

BLUESTAR® Identi-PSA®

Immunochromatographic test
for prostate specific antigen detection
in seminal liquid for use in forensic medicine

Instructions for use

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INTENDED USE

The BLUESTAR® Identi-PSA® test allows the rapid detection of PSA which is present in high concentration in seminal fluid. It can be used directly on crime scenes or on presumed victims of sexual assaults or abuses thanks to the specific components supplied in the kit.

PRINCIPLE

The prostate specific antigen (PSA) is an intracellular glycoprotein (molecular weight: 34,000 daltons) only synthesised by the male prostate gland and in seminal plasma. This protein is now used by the forensic medicine as a choice marker to detect sexual assaults, even when they are committed by men who had vasectomy (1).

BLUESTAR® Identi-PSA® is a rapid qualitative assay for PSA detection from traditional biological samples (serum, plasma, or blood), but also from sperm samples collected with a swab either on the clothes or on the victims' bodies.

The method employs a unique combination of monoclonal dye conjugate (mouse) and monoclonal antibodies (solid phase) to selectively identify PSA antigen in the samples, with a high degree of sensitivity.

As the test sample flows through the absorbent paper, the labelled antibody-dye conjugate binds to the antigen, thus forming an antigen-antibody complex. This complex binds to the anti-PSA antibodies in the positive reaction zone (T) and produces a wine-coloured colour line if the PSA antigen level is higher than 4 ng/ml. If there is no antigen, no line appears in the test zone.

The reaction mixture continues flowing through the absorbent paper, past the test zone and the control zone (C). Unbound conjugate binds to the reagents in the control zone, producing a wine-coloured colour line indicating that the reagents are functioning correctly.

KIT CONTENTS

Each kit contains all the components needed to perform 6 or 24 tests (according to product reference):

Ref. VD-PSA-6: 6 x BLUESTAR® Identi-PSA® tests
Ref. VD-PSA -24: 24 x BLUESTAR® Identi-PSA® tests

Quantity	Component
6 or 24	BLUESTAR® Identi-PSA® device
6 or 24	Collection tube (bottle type) containing 1 ml diluent buffer
6 or 24	Sterile swab
1	Instructions leaflet

STORAGE AND STABILITY

- All the components of BLUESTAR® Identi-PSA® kit should be stored at room temperature (4°C to 30°C).
- **DO NOT FREEZE.**
- The BLUESTAR® Identi-PSA® test is stable until the expiry date mentioned on the foil pouch.

PRECAUTIONS

- This test is for forensic medicine use only.
- Carefully read the instructions before using the test.
- Handle every sample as if it contained infectious agents. After the test is completed, discard samples and swabs with all the required precautions after autoclaving them for at least one hour. Alternatively, they can be treated with a 0.5 to 1% sodium hypochlorite solution for one hour before discarding them.
- Wear protection clothes, such as laboratory coats and disposable gloves to test the samples. Avoid any contact with hands, eyes and nose when collecting and testing the samples.
- Do not eat, drink or smoke in the area where the samples and reagents are handled.
- Do not use beyond the expiry date indicated on the foil pouch.
- Do not use a test if its foil pouch is damaged.
- Use the swabs provided with the kit.

SAMPLE COLLECTION AND PREPARATION

1. The samples should be collected under standard collection conditions (aseptically and so as to avoid any contamination). Each sample should be treated as if it was potentially infectious.
2. Use the swab provided with the test to collect the sample.
3. Ensure not to break the collection tube tip.
4. Unscrew the cap of the tube, by keeping it vertically in order not to spill the diluent buffer.
5. Collect the samples of the presumed sperm trace with the sterile swab provided with the test (in case of dry sample, it is possible to previously humidify the swab with the diluent buffer contained into the collection tube).
6. Immerse the swab, by vigorously shaking it for 10 seconds, into the tube containing the buffer so that the sample is correctly mixed with the buffer.
7. Remove the swab from the plastic tube while squeezing it against the tube wall to extract the most liquid possible.
8. Dispose of the swab, then rescrew the cap back onto the tube.

