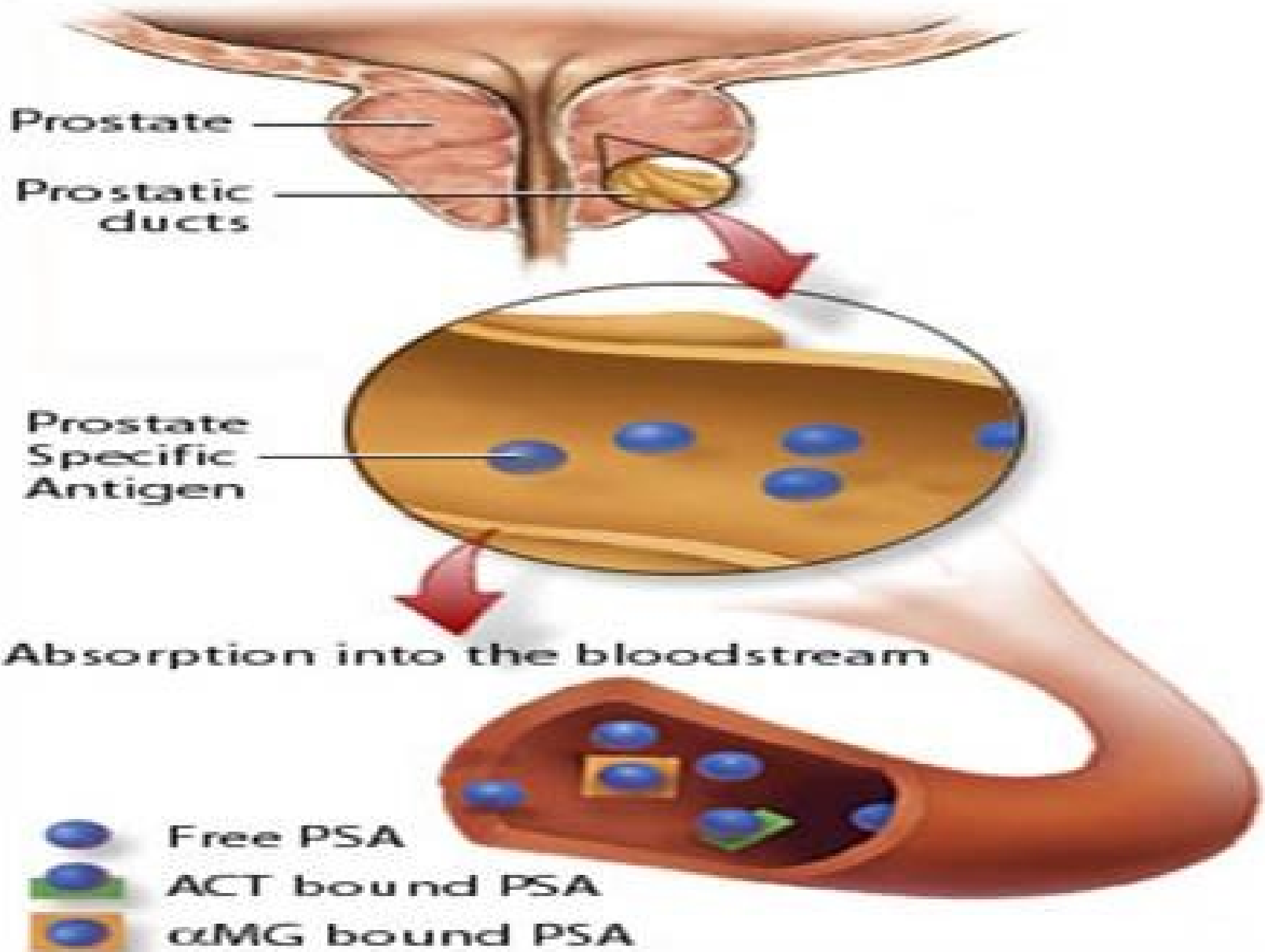

Prostate-Specific Antigen (PSA)

