

PSEP Diagnostic Kit

- ▶ Elisa
- ▶ Colloidal Gold

About OCBT

- One of the subsidiary companies of Da An Gene Lot, Cd.
- Located in Jiangsu Province, China.
- Established in 2010 as a high-tech joint venture
- Devoted to innovative bio-technologies of cancer diagnostics and therapeutics.
- Modern, high-class manufactory center
- Offering advanced diagnostic platforms for early detection of solid tumors
- Based on non-invasive bio-markers in body fluids



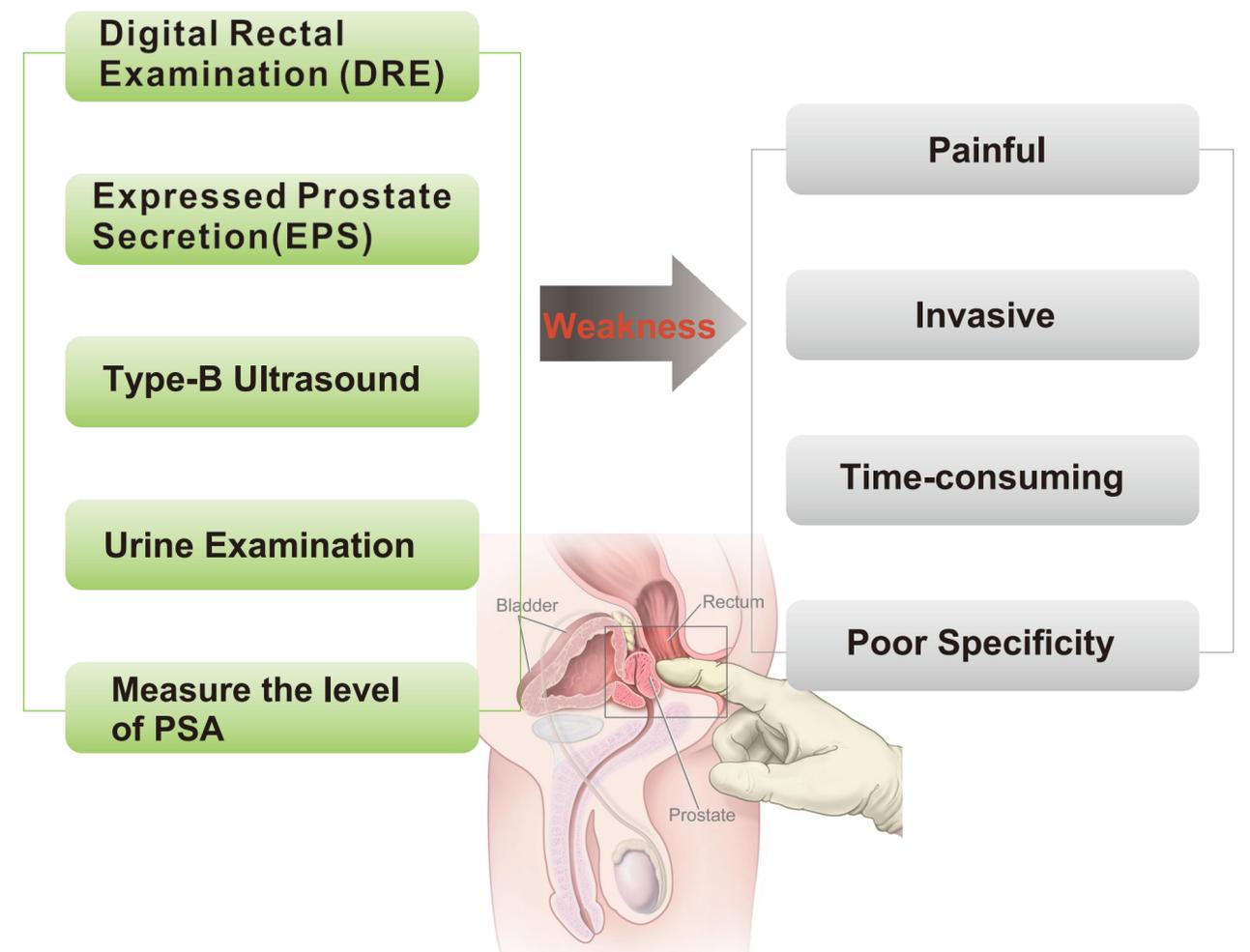
About Prostatitis

- Chronic prostatitis is one of the most common urological diseases of young and middle-aged males. It can be up to 30% patients seen in urology clinics. More than 50% of adult males had or have symptoms of chronic prostatitis in different periods.
- Patients with chronic prostatitis are 10 times more likely to develop prostate cancer.
- About 20% of patients with chronic prostatitis will develop prostate cancer in the end.
- 40% of patients with chronic prostatitis are at risk of becoming infertile.



