients with prostate cancer, benign prostatic hyperplasia, prostatitis or even after the procedures such as digital rectal exam
- In Asian population, only 16% of men with a PSA level 4- 10 ng/ml are diagnosed with prostate cancer on biopsy
- More than two thirds of patients with PSA levels greater than 4 ng/mL do not have prostate cancer
- PSA values between 4-10ng/ml are referred to as "gray zone", management of which is not universal and lacks clear and straightforward surveillance guidelines



A = ideal situation - clear to discriminate

B = difficult situation - overlapping of both groups

Biochemia Medica 2010;20(2):147-53. <http://dx.doi.org/10.11613/BM.2010.017>

Factors Contributing to Increased PSA Levels

PSA is not specific to prostate cancer and may be elevated due to many non-cancer related reasons

- **An enlarged prostate** : Conditions such as benign prostatic hyperplasia (BPH), a non-cancerous enlargement of the prostate that affects many men as they grow older
- **Prostatitis** : Inflammation of prostate also called prostatitis
- **Ejaculation** : Temporary increase in PSA
- **Mechanical pressure to the prostate gland** : Any mechanical pressure to the gland (e.g. riding a bicycle) or prostate gland massage may cause temporary increase in PSA
- **Certain urologic procedures** : Digital rectal exam (DRE), prostate biopsy or cystoscopy, can result in higher PSA levels for a short time
- **Certain medications** : Taking male hormones like testosterone (or other medications raising testosterone levels) may cause a rise in PSA

Facts About Prostate Biopsy

Prostate biopsy is often recommended when there is an abnormal digital rectal exam or elevated PSA (>4.0 ng/ml) or PSA velocity for men over 50. Note that prostate biopsy is not always needed for men with PSA levels 4-10ng/mL.

Prostate biopsy requires preparation for the procedure

- Urine sample for urinalysis. If inflammation is present, the procedure will be postponed until the infection is cleared up after the antibiotic treatment.
- Medications potentially causing bleeding must be stopped several days prior to the procedure. Such medication list includes warfarin, ibuprofen, aspirin, certain herbal supplements.
- Cleansing enema must be administered at home prior to the procedure.
- Antibiotics must be taken 30-60 minutes prior to the procedure.

Prostate biopsy is an invasive procedure

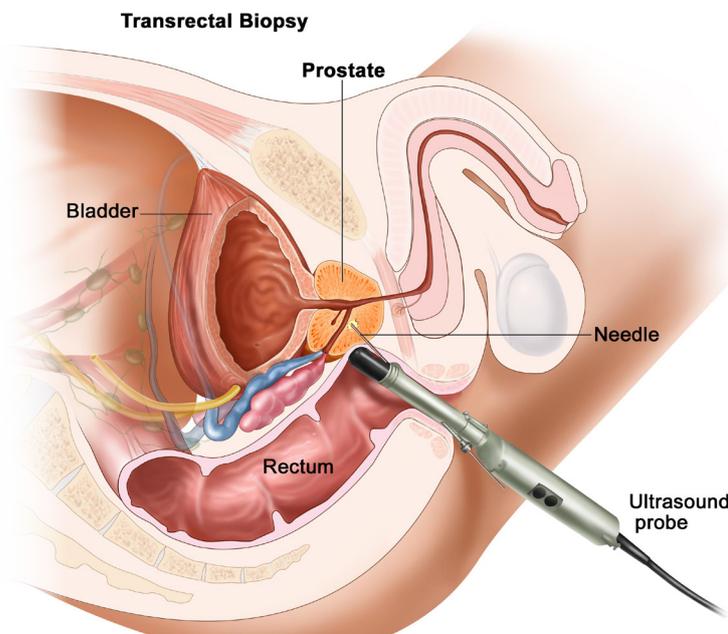
Prostate biopsy samples can be collected in several ways:

- **Transrectal biopsy** : Passing the needle through the wall of the rectum is the most common way of performing a prostate biopsy.
- **Transperineal biopsy** : Inserting the needle through the area of skin between the anus and scrotum. A small incision is made in the perineum (area of skin between the anus and the scrotum), and the biopsy needle is inserted through the incision into the prostate gland to draw out a sample of tissue. This is an MRI or CT guided procedure.
- 6-12 samples will be taken depending on the area to be examined.

Facts About Prostate Biopsy

Prostate Biopsy is Associated with Side Effects

- **Difficulty urinating.** In some men, procedure may cause difficulty while urinating. Rarely, a temporary urinary catheter must be inserted.
- **Infection.** Rarely, men who have a prostate biopsy develop an infection of the urinary tract or prostate that requires treatment with antibiotics.
- **Bleeding at the biopsy site.** Rectal bleeding is common after a prostate biopsy.
- Allergic reaction to the anesthetic given during the procedure
- Blood in urine
- Blood in semen



Unnecessary Biopsies Cause Anxiety, Uncertainty, and Side-Effects

- Hematuria reported up to 84% of cases
- Rectal bleeding reported up to 45% of cases
- Hematospermia reported up to 93% of cases
- Hospital admittance from infection reported up to 3-5% of cases
- Other side effects include pain, urinary tract infection, erectile dysfunction

Loeb et al. European Urology, Volume 64 Issue 6, December 2013

How to Make an Informed Decision

In the era of Precision Medicine, even cancer screening and surveillance can be personalized to an individual's specific needs.

If you are over 50 years of age, have symptoms, family history or other risk factors

- Talk to your doctor
- Receive standard of care testing
- Consider non-invasive testing by CellMax Prostate Cancer Test if your PSA falls within 4-10ng/mL
- Avoid unnecessary biopsy and uncertainty related to your health by considering CellMax Prostate Cancer Test
- Consider CellMax DNA Genetic Cancer Risk Test for inherited germline mutations if you have a strong family history

Test Report

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Test Report

Disclaimer

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Clinical decisions regarding care and treatment of patients should not be solely based on this test. How this information is used to guide patient care is the responsibility of the physician. The CellMax Life test is designed to assist health care practitioners in providing additional clinical information.

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