SPECTRUM
MEDICAL DIAGNOSTICS

PSA Rapid Test

QUICK REFERENCE INSTRUCTIONS

Please refer to the Package Insert for complete instructions. Read the complete test procedure before performing the test.

Before Running The Test

- Before running the test, please ensure that you have read all the information in this package insert.
- This PSA Rapid Test Cassette (Whole Blood/Serum/Plasma) is intended for professional in vitro diagnostic use only.
- Follow the specimen collection and preparation instructions carefully, and make sure all materials are at room temperature before testing.

Intended Use

- The PSA Rapid Test Cassette (Whole Blood/Serum/Plasma) is a professional in vitro diagnostic test for the qualitative detection of Prostate Specific Antigen (PSA).
- It is used to semi-quantitatively detect total PSA levels in whole blood, serum, or plasma.
- The test aids in the diagnosis and monitoring of prostate conditions, including prostate cancer, benign prostatic hyperplasia, and prostatitis.
- It has a cutoff value of 3ng/ml and a reference value of 10ng/ml.

Warnings & Precautions

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch or closed canister until ready to use.
3. Do not eat, drink, or smoke in the area where the specimens or kits are handled.
4. Do not use the test if the pouch is damaged.
5. All specimens should be considered potentially hazardous and handled following the same precautions as an infectious agent.
6. Humidity and temperature can adversely affect results.
7. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are being tested.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use it beyond the expiration date.

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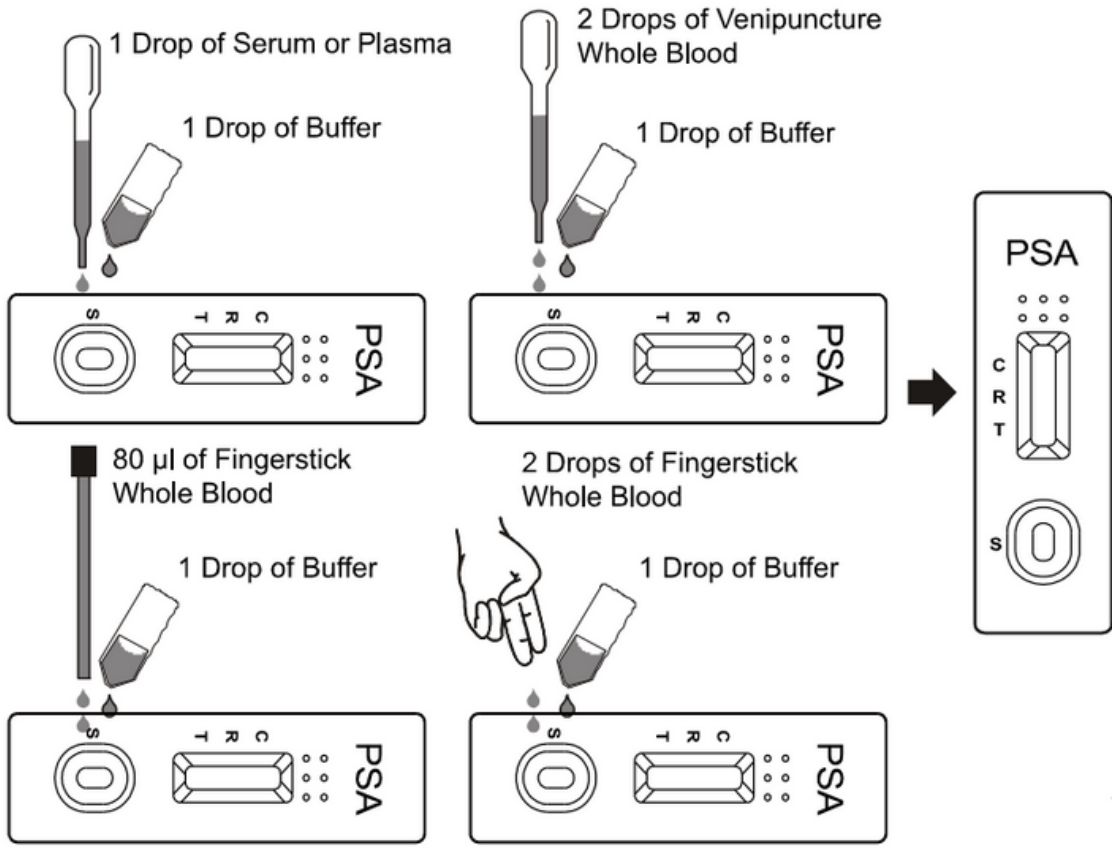
Test Procedure

1. Allow the test cassette, specimen, buffer, and/or controls to reach room temperature (15-30°C) before testing.
2. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Twist off the tab of the buffer vial without squeezing and place it on a clean and level surface.
3. Place the test cassette on a clean and level surface.

