

PrivaFone, Inc.
PO Box 300
Fort Meade, SD 57741

Specification Sheet

Tel. +1 605-347-7566

InSite® PSA Test Strip

Item No. SD6

Diagnostic test for the detection of semen in forensic investigations by the semi-quantitative determination of prostate-specific antigen (PSA)

Intended Use

The InSite® PSA test strip is a rapid binding test for the detection of PSA in seminal plasma in forensic investigations. A POSITIVE test is indicated by the presence of two red lines on the test strip. The test is also semi-quantitative, which in case of a strongly positive test gives a specificity of 100% for semen.

Introduction

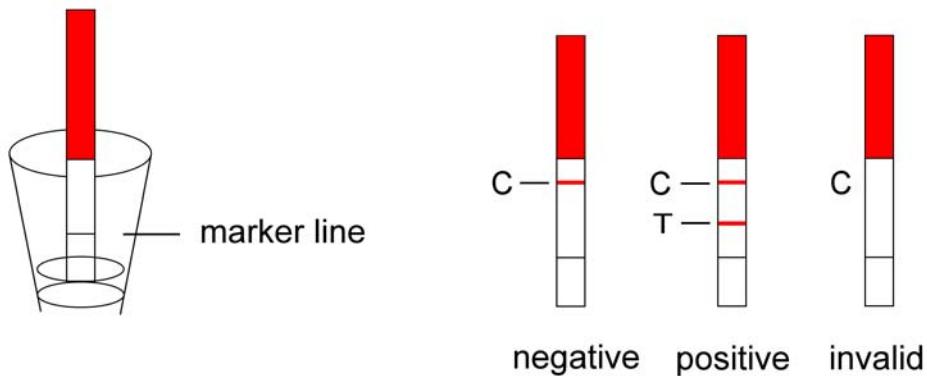
PSA (prostate-specific antigen) is a protease which is produced by acinar and epithelial ductal cells of the prostate gland (Ref. 1). Its substrate is semenogelin, a structural protein produced by the seminal vesicles (Ref. 2). Its function it to liquefy semen over a period of about 30 min after ejaculation, giving spermatozoa time to capacitate (lose their cell membranes) which exposes proteins in the acrosomal head, making possible penetration of an ovum. PSA is found in high concentrations in semen (about 4 mg/mL), making it useful as a marker for the forensic determination of even small amounts of seminal fluid. It is stable when dry, and has been found in semen stains 30 years old (Ref 3).

Although PSA is also found in small amounts in other bodily fluids in both men and women, these small amounts have been shown not to interfere with the forensic determination of semen by immunochromatographic tests (Ref. 4). The lateral flow strip employed in the InSite® test is about 1000x more sensitive than the corresponding acid phosphatase (AP) test, and in addition is specific for PSA. In case of a strongly positive test, this specificity is 100%, leaving no doubt that the material being tested does in fact contain semen.

Description of the test

The InSite® PSA test strip is a sandwich immunoassay which contains both monoclonal and polyclonal mouse antibodies to PSA as active elements. The monoclonal antibody is gold-labeled and contained in the mobile phase at the lower end of the strip, while the polyclonal antibody is fixed at the test region. The strip also has a goat anti-mouse antibody fixed at the control region. Upon exposure to PSA, the gold-labeled antibody forms a gold-labeled antibody-PSA complex and moves up the strip chromatographically until it reaches the test region, where it binds to the second anti-PSA antibody, turning the test line red. Unbound gold-labeled antibody continues moving up the strip until it reaches the control region, turning the control line red. The control line is also calibrated to correspond to a PSA concentration of 4 ng/mL.

If there is PSA in the sample (and by implication semen), then the test strip will show two red lines. If no PSA is detectable, the test will show only one red line. If the test is invalid, no red lines will appear. This is illustrated in the following diagram:



Materials

The InSite® PSA test strip comes sealed in individual pouches with a desiccant packet.

Storage and Stability

Strips should be stored in a cool, dry place. They may be refrigerated, but not frozen. They must remain in the sealed pouch (and if necessary brought to room temperature) before use. They are stable until the expiration date shown on the pouch.

Sensitivity

The test is capable of detecting PSA at a concentration of 2 ng/mL at least, with faint test lines still visible at 0.5 ng/mL. This corresponds to a detection limit of about 1/10,000,000 dilution of semen.

Specificity

The test is 100% specific at a PSA concentration of 4 ng/ml, and 90% specific at a concentration of 2 ng/mL (Ref. 5). This means that if the test line is equal or greater in intensity to the control line, that there is a 100% chance that the item being tested contains semen.

Test procedure

Place 15 mL of water in a cup (for example a coffee cup) using a supplied dropper. Then, place the item to be tested (for example the crotch portion of a pair of women's underwear) into the cup and extract it by repeatedly allowing water to soak in, then pressing it out. Finally, wring out the item into the cup. Place a PSA test strip into the vessel and wait 10 minutes. (Do not

immerse past the marker line.) Then, take the test strip out and lay it on a clean, dry surface. Read the test strip after 10 minutes. A POSITIVE test is indicated by two lines as shown in the diagram above.

Alternative procedure: wrap the stained fabric around a wet cotton-tipped swab so that the swab becomes saturated. Then, swirl the swab in a small cup containing 25 drops of water. Repeat this two times. Do the PSA test as usual. This method preserves the stain on the item, which you may then send off for DNA analysis.

If you are testing absorptive pads (used during a woman's menstrual period), then place 25 mL of water into the cup (for a full pad) or 10 mL for a mini-pad. Then, place the pad into the cup and repeatedly extract it by allowing water to soak in, then pressing it out. Finally, wring out the pad into the cup and discard it. Do the PSA test as usual.

If you are testing a stain on a surface (for example, a car seat), then wipe the stain with a small piece of wet cloth and extract it in a coffee cup by allowing water to soak in, then pressing it out. Finally, wring out the cloth into the cup. Do this three times. Do the PSA test as usual.

NOTE: latex gloves are recommended for these procedures.

Interpretation of test results

If the test line is equal or greater in intensity to the control line, there is a 100% chance that the item being tested contains semen. Conversely, if the test line is weaker than the control line, the chance is only 90%, meaning there is a 10% chance of a false positive result. However, because of the personal and legal implications of a positive test, it is the policy of PrivaFone to regard weak test results as inconclusive, in which case further investigation is indicated.

References

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