CAUTION: It is better to immediately test the sample because PSA is not very stable (from 14 to 47 hours maximum in the vaginal tract). If it is not possible, the sample should be placed in a fridge (+2°C to +8°C) and should be tested within 48 hours.

PROCEDURE

1. Before starting the assay, make sure all the samples and BLUESTAR® Identi-PSA® reaction devices are at room temperature.
2. Remove the reaction device from its protective pouch by tearing along the notches.
3. Break the collection tube tip (Fig. 1), and then squeeze the tube to dispense **4 drops** of the obtained solution into the sample well of the device (▷) (Fig. 2).

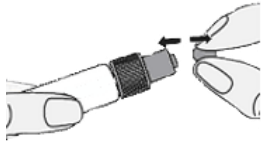


Fig. 1



Fig. 2

4. Read the result after 10 minutes. Do not interpret after 15 minutes.

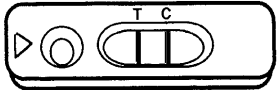
RESULT READING

Negative

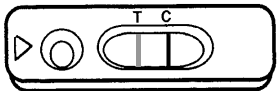


Only one coloured line appears into the control zone (C), indicating the test performed correctly and the reagents worked correctly. No line appears into the test zone (T).

Positive

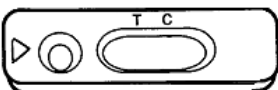


In addition with the coloured line into the control zone (C), a coloured line clearly visible also appears into zone (T), indicating the sample contains PSA.



Even a very pale line should be interpreted as a positive result.

Invalid



If no colour line appears into the control zone (C), the test is invalid. In this case, it is recommended to perform the test again with a new device.

PERFORMANCES

Accuracy

An assessment of the BLUESTAR® Identi-PSA® test was performed in 1997 in order to use it in forensic medicine. The publication of these results shows that the BLUESTAR® Identi-PSA® test is perfectly suitable for this use as far as sensitivity, specificity, and feasibility are concerned. (1)
The test offers both very high sensitivity and high rapidity, as well as simplicity compared with a traditional ELISA method.

Reproducibility

Intra-assay: Within run precision was determined by using 10 replicates of three specimens containing 0, 5 and 10 ng/ml of PSA. The negative and positives values were correctly identified 100% of time.

Inter-assay: Between run precision was determined by using the same three specimens of 0, 5 and 10 ng/ml of PSA in 10

independent assays and with three different lots of reaction device over a 6 months period. Again, the negative and positive values were correctly identified 100% of time.

Sensitivity

The BLUESTAR® Identi-PSA® test can detect PSA levels higher than or equal to 3 ng/ml according to the international PSA standard (CRM 613 N°1004 from the European Standard Office, Belgium 1998). However, some samples containing less than 3 ng/ml may cause positive results.

Hook effect

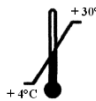


Some samples containing very high PSA levels (up to 10 µg/ml) constantly caused positive results. However, some negative sperm samples caused positive results after 1/100 or 1/1,000 dilution. In case of doubt for some samples, it is then necessary to make another assay after 1/100 or 1/1,000 dilution.

Cross reaction

The BLUESTAR® Identi-PSA® is manufactured using 2 highly sensitive and specific anti-PSA monoclonal antibodies. Therefore no cross reaction has been showed with blood or seminal fluid making this test highly suitable for forensic use.

BIBLIOGRAPHY

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3. **Kuriyama, M, MC Wang, CL Lee, LD Papsidero, C.S. Killian, H. Inaji, N.H. Slack, T. Nishiura, GP. Murphy and T.M. Chu.** 1981. Use of human prostate specific antigen in monitoring cancer. *Cancer res.* 41: 3874-3876.
4. **Liedtke R.L. and JD Batjer.** 1984. Measurement of prostate specific antigen by radioimmunoassay. *Clin. Chem.* 30 : 649-652.

	Temperature limitation +4°C +30°C
	Please read instructions leaflet
	Do not reuse

Ref. VD-PSA-6: 6 x BLUESTAR® Identi-PSA® tests
Ref. VD-PSA -24: 24 x BLUESTAR® Identi-PSA® tests

Made in EU

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