For Fingerstick Whole Blood specimen:

- To use a capillary tube: Fill the capillary tube and transfer approximately 80µL of fingerstick whole blood specimen to the specimen area of the test cassette.
- Add 1 drop of buffer (approximately 40µL) to the specimen area.
- To use hanging drops: Allow 2 hanging drops of fingerstick whole blood specimen (approximately 80µL) to fall into the specimen area of the test cassette.
- Add 1 drop of buffer (approximately 40µL) to the specimen area.

Start the timer and wait for the coloured lines to appear. Read the results at 5 minutes. Do not interpret the result after 10 minutes.



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Positive Result:

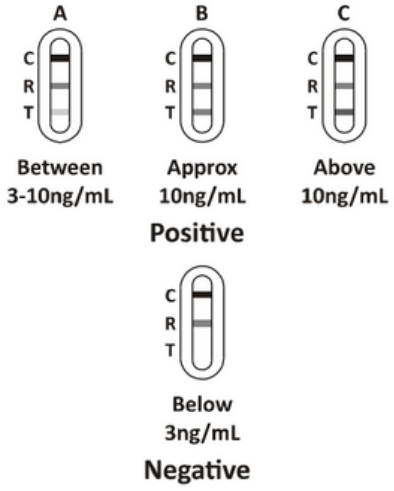
- In a positive result, three distinct colored lines will appear on the test cassette. The intensity of the test line (T) will indicate the PSA level:
- If the test line (T) intensity is weaker than the reference line (R), it suggests a PSA level between 3-10 ng/ml.
- If the test line (T) intensity is equal or close to the reference line (R), it indicates a PSA level of approximately 10 ng/ml.
- If the test line (T) intensity is stronger than the reference line (R), it suggests a PSA level above 10 ng/ml.

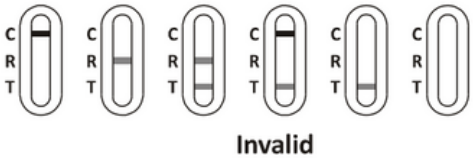
Negative Result:

- In a negative result, colored lines will appear in both the control (C) and reference (R) regions of the test cassette. However, no apparent colored line will appear in the test line region (T).
- This indicates a PSA level below 3 ng/ml, suggesting a negative result for the presence of PSA.

Invalid Result:

- An invalid result is indicated **when the control line fails to appear.**
- This can be due to insufficient specimen volume or incorrect procedural techniques.
- It is advised to review the procedure, repeat the test with a new kit, and ensure proper specimen volume.
- If the problem persists, discontinue using the test kit and contact us at (866) 287-2425 or info@spectrummdx.com





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PSA Rapid Test Training Quiz

What is the intended use of the PSA Rapid Test Cassette?
a) Qualitative detection of Prostate Specific Antigen (PSA) in whole blood only
b) Semi-quantitative detection of PSA in urine samples
c) Quantitative detection of PSA in serum and plasma samples
d) Qualitative detection of PSA in whole blood, serum, or plasma samples

What does a positive result with the PSA Rapid Test Cassette indicate?
a) PSA level between 3-10 ng/ml
b) PSA level below 3 ng/ml
c) PSA level above 10 ng/ml
d) No presence of PSA in the specimen

If the control line (C) or reference line (R) fails to appear, what should you do?
a) Interpret the result as positive
b) Repeat the test with a new cassette
c) Disregard the result and proceed with further testing
d) Assume the test is invalid and discard it

What does a negative result with the PSA Rapid Test Cassette indicate?
a) PSA level below 3 ng/ml
b) PSA level between 3-10 ng/ml
c) PSA level above 10 ng/ml
d) Insufficient specimen volume for accurate interpretation

What is the cutoff value of the PSA Rapid Test Cassette?
a) 1 ng/ml
b) 3 ng/ml
c) 5 ng/ml
d) 10 ng/ml

Which specimen types can be used with the PSA Rapid Test Cassette?
a) Whole blood only
b) Serum and plasma only
c) Whole blood and urine
d) Whole blood, serum, or plasma