OnSite PSA Semi-quantitative Rapid Test - Cassette (Serum / Plasma / Whole Blood)

REF

Catalog Number R2002C

IVD

In vitro Diagnostic

INTENDED USE

The *OnSite* PSA Semi-quantitative Rapid Test is a lateral flow chromatographic immunoassay for the semi-quantitative detection of prostate specific antigen (PSA) in human whole blood, serum or plasma at a cut-off level of 4 ng/mL. It is intended to be used as a screening test and as an aid in the diagnosis of prostate cancer. Any reactive specimen with the *OnSite* PSA Semi-quantitative Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST

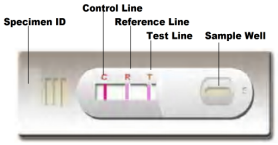
PSA is a serine protease with a molecular weight of approximately 34,000 daltons containing 7% carbohydrate by weight. PSA is immunologically specific for prostatic tissue, exiting in normal, benign hyperplasic, malignant prostate tissue, metastatic prostate carcinoma and in prostate fluid and seminal plasma. PSA is not present in any other normal tissues.

The serum PSA level in healthy men is between 0.1 ng/mL and 2.6 ng/mL. Elevated levels of PSA have been reported in patients with prostate cancer, benign prostate hypertrophy, or inflammatory conditions of other adjacent genitourinary tissues, but not in apparently healthy men, men with non-prostate carcinoma, apparently healthy women, or women with cancer. Studies have suggested that serum PSA is one of the most useful tumor markers in oncology. A PSA level of 4 to 10 ng/mL is considered to be in the "gray-zone", and levels above 10 ng/mL are highly indicative of prostate cancer[3]. Patients with PSA values between 4-10 ng/mL should undergo further analysis of the prostate by biopsy. PSA measurements can enhance early prostate cancer detection when combined with digital rectal examination (DRE). It may also serve as an accurate marker for assessing response to the treatment of prostate cancer. Therefore, measurement of PSA concentration can be an important tool in monitoring patients with prostate cancer and in determining the potential and actual effectiveness of surgery or other therapies.

The *OnSite* PSA Semi-quantitative Rapid Test (Serum/Plasma/Whole Blood) utilizes a polyclonal anti-PSA antibody and colloidal gold conjugated monoclonal anti-PSA antibody to selectively detect total PSA in whole blood, serum or plasma. The test has a cut-off value of 4 ng/mL and a reference value of 10 ng/mL for easy interpretation of the test result.

TEST PRINCIPLE

The *OnSite* PSA Semi-quantitative Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing monoclonal anti-PSA antibodies conjugated with colloidal gold (PSA antibody conjugates) and rabbit IgG, 2) a nitrocellulose membrane strip containing a test line (T line), a reference line (R line) and a control line (C line). The T line is pre-coated with a polyclonal anti-PSA antibody, the R line is coated with goat anti-rabbit IgG antibody, and the C line is pre-coated with goat anti-mouse IgG antibody.



When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the test cassette. PSA, if present in the specimen, will bind to the PSA antibody conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-PSA antibodies.

If the PSA level is between 4-10 ng/mL, the immunocomplex will form a visible burgundy colored T line with its line intensity weaker than the reference line (R). If the PSA level is equal to or higher than 10 ng/mL, the immunocomplex will form a burgundy colored T line with its line intensity equal to or higher than that of the reference line (R).

Absence of the T line suggests the PSA level is lower than 4 ng/mL. The test contains an internal control (C line) which should exhibit a burgundy colored line of the immunocomplex of goat anti-mouse IgG/mouse IgG-gold conjugate regardless of color development on the T line. If the C line does not develop, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a. One cassette device
   b. One desiccant
2. Plastic droppers
3. One package insert (instruction for use)
4. Sample Diluent (1 vial, 5ml)

MATERIALS MAY BE REQUIRED AND NOT PROVIDIED

1. Positive Control
2. Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. A container for holding test specimen

WARNINGS AND PRECAUTIONS

For *in Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15°C-30°C) before use.
5. Do not use components from any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolized blood specimens for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
11. Handle the negative and positive controls in the same manner as patient specimens.
12. The test results should be read within 15 minutes after a specimen is applied to the sample well of the device. Reading the result after 15 minutes may give erroneous results.
13. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2°C - 30°C. The positive and negative controls should be kept at 2°C-8°C or the temperature indicated. If stored at 2°C - 8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Avoid examination and sampling of prostate tissue at least two weeks prior to collecting blood sample for the test, as these may lead to leaking of PSA into the blood stream, generating a false test result.

Plasma

Step 1: Collect blood specimen into lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively, in Vacutainer®) by veinpuncture.
Step 2: Separate the plasma by centrifugation.
Step 3: Carefully withdraw the plasma into new pre-labeled tube.

Serum

Step 1: Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
Step 2: Allow the blood to clot.
Step 3: Separate the serum by centrifugation.
Step 4: Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2° C - 8°C if not tested immediately for up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Blood

Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use hemolized blood for testing.

Whole blood specimens should be stored in refrigeration (2°C - 8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.