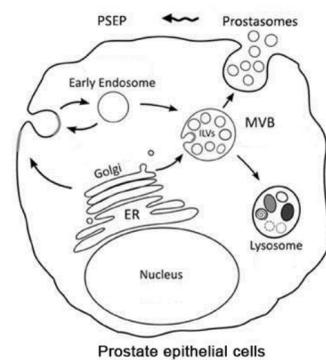
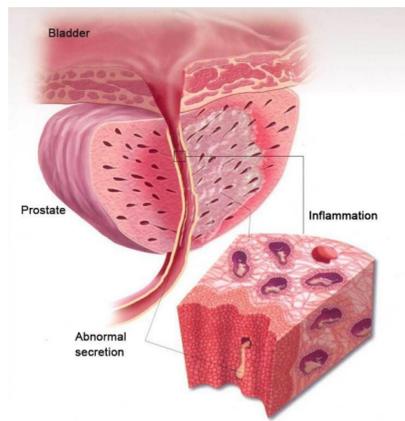
Current Detection Means for Non-bacterial Chronic Prostatitis

- The **DRE** or digital rectal examination: This technique requires doctor to wear gloves which coated with anesthetic-containing lubricating fluid and then insert the index finger from the anus into the patient's rectum to check whether the prostate has lumps or nodules .
- The **EPS** or expressed prostate secretion: Capture the prostate secretion while doing DRE, check the PH value and the number of white blood cells and lecithin body in it.
- **PSA** or prostate specific antigen: Measure the value of PSA. If you have a problem with your prostate, such as prostate cancer an enlarged prostate or an infection of the prostate (prostatitis), the PSA value in your blood will rise.



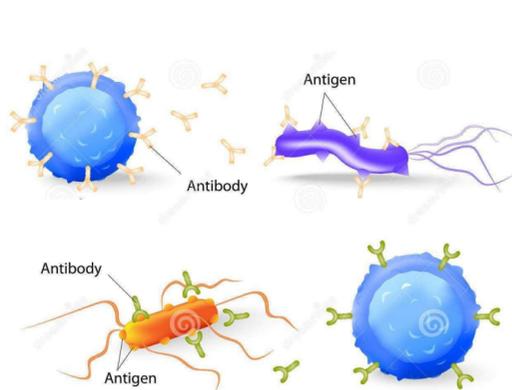
What is PSEP(Prostatic Exosomal Protein)?

- Prostatosomes are exosomes or Multivesicular bodies (MVB) with mean diameter of 150 nm and produced and excreted by the prostate. They are found in storage vesicles and secreted by prostate acinar cells.
- The prostatosomes consist of hundreds of proteins and have been ascribed different biologic activities. Although exosomes are commonly produced in many cell types, there are increasing evidences that prostatosomes are unique structures derived mainly from the prostate glands.
- We name the protein we found as Prostatic Exosomal Protein (PSEP). According to a number of clinical studies, rising PSEP is a reliable indicator of chronic prostatitis. Earlier research studies find that by antibody-based ELISA, the elevation of PSEP can be easily detected in the urine of patients with chronic prostatitis.

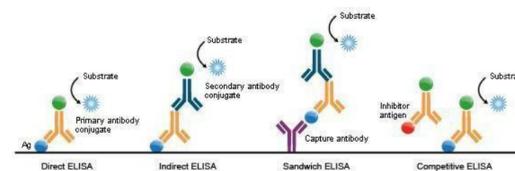


How does PSEP diagnostic kit work?

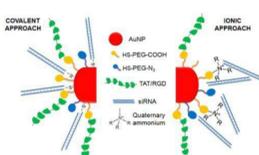
- PSEP was used as antigen to immunize mice to obtain monoclonal antibodies and establish ELISA method as well as the more recently developed colloidal gold test strip POCT method. can be easily detected in the urine of patients with Chronic Prostatitis.
- The elevation of PSEP can be easily detected in the urine of patients with chronic prostatitis.
- Orthogonal tests were used to determine the best workable concentration for each component in the kit.
- Take the urine samples of different concentrations (e.g., one negative sample and one positive sample), use ELISA method to perform tests on multiple wells of the micro-well plate for each sample, and calculate CV.