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- The diagnosis of prostate cancer hinges on three primary factors: **digital rectal exam, or DRE**, (to be discussed)
 - **PSA testing**, (discussed here)
 - and **ultrasound-guided biopsy**.
 - **DRE and PSA testing are to be used for screening, and ultrasound-guided for confirmation.**
 - **DRE is still important, even with the availability of PSA testing.**
 - **But it's of limited value, because only approximately 50% of palpable lesions are carcinoma. In addition, most men with prostate cancer have no nodules.**
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Test Overview

- Prostate-specific antigen (PSA) is a glycoprotein protease made in and secreted exclusively by the epithelial cells of the prostate; where it may be bound to two proteins: anti-chymotrypsin (ACT) and alpha macroglobulin (aMG) .
- Prostate-specific antigen (PSA) is released into a man's blood by his prostate gland.
- Epithelial cells make some of the semen that comes out of the penis at the time of sexual climax (orgasm).
- PSA helps to keep the semen in its liquid form. Small amounts of the protein get into the circulation and can be measured in the blood.
- PSA itself has no known effect outside the prostate.
- **The "PSA test" measures the level of free and bound prostate-specific antigen (PSA) in the blood.**
- **Low amounts of PSA may be found in the blood of healthy men, but the amount of PSA in the blood normally increases as a man's prostate enlarges with age, as well as in prostate disease or trauma states.**
- It is also increased by inflammation of the prostate gland (prostatitis) and by prostate cancer.



Indications for the PSA test.

- The prostate-specific antigen (PSA) test is done to:
 - Screen men for prostate cancer.
 - Monitor the development of prostate cancer and the response to treatment.
 - **A PSA test is an effective screening test for prostate cancer. However, other medical conditions can cause high PSA levels; therefore, other tests (such as a prostate biopsy) are needed to confirm a diagnosis of prostate cancer.**
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- **The prostate-specific antigen (PSA) test is done to:**
 - Determine whether urinary symptoms (such as difficulty in urinating) or lumps found during a digital rectal exam or a transrectal ultrasound may be caused by prostate cancer.
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Monitor the development of prostate cancer and the response to treatment.

If PSA levels are increasing, the cancer may be growing or spreading.

Successful treatment of prostate cancer usually causes PSA levels to stop rising and sometimes causes them to drop.

The amount of PSA is often undetectable in a man who has been treated for prostate cancer by having his prostate gland removed.

PSA levels that rise after prostate removal indicate that the cancer may have spread to another part of the body or has recurred at the prostate site.

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- **Screen men for prostate cancer.** Screening is usually done for men older than age 50 or for those who have a higher-than-normal risk of developing prostate cancer (such as men with a family history of prostate cancer).
 - **A PSA test is an effective screening test for prostate cancer.**
 - **However, other medical conditions can cause high PSA levels; therefore, other tests (such as a prostate biopsy) are needed to confirm a diagnosis of prostate cancer.**
 - Also, the frequency of PSA testing to screen for prostate cancer is somewhat controversial because of the uncertain impact of treatment on survival.
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How To Prepare

- Before having a test for prostate-specific antigen (PSA), patients should :
 - Refrain from sexual activity for 2 to 3 days prior to testing.
 - Wait several weeks after having a cystoscopy.
 - Wait until a urinary tract infection or prostatitis has cleared up.
 - Talk to your health professional about any concerns you have regarding the need for the test, its risks, or how it will be done.
 - Complete the medical test information form to help you understand the importance of the test.
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- Before having a PSA test, you should consider what you will do if your PSA level is found to be high.
 - Prostate cancer often grows very slowly, without causing major problems. **Detecting prostate cancer early and treating it may prevent some cancer-related health problems and reduce the risk of dying from the cancer.**
 - However, some treatments for prostate cancer can cause complications, such as the inability to control urination (incontinence) or the inability to have an erection (erectile dysfunction).
 - Therefore, some men may reasonably choose not to treat prostate cancer if it is detected. These men do not need a PSA test.
 - For example, a man older than age 75 who has no bothersome symptoms of prostate cancer may choose not to treat the cancer if it is found, so he would not need a PSA test.
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How It Is Done

