Human Semen Rapid Test Dipstick(Stain)
Package Insert

REF OHS-901	English

A rapid test for the qualitative detection of PSA for assessing presence of Human Semen in vaginal fluid or other areas, where a liquid/ stain is suspected to be semen.
For forensic use only.

【INTENTED USE】

The Human Semen Rapid Test Dipstick is a rapid chromatographic immunoassay for qualitative detection of PSA found in human semen in vagina using swab specimen as an evidence for coitus or other areas, where a stain/ liquid is suspected to be semen.

【SUMMARY】

Rape, as the criminal activity, exist every country. An examination after rape requires the use of a reliable semen detection test that is sensitive and has very good negative predictive power.[1] the PSA test is the best marker of the presence of semen and is well suited for use in emergency consultations. [1] PSA (Prostate-specific antigen) is a glycoprotein produced in the prostate and secreted into the seminal fluid. PSA is one of the major proteins in seminal fluid. The fact that PSA is found only at very low concentrations in female vaginal fluid (0.4-0.9 ng/mL and 0.0-1.25 ng/mL, respectively)[2,3] makes PSA an important marker in forensic science for the detection of even small amounts of seminal fluid in vagina to confirm coitus. Human Semen Rapid Test detects PSA to confirm the presence of semen in vaginal fluids collected with the swab. The test just confirms the presence of PSA as a result of seminal ejaculation, without any indication for coitus being forced sexual assault (Rape) or consensual.

【PRINCIPLE】

The Human Semen Rapid Test Dipstick (Stain) is a qualitative, lateral flow immunoassay for the detection of PSA found in human semen in vaginal fluid. The membrane is pre-coated with PSA antibodies on the test line region. During testing, the specimen reacts with the particle coated with anti-PSA antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-PSA antibodies on the membrane and generate a colored line.

【REAGENTS】

The test dipstick contains PSA monoclonal antibody conjugated particles and PSA monoclonal antibody coated on the membrane.

【PRECAUTIONS】

Please read all the information in this package insert before performing the test.

1. For forensic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch or closed canister until ready to use.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Do not use the test if the pouch is damaged.
5. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
6. Wear protective clothing such as laboratory coats, disposable gloves or eye protection when specimens are being tested.
7. The used test should be discarded according to local regulations.
8. Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The Human Semen Rapid Test Dipstick (Stain) can be performed using soaking solution of uncertainty stain.
- **Specimen collection from vagina:** Before specimen collection, remove excess mucus from the endocervical area with a cotton ball and discard. The swab should be inserted into the endocervical canal, past the squamocolumnar junction until most of the tip is no longer visible. Firmly rotate the swab 360°in one direction (clockwise or counterclockwise), let stand for 15 seconds, then withdraw the swab. Avoid contamination from exocervical or vaginal cells. Do not use 0.9% sodium chloride to treat swabs before collection specimens. Dispense the tip of the swab thus obtained in a sterile cup of clean water **(Approx. 30 ml water)** and mix well by rotating the swab for 10 times. Allow swab to be in the water for at least 2 minutes.
- **Specimen collection from other sources:** Place the sterile swab in clean water for a while, then wipe the suspected place (liquefied or dry stain) with the swab for 3 times, then place the moist swab into the water **(Approx. 30 ml water)** and turn the swab in one position for 10 times. Allow swab to be in water for at least 2 minutes. Alternatively, If the suspected stain is on a piece of cloth, such as trousers or bed sheet, the cloth around the stain can be cut out and put in the water kept for specimen collection processing **(Approx. 30 ml water)**.
- The Test Solution thus prepared with the mix of specimen obtained through swab or cloth and water **(Approx. 30 ml water)** should be used as specimen for testing as soon as possible, best results would be obtained within 1 hour of this Test Solution preparation.

【MATERIALS】

Materials provided

- Test dipsticks
- Package insert

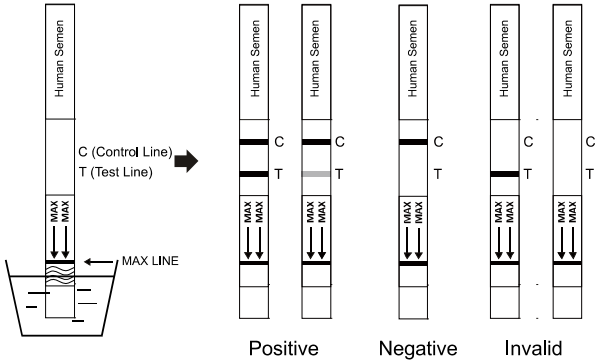
Materials required but not provided

- Plastic cup
- Water
- Sterile swab
- Timer

【DIRECTIONS FOR USE】

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test dipstick from the sealed pouch and use it as soon as possible.
2. With arrows pointing toward the Test Solution, immerse the test dipstick vertically in the Test Solution for 10-15 seconds. DO NOT PASS THE "MAX" LINE on the lower strip label of the dipstick when immersing the dipstick.
3. Place the dipstick on a level and clean desk, start the timer and wait for the color line (s) to appear. Read the result at 5 minutes, do not interpret the result after 10 minutes.



【INTERPRETATION OF RESULTS】

POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of human semen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, 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..

【CUT-OFF】

The minimum indicative level of PSA for human semen is generally agreed to be 4ng/ml. The Human Semen Rapid Test Dipstick (Stain) has been designed to detect PSA level above 4 ng/ml as a marker for presence of semen in vagina or other stains.

【BIBLIOGRAPHY】

1. Nadia Khaldi,1 M.D.; Alain Miras, M.D.; Koffi Botti, M.D.; Larbi Benali; and Sophie Gromb, M.D., Ph.D., J.D. Evaluation of Three Rapid Detection Methods for the Forensic Identification of Seminal Fluid in Rape Cases
2. Lawson et al. (1998) Objective markers of condom failure. Sex Transm Dis 25:427-423
3. Macaluso et al. (1999) Prostate-specific antigen in vaginal fluid as a biologic marker of condome failure. Contraception 59: 195-201

Index of Symbols

⚠	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by	2	Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

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