PROSTATE SPECIFIC ANTIGEN (PSA) RAPID TEST DEVICE (WHOLE BLOOD/SERUM/PLASMA)

HOMEMED

INTENDED USE

The semi-quantitative PSA Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the semi-quantitative presumptive detection of prostate specific antigens in human whole blood, serum or plasma specimens.

INTRODUCTION

Prostate Specific Antigen (PSA) is a 33 kDa protein that is synthesised in the prostatic gland. It functions as a serine protease and serves to liquefy the seminal fluid. As demonstrated by immunohistological studies, PSA is localised in the cytoplasm of prostate acinar cells, ductal epithelium and in the secretion on the ductal lumina, present in normal, benign hyperplastic and malignant prostate tissues as well as in metastatic prostate cancer and in seminal fluid. An elevation of the serum concentration is reported in patients with both benign prostatic hypertrophy prostate carcinoma, but rarely in healthy men and is absent in normal women. PSA is not present in any other normal tissue obtained from men, nor is it produced by cancers of the breast, lung, colon, rectum, stomach, pancreas and thyroid. The PSA level in serum or plasma of normal healthy men should be lower than 4 ng/ml, so the reference line is designed to be approximately the intensity of 10 ng/ml. If the structural integrity of the prostate is disturbed and/or the gland size is increased, the amount of PSA in the blood serum/plasma may become elevated, reaching levels of up to 200 ng/ml. At a cut-off level of 4 ng/ml PSA, further medical analysis is recommended, although at a concentration range between 4-10 ng/ml PSA the elevated levels are commonly not caused by cancer but by other factors such as benign prostatic hyperplasia or prostatitis. Plasma concentrations of >10 ng/ml PSA strongly indicate the presence of prostatic carcinoma. Although a race- and/or age-dependent modification of the cut-off has been discussed in the literature, the amount of 4 ng/ml PSA is the generally accepted value at which follow-up examinations of the patient should be started.

PRINCIPLE

The PSA Rapid Test Device (Whole Blood/Serum/Plasma) detects prostate specific antigens through visual interpretation of colour development on the test strip. PSA antibodies are immobilised on the test region of the test strip. During testing, the specimen reacts with PSA antibodies conjugated to coloured particles and precoated onto the sample pad of the test. The mixture then migrates through the test strip by capillary action and interacts with reagents on the membrane. If there is sufficient PSA in the specimen, a coloured line will form at the test line region on the test strip. A test line (T) that is lighter than the reference line (R) indicates that the PSA level in the specimen is between 4-10 ng/ml. A test line (T) of equal intensity or close to the reference line (R) indicates that the PSA level in the specimen is approximately 10 ng/ml. A test line (T) that is darker than the reference line (R) indicates that the PSA level in the specimen is above 10 ng/ml. The appearance of a coloured line at the control line region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials provided	**Materials not provided**
Individually packed test	Timer
Disposable pipette	
Safety lancet	
Buffer	
Package insert	

PRECAUTIONS

For professional *in vitro* diagnostic use only.

- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g. do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers and/or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The PSA Rapid Test Device (Whole Blood/Serum/Plasma) is intended for use with human whole blood, serum or plasma specimens only.
- Intake of Finasteride (5-reductaseinhibitor) will reduce the PSA concentration by max. 50%. This should be considered when interpreting the test results.
- Different factors could increase the PSA level in blood serum and should be avoided before a PSA test is done:
  - ♦ Cycling: Avoid 24 hours prior to testing
  - ♦ Sexual activity (Ejaculation): Avoid 24-48 hours prior to testing
  - ♦ Prostate manipulation: Avoid PSA testing as per below:

Examination	**Period to avoid PSA testing**
Prostatic biopsy	> 6 weeks
Transurethal resection of the prostate	> 6 weeks
Transrectal prostatic ultrasound	> 1 week
Rigid Cytoscopy	> 1 week
Digital rectal examination	3 days – 1 week
Prostatic massage	> 1 week

- Only clear, non-hemolysed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Containers containing anticoagulants such as EDTA, citrate or heparin should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

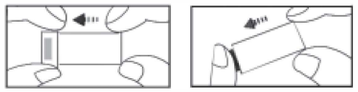
PROCEDURE

Bring test, buffer, specimen and/or controls to room temperature (15-30°C) before use.

