

Healthy prostate, Happy life.

Prostate Exosomal Protein (PSEP) Diagnostic Kit

An innovative diagnostic indicator for prostatitis



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- Innovative
- Urine-based
- Non-invasive
- Simple
- Reliable



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About Us

Hunan Youli Biotech Co., Ltd. was established in 2019 as a high-tech joint venture in Hunan province, China. Youli specializes in development and manufacture of vitro diagnostic products for series diseases based on urine. We are dedicated to provide reliable and high-quality products to improve patients' treatment efficiency. As a wholly-owned subsidiary of OCBT, Youli aims to make a significant impact in the field of in vitro diagnostics. Hunan Youli Biotech Co., Ltd. is a strategic partner with Daan Gene Co. Ltd. The collaboration between Daan Gene and Youli will combine the strength and capabilities of both companies and lay a solid foundation for both parties' overseas markets.

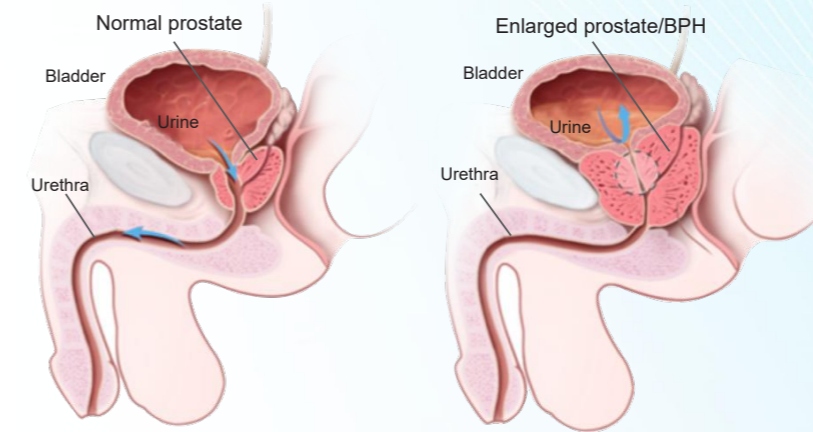


Certificates



About Prostatitis

Prostatitis is a medical condition that involves inflammation or infection of the prostate gland. The prostate gland is a walnut-sized gland in males that sits below the bladder and surrounds the urethra. It produces seminal fluid, which nourishes and transports sperm during ejaculation. Prostatitis can be painful and uncomfortable, affecting a man's urinary and sexual functions.

