DRG

DRG® PSA Rapid Test (RAP-3539)

Revised 4 Jan. 2011 rm (Vers. 2.1) **USA: RUO**

This kit is intended for Research Use Only.

Not for use in diagnostic procedures.

TEST PRINCIPLE

The PSA Screen Test utilizes two site sandwich immunoassay technology and specific antibodies to PSA for the semi-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 reacts with anti-PSA gold-conjugate. The mixture then moves laterally 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. PSA internal standard is pre-coated on the reference band region indicates equal 4ng/ml of PSA concentration. And followed by a built-in system control with anti-PSA antibody on the control band region. Both of the color bands in the reference region and control region will always appear regardless the presence of PSA in serum sample.

REAGENTS PROVIDED

A test device is packed in a protective pouch.
Test running buffer is ready for use.

STORAGE AND STABILITY

The test device is to be stored refrigerated or at room temperature (2-30°C) under dry condition for the duration of the shelf life (normally 18 months).

PRECAUTION

1.For Research Use Only.
2.Do not use after expiration date.
3.Test device should remain sealed in pouch until ready for use.

SERUM SPECIMEN COLLECTION

1.Collect blood and coagulate blood specimen following standard clinical procedure.
2.Remove serum by centrifugation. Specimens can be stored refrigerated at 2-8°C up to 3 days. Freeze specimen at -20°C or lower for long term storage.
3.Avoid repeated freezing and thawing of specimens.

ASSAY PROCEDURE

1.Remove the device from the protective pouch and label the device with specimen identification.
2.Add 25 ul of serum to the Sample Well (for Card) or Sample Pad (for Dipstick). Than add 3 drops (150 ul) of test running buffer into the sample well or sample pad.
3.Observe the colored band developed over the control region (C), indicating the assay is complete.
4.Read the result within 10 minutes. Do not interpret the result after 15 minutes.

DRG International Inc., USA
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INTERPRETATION OF RESULTS

Positive:

Three bands appear:

Test Band (1st line): Test Probe
Reference Band (2nd line): Internal Standard
Control Band (3rd line): System Control

Negative:

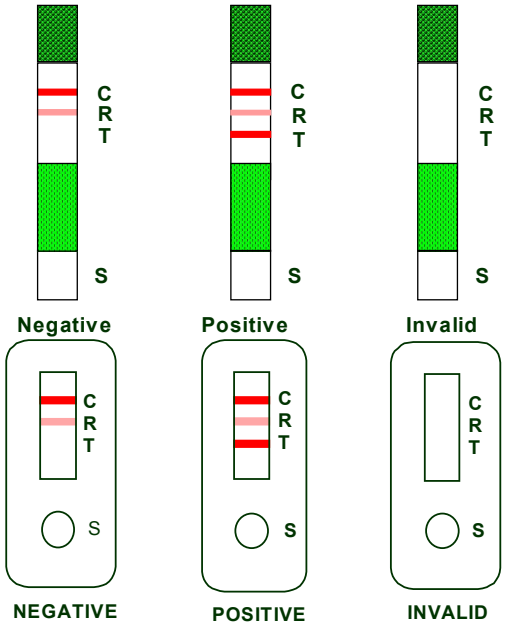
Two bands appear: one in the control region and one in the reference region. No colored band appears or a very faint band appears in the test region (T), indicating the absence of PSA or that PSA concentrations in the sample are below the cut-off detection level (4 ng/ml).

Invalid:

Both or either the control band (C) or reference band (R) fail(s) to appear after 10 minutes. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control band and/or reference band failure. If results are invalid, review the procedure and repeat the test with a new test device.

Note:

Do not interpret results after 15 minutes. The test band intensity may be weaker or stronger than that of the control band, but a very faint band in the test region indicates that the concentration of PSA is near the cut-off detection level. The sample should be re-tested or confirmed with a more specific method before a positive determination is made.



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