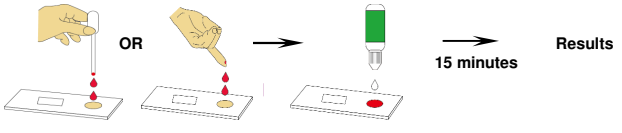
ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.

Step 2: When ready to test, open the pouch at the notch and remove the device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with the specimen's ID number.

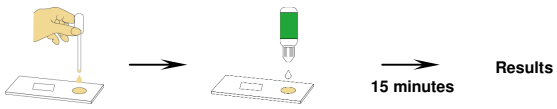
Step 4: **For whole blood test**
Apply 2 drops of whole blood (about 80-100 µL) to the sample well.
Then add one drop (about 35-50 µL) of Sample Diluent immediately.



2 drops of whole blood **1 drop of sample diluent**

For serum or plasma test

Fill the plastic dropper with the specimen.
Holding the dropper vertically, dispense 1 drop (about 30-45 µL) of specimen into the sample well making sure that there are no air bubbles.
Then add one drop (about 35-50 µL) of Sample Diluent immediately.



1 drop of specimen **1 drop of sample diluent**

Step 5: Set up the timer.

Step 6: Results can be read within 15 minutes.

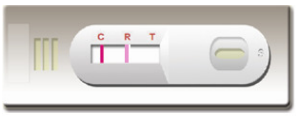
Do not read the result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

1. **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding the specimen and the sample diluent. If the C line does not develop, review the whole procedure and repeat the test with a new device.
2. **External Control:** Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
   a. New operator uses the kit, prior to performing testing of specimens.
   b. A new lot of test kits is used.
   c. A new shipment of kits is used.
   d. The temperature used during storage of the kits fall outside of 2°C - 30°C.
   e. The temperature of the test area falls outside of 15° - 30°C.
   f. To verify a higher than expected frequency of positive or negative results.
   g. To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

1. NEGATIVE RESULT: If only the C line and the R line are developed, the test indicates PSA is not present or its level is less than the 4 ng/mL cutoff value. The result is negative.



2. **POSITIVE RESULT:**

2.1 If the C, R, and T lines are all developed and the test line (T) intensity is weaker than the reference line (R), the test indicates a PSA level between 4-10 ng/mL. The result is positive.

2.2 If the C, R, and T lines are all developed and the test line (T) intensity is equal or close to the reference line (R), the test indicates the level of PSA is approximately 10 ng/mL. The result is positive.

2.3 If the C, R, and T lines are all developed and the test line (T) intensity is stronger than the reference line (R), the test indicates the level of PSA is higher than 10 ng/mL. The result is positive.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

3. INVALID: If the **control line (C) or reference line (R) fail(s) to appear** the assay is invalid regardless of color development on the T line as indicated below. Review the procedure and repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

Clinical Performance

A total of 400 samples from susceptible subjects were tested by the *OnSite* PSA Semi-quantitative Rapid Test and by a US FDA licensed EIA. Comparison for all subjects is shown in the following table:

	OnSite PSA Semi-quantitative Rapid Test		
EIA	**Positive**	**Negative**	**Total**
Positive*	10	0	10
Negative*	6	384	390
Total	16	384	400

Note: Positive is defined as levels of PSA ≥ 4 ng/mL
Negative is defined as levels of PSA < 4 ng/mL

Relative Sensitivity= 100%; Relative Specificity= 99%; Overall Agreement= 98.5%

LIMITATIONS OF TEST

1. The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of elevated PSA in whole blood, serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The *OnSite* PSA Semi-quantitative Rapid Test is limited to the semi-quantitative detection of PSA at a cut-off level of 4.0 ng/mL in human whole blood, serum or plasma. It should not be used as the sole criteria for the diagnosis of Prostate Cancer.
3. A significant number of patients with BPH (more that 15%) and less than 1% of healthy individuals have elevated PSA. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.
4. PSA levels may be unreliable in patients who receive hormone therapy or prostate gland manipulation.
5. High concentrations of PSA may produce a dose hook effect resulting in false negative results. High dose hook effect has not been observed with this test up to 30,000 ng/mL PSA.

REFERENCES

1. Oeterling J.E. J.Urol., 1991, 145:907-923.
2. Lange pH.: The value of whole blood or serum prostate specific antigen determinations before and after radical prostatectomy. J.Urol., 1989, 141:873-879.
3. Starney TA.: Prostate specific antigen in the diagnosis and treatment of adenocarcinoma of the prostate untreated patients. J.Urol., 1989, 141:1070-1075.
4. Schifman RB.: Analytical and physiological characteristics of prostate specific antigen and prostate acid phosphatase in whole blood or serum compared. Clin. Chem., 1987, 33:2086-2088.

Index of Symbols

	Consult instructions for use	IVD	For *in vitro* diagnostic use only		Use by
REF	Catalog #	LOT	Lot Number	Σ N	Tests per kit
2°C 30°C	Store between 2-30°C		Do not reuse		
	Manufacturer		Date of manufacture		

CTK Biotech, Inc.
10110 Mesa Rim Road
San Diego, CA 92121, USA
Tel: 858-457-8698
Fax: 858-535-1739
E-mail: info@ctkbiotech.com

PI-R2002C Rev. D
Effective date: 2013-06-11

For Export Only. Not For Resale In The USA.