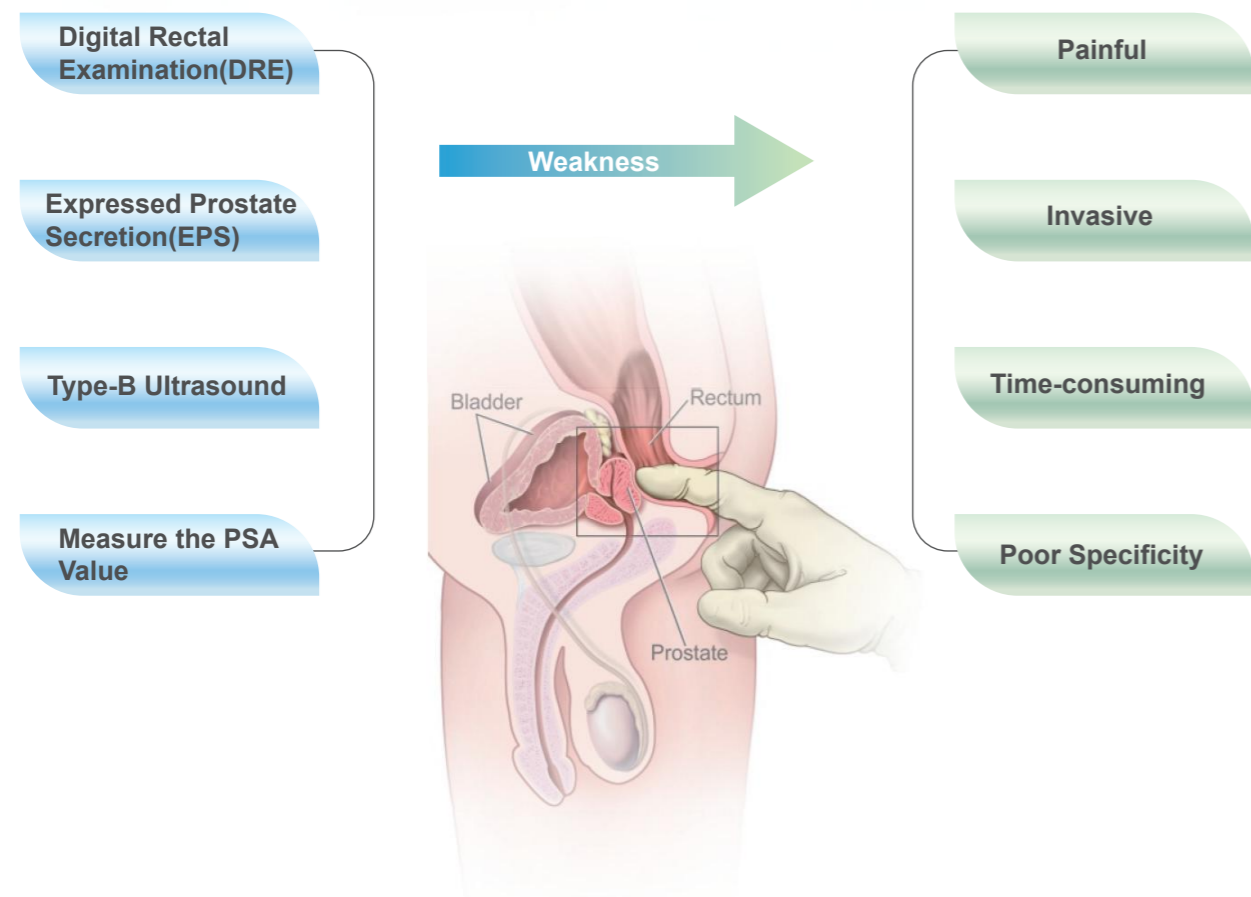


Prostatitis Classification by NIH

Classification	Category	Rate	Description	Symptoms	Treatment
Acute bacterial prostatitis (ABP)	Category I	/	Bacterial infection of the prostate	Rapid onset of fever, chills, urinary changes, ejaculatory pain, pelvic pain	Antibiotics
Chronic bacterial prostatitis (CBP)	Category II	5%-8%	Long-lasting bacterial infection of the prostate	Lower back pain, pelvic pain, urinary changes (frequency, urgency, dysuria), painful ejaculation	Long-term antibiotics, anti-inflammatory medications, alpha-blockers, lifestyle changes
Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS)	Category III	Over 90%	Inflammation of the prostate or nerves supplying the area; not an infection	Pelvic pain, lower back pain, perineal pain, dysuria, nocturia, urgent urination, painful ejaculation	NSAIDs, alpha-blockers, antidepressants, muscle relaxants, physical therapy, lifestyle changes
Asymptomatic inflammatory prostatitis (AIP)	Category IV	/	Inflammation of the prostate without symptoms	No noticeable symptoms	Monitoring, targeted treatment if an underlying cause is identified

Current Examination Methods

Must: Medical history, Physical (Including Rectal Digital Examination), Urine Test, EPS
Recommended: NIH-CPSI, "Four Cup", "Two Cup", Ultrasound
Selective: Laboratory (Pathogens, Semen, Urine Cytology, PSA) , Equipment guided (Urine flow rate, Urine dynamics, bladder scope), Imaging(CT, MRI), Prostatic biopsy

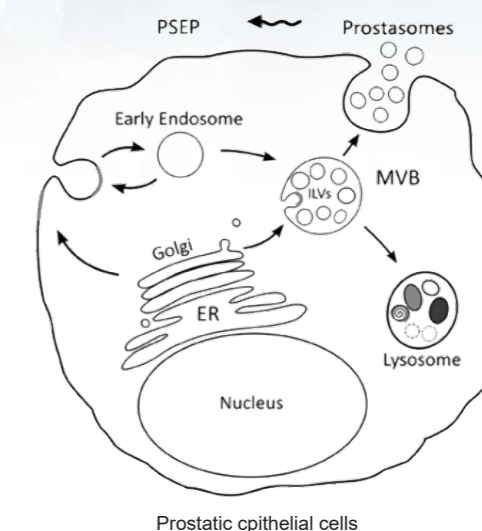


To address these issues, we have developed cutting-edge diagnostic kits based on our patented biomarker, Prostatic Exosomal Protein (PSEP).

The PSEP test is a urine-based, non-invasive solution that requires only urine sample to accurately diagnose chronic prostatitis. This safe and effective method has shown great promise in clinical practice and is poised to revolutionize the way prostatitis is diagnosed.

What is prostatic exosomal protein (PSEP)

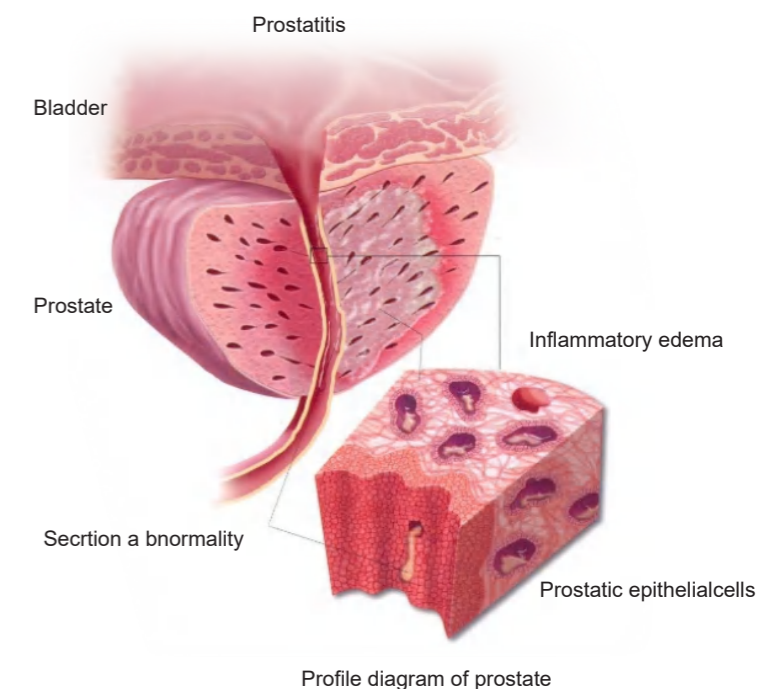
Prostasomes exist in human prostatic ducts, located to where Golgi is enriched in the glandular epithelium. They are a subcellular structure with an average diameter of 80-150 nm, which are excreted by prostate epithelial cells into the catheter lumen through exocytosis and excretion. Prostasomes excrete the prostatic exosomal protein (PSEP) and the PSEP enters the urethra to combine with urine.