1. Remove the test, safety lancet, alcohol swab and buffer from the sealed pouch and place it on a clean, level surface. Label the device with patient or control identification. The test should be performed

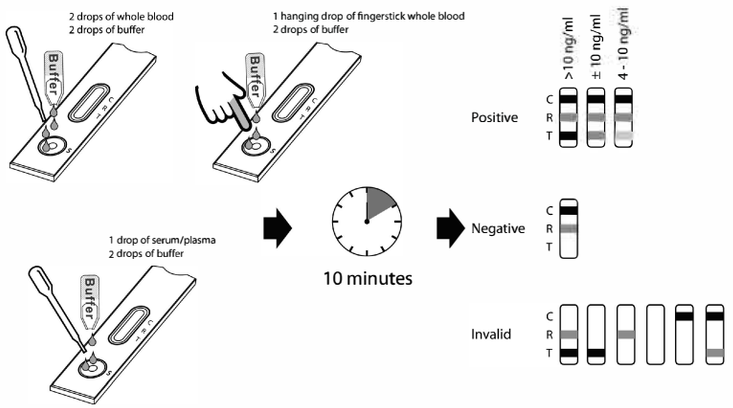
immediately after opening.

2. Clean the puncture site with the alcohol swab provided.
3. Carefully remove the cap from the safety lancet. Push the safety lancet firmly against the puncture site until it pricks the finger.



4. Twist off the cap of the buffer ampule.

5. **Using whole blood:**
   Transfer 2 drops of whole blood to the specimen well (S) of the device with the provided disposable pipette, then add 2 drops of buffer and start the timer.
   OR
   Allow 1 hanging drop of fingerstick whole blood to fall into the center of the specimen well (S) of the test device, then add 2 drops of buffer and start the timer.
   Using serum/plasma:
   Transfer 1 drop of serum/plasma to the specimen well (S) of the device with the provided disposable pipette, then add 2 drops of buff er and start the timer.
6. Avoid trapping air bubbles in the specimen well (S) and do not add any solution to the result area. As the test begins to work, colour will migrate across the membrane.
7. Wait for the coloured lines to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Refer to the illustration above)

Positive: Three coloured lines appear - one line appears in the control line region (C) , one line appears in the test line region (T) and one line appears in the reference line region (R).

- A test line (T) that is lighter than the reference line (R) indicates a PSA level between 4 and 10 ng/mL.
- A test line (T) of equal intensity or close to the reference line (R) indicates a PSA level of approximately 10 ng/mL.
- A test line (T) that is darker than the reference line (R) indicates a PSA level above 10 ng/mL.

Negative: Only two coloured lines appear - one line appears in the control line region (C) and another line appears in the reference line region (R). No coloured line appears in the test line region (T).

Invalid: Control line fails to appear. Results from any test which has not produced a control line at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of colour in the test line region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of colour in the test line region should be considered positive.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A coloured line appearing in the control line region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The PSA Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of PSA in the specimen and should not be used as the sole criteria for the diagnosis of prostatic disease.
2. A significant number of patients with BPH (more that 15%) and less than 1% of healthy individuals have elevated PSA. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
3. Specimens from patients who have received mouse monoclonal antibodies for diagnostic or therapeutical use may contain human anti-mouse antibodies. Such specimens may show either elevated or depressed values when tested with assay kits that utilise mouse monoclonal antibodies.

PERFORMANCE CHARACTERISTICS

Table: PSA Rapid Test vs. EIA

Relative Sensitivity: >98.8% (96.4%-99.6%)*		**PSA Rapid Test**			
			+	-	**Total**
Relative Specificity: >98.6% (96.8%-99.4%)*	**ELA**	+	241	3	**244**
Overall Agreement: >98.7% (97.4%-99.3%)*		-	5	356	**361**
***95% Confidence Interval**			246	359	605

LITERATURE REFERENCES

1. Fritsche, H,A, und R,J. Babalan; Analytical performance goals for measuring prostate-specific antigen: Clin, Chem, 39,1529-1529 (1993)
2. Lange, p, et al,: The value of serum prostate-specific antigen determinations before and after radical prostatectomy, J, Urol, 141,873 (1989)
3. Stamey, T, et al,; Prostate-specific antigen as serum marker for adenocarcinoma of the prostate, N, Engl, J, Med, 317,909-916 (1987)
4. Hammerer P. and Huland H., Der Onkologe (1996), Vol 2: 218-223
5. Jung K. et al., Urology (1999), Vol 53: 155-160
6. Milford Ward A. et al., Ann Clin Biochem (2001), Vol 38: 633-651

GLOSSARY OF SYMBOLS

Σ 1	Catalog number	2°C 30°C	Temperature limitation
i	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Do not reuse

HCR: Homemed (Pty) Ltd, Co Reg 2003/022932/07
100 Sovereign Drive, Route 21 Corporate Park,
Nellmapius Drive, Irene, Pretoria, South Africa.
Tel: 0861 106 150, www.homemed.co.za

Assure Tech. (Hangzhou) Co., Ltd.
Building 4, No. 1418-50, Moganshan Road,
Gongshu District, Hangzhou, 310011
Zhejiang, P.R. China
www.diareagent.com

Number: 1110021923
REV 2.0/Effective date: 2021-10-15