- The health professional drawing blood will wrap an elastic band around your upper arm to temporarily stop the flow of blood through the veins of your arm.
 - This makes it easier to insert a needle into your vein properly, because the veins below the band get larger and do not collapse easily.
 - The needle site is cleaned with alcohol and the needle is inserted.
 - More than one needle stick may be needed if the needle is not properly placed or if the vein cannot supply enough blood.
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- After the needle is properly placed, a collection tube will be attached to the needle and blood will flow into it. Sometimes more than one tube of blood is collected.
 - When enough blood has been collected, the band around your arm will be removed.
 - A gauze pad or cotton ball will be placed over the puncture site as the needle is withdrawn.
 - Pressure is applied to the puncture site for several minutes, and then a small bandage is often placed over it.
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How It Feels

- You may feel nothing at all from the needle puncture, or you may feel a brief sting or pinch as the needle goes through the skin. Some people feel a stinging pain while the needle is in the vein. However, many people do not feel any pain (or have only minor discomfort) once the needle is positioned in the vein. The amount of pain you feel depends on the skill of the health professional drawing the blood, the condition of your veins, and your sensitivity to pain.
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- There is very little risk of complications from having blood drawn from a vein.
- You may develop a small bruise at the puncture site. You can reduce the risk of bruising by keeping pressure on the site for several minutes after the needle is withdrawn.
- Rarely, the vein may become inflamed after the blood sample is taken.
- This condition is called phlebitis and is usually treated by applying a warm compress several times daily.
- Continued bleeding can be a problem for people with bleeding disorders.
- **Aspirin, warfarin (Coumadin), and other blood-thinning medications can also make bleeding more likely.**
- If you have bleeding or clotting problems, or if you take blood-thinning medication, tell the health professional before your blood is drawn.

Results

Normal

- **Normal values may vary from lab to lab.**
- **Because normal prostate-specific antigen (PSA) levels seem to increase with age, age-specific ranges may be used.**
- However, the use of age-specific ranges is controversial and some health professionals prefer to use one range for all ages.
- For this reason, it is important to discuss your test results with your health professional

Total prostate-specific antigen (PSA)

Men younger than 40:	Less than 2.0 nanograms per milliliter (ng/mL)
Men age 40 to 50:	Less than 2.5 ng/mL
Men age 51 to 60:	Less than 3.5 ng/mL
Men age 61 to 70:	Less than 4.5 ng/mL
Men over age 70:	Less than 6.5 ng/mL

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- **The PSA is normally less than 4 ng/mL** (normal ranges vary depending upon which assay is used).
 - Most men have levels under 4 nanograms per milliliter (ng/mL) of blood.
 - **PSA levels from 4 to 10 ng/mL are borderline.**
 - Patients with PSA levels in the borderline range between 4 and 10, have about a 25% chance of having prostate cancer. To repeat, **a serum level between 4 and 10 nanograms per milliliter translates into a 1 in 4 chance of having prostate cancer.**
 - About 20% to 30% of men (20 to 30 men in 100) with PSA levels in this range have prostate cancer.
 - A transrectal ultrasound (TRUS) and prostate biopsy are needed to confirm cancer.
 - **If this level is above 10 nanograms per milliliter the risk increases to 2 in 3 of harboring an occult prostate cancer.**
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- **When prostate cancer develops, the PSA level usually goes above 4.**
- **PSA levels above 10 ng/mL are high.**
- **For patients with PSA levels more than 10 ng/mL, the chance of having prostate cancer is over 67% and the risk increases further as the PSA level increases.**
- **About 40% to 60% of men (40 to 60 men in 100) with PSA levels in this range have prostate cancer. That is, for such patients the risk increases to 2 in 3 of harboring an occult prostate cancer. A transrectal ultrasound (TRUS) and prostate biopsy are needed to confirm cancer.**
- **However, high levels do not always mean prostate cancer is present. PSA levels may also be high if the prostate gland is enlarged (benign prostatic hypertrophy) or inflamed (prostatitis).**