•Antigen-specific respond



•PESP Diagnostic Kit(Elisa)



•PSEP Diagnostic Device (Colloidal Gold Test Strip)

Four Reasons to Choose PSEP Diagnostic Kit

- Innovative, non-invasive and urine-based diagnostic test. Classical
- antigen-specific response, stable, simple and efficient.
- 85% specificity and 90% sensitivity.
- Uses in clinical diagnosis and early detection with broad market perspective.

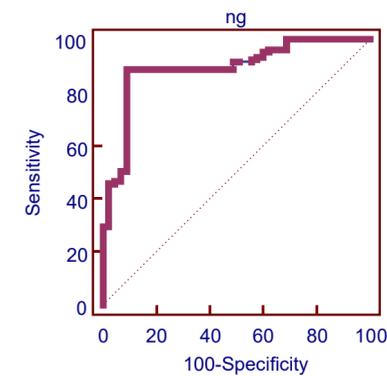


Figure1: Accuracy Test(ROC Analysis) Evaluation

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The area under ROC is 0.927 which supports the usefulness of PSEP test for diagnosis of chronic prostatitis.

Group	N	Mean	SD	Median
case	245	4.3225	4.8610	0.9780
control	105	0.6956	0.9780	0.6000

Figure2: Comparison between Normal people and patients with Chronic Prostatitis

Figure 2: Compared with normal people, patients with chronic prostatitis displayed increased PSEP in the urine.

*Note: z=12.677; P<0.05

Clinical GS \ PSEP	Clinical GS		Total
	Positive	Negative	
Positive	217	10	227
Negative	28	95	123
Total	245	105	350

Figure3: The experiment consists of 350 cases

Figure 3: 1. Sensitivity, specificity and accordance rate

Compared with the clinical gold standard (GS), the sensitivity of the PSEP test kit is 88.57%, and the specificity is 90.48%. The total coincidence rate is 89.14%.

2. Consistency analysis

Use of SPSS (16.0) to test the PSEP test kit's consistency with the GS showed Kappa=0.754 (95%CI=0.68~0.827), demonstrating that the two are highly consistent with each other.

Prostatic Exosomal Protein (PSEP) Diagnostic Kits (Enzyme-Linked Immunosorbent Assay)



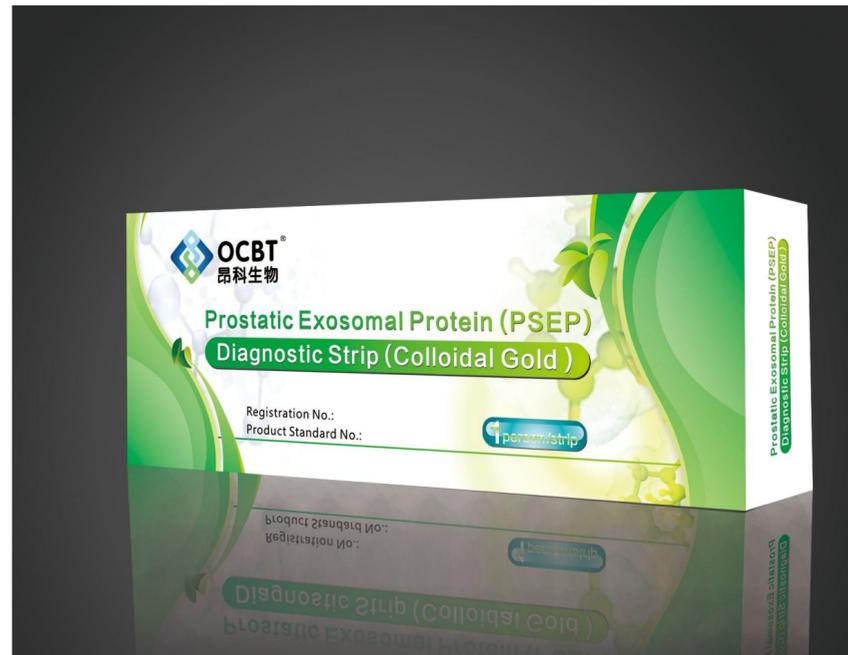
- I nnovative urine-based kit
- N on-invasive
- S pecificity
- C lassical Elisa

Patents



Prostatic Exosomal Protein(PSEP) Diagnostic Device (Colloidal Gold)

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- P oct



Certifications

