

# INTEX<sup>®</sup>-PSA Test

Rapid test for the determination of prostata specific antigen

## **Fast and reliable Diagnosis – immediate Therapy**

Since the sensitivity of INTEX<sup>®</sup>-PSA Test has been adjusted to show a positive reaction with PSA levels of 4.0 ng/ml or more, it is a very helpful and an easy method of screening of prostate disorders (mainly cancer).

The prostate specific antigen (PSA) is a glycoprotein of approximately 34 kDa (free conformation). It has a serin-protease enzymatic activity and plays an important role in liquefaction-gelification of the seminal fluid.

PSA present in the specimen reacts with the colloidal latex particles coated with specific monoclonal antibodies against PSA. This colloidal complex particles-antibodies-PSA migrates by a chromatographic process to the reaction zone. In this zone there are antibodies to the PSA that will react with the complex colloidal latex particles-antibodies-PSA. This reaction originates the formation of a red deposit.

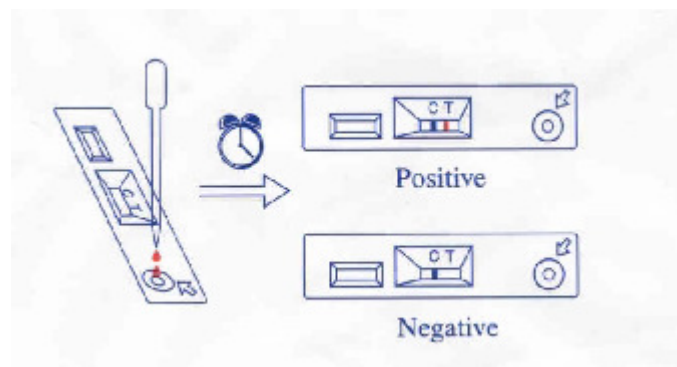
### Test characteristics

- **Easy handling**
- **Simple, accurate interpretation of results in 5 minutes**
- **Semi-quantitative results**
- **Cut off: 4 ng/ml**
- **Built in test control**
- **Storage at room temperature up to 18 months**



### Test procedure

- ① Remove the INTEX<sup>®</sup>-PSA Test device from its sealed bag after getting room temperature and just before using.
- ② Slowly place 4 drops or 125 µl of clear serum onto the round window marked with an arrow (sample window)
- ③ Read after 5 minutes.



**NEGATIVE:** Only one **BLUE** band appears across the result window (SIMPLE: close to the letter "C" control)

**POSITIVE:** In addition to the **BLUE** control band, a distinguishable **PINK-RED** band also appears across the result window (SIMPLE: close to the letter "T" test). The intensity of the line depends on the concentration of antigen.

If no blue line appears, the test is **INVALID**, it has not been correctly runned, the reactives has been damaged or the sample added was incorrect. Run another test.

In order to obtain the correct sensitivity with INTEX<sup>®</sup>-PSA Test and in order to assure negative results the final reading time should be 5 minutes. Any line or colour that should appear after 5 minutes has no diagnostic value.

## Sensitivity

The INTEX<sup>®</sup>-PSA Test will give a positive result with specimens containing more than 4.0 ng/ml of PSA, as evaluated with the standards of PSA and PSA-ACT of SCRIPPS Laboratories, USA.

The use of human serum as diluent of PSA antigens for control purposes is not recommended because the reached sensitivity varies between different sources.


<u>ng/ml</u>	<u>PSA</u>	<u>PSA-ACT</u>
64	+	+
32	+	+
16	+	+
8	+	+
4	±	±
2	—	—
1	—	—
0	—	—

## Specificity: 95%

198 fresh sera samples (from a local Hospital in Zaragoza, Spain) were tested in duplicate:

		ELISA	
		positive	negative
INTEX <sup>®</sup> -PSA Test	positive	2	3
	negative	0	193

INTEX <sup>®</sup> -PSA Test	▽	REF
	12 Test cassettes	TMPSA12

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**INTEX<sup>®</sup>**  
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