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- **PSA has the highest predictive value of any single test, but it is still not specific for prostate cancer.**
 - **Many men with benign prostatic hyperplasia have a PSA of greater than 4 nanograms per milliliter. About 25% of all men with prostate cancer have a PSA level of less than 4 nanograms per milliliter.**
 - **A rising PSA (more than 0.75 ng/mL per year) is suspicious for prostatic carcinoma, even if the PSA is in the normal range.**
 - **A mildly increased PSA (4 to 10 ng/mL) in a patient with a very large prostate can be due to nodular hyperplasia, or to prostatitis, rather than carcinoma.**
 - **With benign prostate conditions, there is more free PSA, while cancer produces more of the attached form.**
 - **Good doctors always treat PATIENTS rather than TEST RESULTS.**
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- **To make PSA levels more cancer specific, a number of modifying factors have been suggested to sharpen the diagnostic acumen for the recognition of prostate cancer.**
- **They include: using age-adjusted levels, recognizing that older men have higher levels;**
- **looking at PSA density, recognizing that prostate cancer packs in more PSA than does benign prostatic hyperplasia;**
- **determining PSA velocity, or the rate at which PSA levels are rising from year to year in men at risk. Cancer makes these levels rise faster than does benign prostatic hyperplasia;**
- **and measuring percent free PSA.**

FACTORS THAT AFFECT THE PSA TEST AND THAT MIGHT CAUSE FALSE NEGATIVE RESULTS

- **Recent sexual activity or a cystoscopy test may cause prostate-specific antigen (PSA) levels to rise.** Since ejaculation can cause a temporary increase in blood PSA levels, patients should abstain from ejaculation for 2 days before testing- so some doctors will suggest that men abstain from ejaculation for 2 days before testing.
- **Large doses of some medications used to treat cancer—such as cyclophosphamide (Cytoxan, Neosar), diethylstilbestrol, and methotrexate —can interfere with test results.**
- **Drugs like finasteride (Proscar or Propecia) or dutasteride (Avodart)** used to prevent further enlargement of the prostate gland in men with benign prostatic hypertrophy (BPH), may **falsely lower PSA levels.** So your doctor must be informed if you are taking these drugs
- Some **herbal preparations** that are dietary supplements marketed "for prostate health" may also mask an elevated PSA level, which is why it is important to let your doctor know if you are taking any type of supplement. However, **Saw palmetto (an herb used by some men to treat BPH) does not seem to interfere with the measurement of PSA**
- **Rough handling, contamination, or inadequate refrigeration of the blood sample can cause inaccurate test results.**

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- **REMEMBER**
 - **PSA level can also be raised in :**
 - noncancerous enlargement of the prostate (called **benign prostatic hyperplasia, or BPH**) something many men have as they grow older.
 - **Prostatitis**, an inflammation of the prostate gland.
 - PSA levels also **normally go up slowly as men age, even if there is no prostate abnormality.**
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- **When combined with a digital rectal exam, the prostate-specific antigen (PSA) test improves the likelihood of detecting prostate cancer.**
 - **Remember: PSA levels within the normal ranges do not exclude the possibility of prostate cancer.**
 - **Some men with prostate cancer have normal PSA levels.**
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- Since the risk for **prostate cancer** increases with age, it is recommended that a **PSA test and DRE** be performed annually for all men once they reach 50 years of age.

Men in high-risk groups, such as African Americans and those with blood relatives who have had prostate cancer, should begin testing at age 40 and consult with their health care professional for advice on more frequent testing.

What are the limitations of the PSA test?

- A few percent of prostate cancers do not produce detectable increases in the blood PSA, even with advanced disease.
- Many early cancers will also not produce enough PSA to cause a significantly abnormal blood level.
- It is therefore important not to rely only on blood PSA testing.
- The most useful additional test is a physical prostate examination by a doctor known as the digital rectal exam (DRE).
- During this examination a doctor inserts a finger into the rectum to feel the prostate for lumps, size, shape, tenderness, and hardness

- **Note: PSA is not diagnostic of cancer**

- **Complexed PSA Test is More Accurate Than Traditional PSA Test in Detecting Prostate Cancer**

