DRG® PSA Rapid Test (RAP-2611)

Revised 17 Aug. 2007 **RUO in the USA**

SUMMARY
Prostate specific antigen (PSA) is a serum protease that is found only in the prostate within the epithelial cells of the acini and ducts. Normal PSA concentration in human serum is 0.1-2.6 ng/ml. Reports have suggested that elevated level of serum PSA is the most useful tumor markers in diagnosis of prostate cancers. The PSA Rapid Test is an immunochromatography rapid test. It is designed to detect human PSA concentration in serum as low as 4 ng/ml within 5 minutes.

PRINCIPLE
The PSA Rapid Test utilizes two sites sandwich immunoassay technology and specific antibodies to PSA for the qualitative detection of PSA concentration in serum. PSA specific antibodies are pre-coated onto membrane as a capture reagent on the test band region. During the assay the specimen serum is allow to react with anti-PSA gold-conjugate. The mixture then moves lacterally on the membrane chromatographically to the test region with immobilized anti-PSA on the membrane. If PSA is present in the specimen, a color band is formed in the test region. Absence of the color band in the control region will always appear regardless the presence of PSA in serum.

REAGENTS PROVIDED
A test device is packed in a protection pouch.

STORAGE AND STABILITY
The test device is to be stored refrigerated or at room temperature (2-25ºC) under dry condition for the duration of the shelf life (normally 12 months).

PRECAUTION
1. For *in vitro* use only. This kit is intended for Research Use Only. In the United States.
2. Do not use after expiration date.
3. Test device should remain sealed in pouch until ready for use.

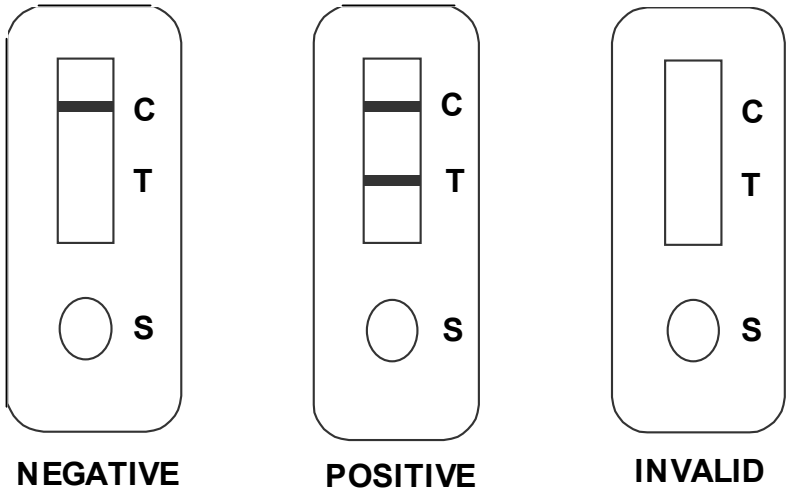
SPECIMEN COLLECTION AND STORAGE
1. Collect blood and coagulate blood specimen following standard clinical procedure.
2. Remove serum by centrifugation. Specimens can be stored under refrigeration up to 3 days. Freeze specimen at -20 ºC or lower for long term storage.
3. Avoid repeated freezing and thawing of specimens.

ASSAY PROCEDURE
1. Remove the device from the protected pouch and label the device with specimen identification.
2. Add 3 drops (150 µl) of serum to the sample well (S).
3. Observe the colored band developed over the control region (C), indicating the assay is complete.
4. Read the result within 5 minutes. Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULT
POSITIVE
Presence of two pink colored and visible bands within the test region indicates presence of PSA with 4 ng/ml or higher in serum.

NEGATIVE
Presence of a single pink colored band in the control region (C) indicates absence of PSA or the concentration of PSA in serum is below the detection level (4 ng/ml).

INVALID
If after 10 minutes no band is visible within the test window, the result is invalid. The protocol may not have been followed correctly or the test unite may have deteriorated. The test should be repeated with a new kit. **Note:** DO NOT interpret result after 10 minutes.



LIMITATION
The rapid test result should be used as an aid in diagnosis and should not be interpreted as diagnostic be themselves.

REFERENCE
1. Oeterling J. E.: J. Urol., 1991, 145:907-923
2. Lange PH.: the value of 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 prostic acid phosphates in serum compared. Clin. Chem., 1987, 33:2086-2088.