<http://psa-rising.com/med/psa/complexed.htm>

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- Experts disagree about the frequency of PSA testing to screen for prostate cancer.
 - The American Cancer Society (ACS) recommends an annual PSA test and DRE for men age 50 and older who have life expectancy of at least 10 years.
 - ACS also recommends annual screening, beginning at age 45, for men who are at high risk for prostate cancer (such as black men and men who have a family history of prostate cancer).
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- **Other groups (such as the National Cancer Institute and the U.S. Preventive Services Task Force) believe there is not enough evidence to recommend routine screening with the PSA test for all men.**
 - **Groups that do not recommend annual screening cite the high rate of false-negative and false-positive results, the costs and risks of further tests, and the uncertain impact of treatment on survival.**
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- Experts also disagree about the type of testing that is appropriate if the PSA level is high. The decision may depend on:
 - Results of the digital rectal exam.
 - The man's age and health.
 - The costs and risks of more tests and treatments.
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- Other related tests are being evaluated for their ability to distinguish between prostate cancer and benign prostatic hypertrophy.
 - **One other method of reporting PSA levels, called percent free prostate-specific antigen (free PSA), may be used to help predict the chance that a prostate problem is noncancerous (benign) or related to cancer.**
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Free prostate-specific antigen (free PSA)

Percent free PSA	Probability of cancer
greater than 25%:	8%
20%–25%:	16%
15%–20%:	20%
10%–15%:	28%
0–10%:	56%

What is the free PSA test?

- Most of the PSA protein released into the blood becomes attached to other blood proteins. The PSA that does not become attached is known as free PSA and can be measured.
 - It has been found that the level of free PSA is decreased in men who have prostate cancer compared to those with benign conditions.
 - The exact level depends upon which test the laboratory uses, but generally less than 10% free PSA is suggestive of cancer.
 - This test is most helpful when the usual PSA test is between 4 and 10 ng/mL
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- **Low free PSA values (less than 15%) are more likely to be caused by prostate cancer than high free PSA values.**
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- - **The prostate-specific antigen density (PSAD) test** compares the PSA value to the size of the prostate gland. The size of the prostate is measured using transrectal ultrasound (TRUS).
 - **The PSA velocity test** is a measure of how rapidly PSA levels are increasing over time. PSA levels appear to increase more rapidly over time in men with prostate cancer and more slowly in men with prostate enlargement (benign prostatic hypertrophy).
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- **Complexed prostate-specific antigen (cPSA)** is a fairly new test to help detect prostate cancer.
 - When used in combination with a digital rectal exam, the cPSA test is similar to the total PSA test in its ability to detect prostate cancer.
 - The cPSA test currently is not widely available.
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- In conclusion, prostate cancer is a common and deadly disease. **PSA, DRE, and the ultrasound-guided biopsy remain the mainstays of screening and diagnosis.**
 - **Grading and staging the disease is extremely important in determining treatment.**
 - **Risk factor assessment**, something we have not really thought about previously, **has become increasingly important, not just to heighten our index of suspicion for individual men, but to consider preventive treatment in individuals who are at very high risk.**
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The BioSafe PSA Test

- The **BioSafe PSA Prostate Cancer Screening Test** combines the convenience of a home sample collection with the accuracy of a certified clinical laboratory determination.

The **BioSafe PSA Prostate Cancer Screening Test** provides you with an accurate, convenient, and cost-effective way to measure your **PSA blood level**.

- Accurate results from a certified laboratory
- A safe and convenient home blood sample collection kit - just prick your finger
- Clear, step-by-step instructions included
- Includes postage & lab services
- Results in 5 days
- Approved for sale in the U.S. and Canada
- \$39.95



■ Since the risk for **prostate cancer** increases with age, it is recommended that a **PSA test** be performed annually for all men once they reach 50 years of age.

Men in high-risk groups, such as African Americans and those with blood relatives who have had prostate cancer, should begin testing at age 40 and consult with their health care professional for advice on more frequent testing.

BioSafe PSA Prostate Cancer Screening Test provides the same clinical results that can be obtained from a local laboratory, but without the inconvenience of keeping an appointment and the need to draw blood from the arm. The process is very quick and virtually painless.

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- A special finger lancet is supplied in the BioSafe Blood Collection Kit. With it, three drops of blood are taken from a micro-nick of the finger, placed on a special collection card to dry, inserted into the special mailer provided, and then sent (postage paid) to BioSafe's CLIA certified laboratory for analysis. Test results are available in approximately 5 days.
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The Finger Nick



The Collection System

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- Results are promptly sent back to the person who took the test and/or that person's designated health care professional.
 - The BioSafe PSA Prostate Cancer Screening Test is accurate, private, convenient, easy-to-use and reasonably priced at \$39.95.
 - Everything is included, there are no extra charges. A toll free BioSAfe Customer Care phone number comes with your test package.
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