Molecular pattern diagram of PSEP excretion

Why PSEP can be detected in the urine

PSEP has strong antioxidant and antibacterial functions due to its unique lipid structure and composition. During inflammation, the permeability of prostate epithelium increase, and prostasome secretion will also increase. Therefore, we can perform a urine-based test to record PSEP.



Advantage of PSEP

As initial screening tool for CP/CPPS, PSEP provides the world's ONLY objective laboratory biomarker for CP/CPPS

- **Non-invasive** — Urine based, painless, and physician friendly
- **Objective** — Not relying on physician experiences
- **Specificity** — Reflect CP/CPPS
- **Accurate and Reliable**

Among nearly 10000 clinical trial samples, 245 patients with prostatitis and 105 normal individuals were randomly selected for inclusion. The results are as follows:

Evaluation of accuracy test (ROC Analysis)

The area below the ROC is 0.927, indicating that the PESP diagnosis kit is valuable for the diagnosis of chronic prostatitis.

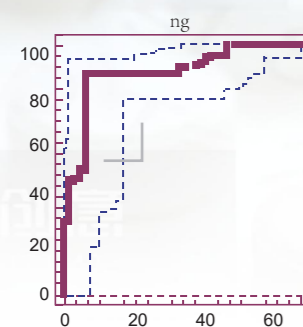


Fig. 1 ROC analysis

Comparison of the PESP level

The PESP level in urine of patients with chronic prostatitis is significantly higher than that of healthy individual.

Group	N	Mean	SD	Median
case	245	4.3225	4.8610	4.5780
control	105	0.6956	0.9780	0.6000

Table 1 Comparison of the PESP level in urine between normal people and patients with chronic prostatitis (ng/mL)

Evaluation of sensitivity, specificity and percent agreement

The clinical sensitivity of this kit is 88.57%, and the clinical specificity is 90.48%. The total percent agreement is 89.14%. The consistency test between the PSEP diagnosis kit and clinical gold standard (GS) is performed by SPSS (16.0). The result shows that Kappa=0.754 (95%CI= 0.68~0.827), indicating that these two methods are highly consistent.

Result		Clinical GS		Total
		Positive	Negative	
Test Kit	Positive	217	10	227
	Negative	28	95	123
Total		245	105	350

Table 2 The result of the clinical GS and the test kit

Clinical Application

A new indicator with high specificity for chronic prostatitis as an auxiliary diagnosis

PSEP test is a new diagnostic indicator for prostatitis, which is painless, non-invasive and easy to use. It is expected to replace the existing traditional diagnostic methods. It is with a clinical coincidence rate of over 89% and can provide reference and guidance for clinical medicine effects.

A predictive indicator in male physical screening for disease prevention

Middle-aged men are at a high risk for chronic prostatitis, so paying attention to prostate health is especially important. Chronic prostatitis is prone to recurrent attacks and can be difficult to cure. Early screening and intervention can help control the disease's progression, prevent worsening and recurrence.

Guide medication in the treatment of chronic prostatitis

Chronic prostatitis is prone to recurrent attacks. PSEP test can provide objective and quantitative indicator which serve as a guide of medication and as an assessment of the treatment.



Applicable Clinical Departments



Urology



Oncology



Reproductive
Medicine



Physical
Examination

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



Features

- Non-invasive:** Urine based test, which is painless and physician friendly
- Objective:** Provide objective indication, diagnosis do not rely on physician's subject judgement
- Accurate and reliable:** With Sensitivity 89%, Specificity 90%

Specification

- Sample:** Random urine
- Applicable Instrument:** Spectrometer pipetter washer, Water bath
- Test time:** about 3 hrs
- Intra-group:** CV<10%
- Between Lots:** CV<15%
- Cutoff value:** PSEP≤1.20ng/ml (normal); PSEP>1.20 ng/ml (indicative of CP/CPSP)

Order Information

Product	Package Specifications	Storage Condition
Prostatic Exosomal Protein Diagnostic Kits (Enzyme-Linked Immunosorbent Assay)	90 tests / kit	2 - 8°C Away from light

Prostatic Exosomal Protein (PSEP) Diagnostic Kits (Fluorescence Immunochromatography)



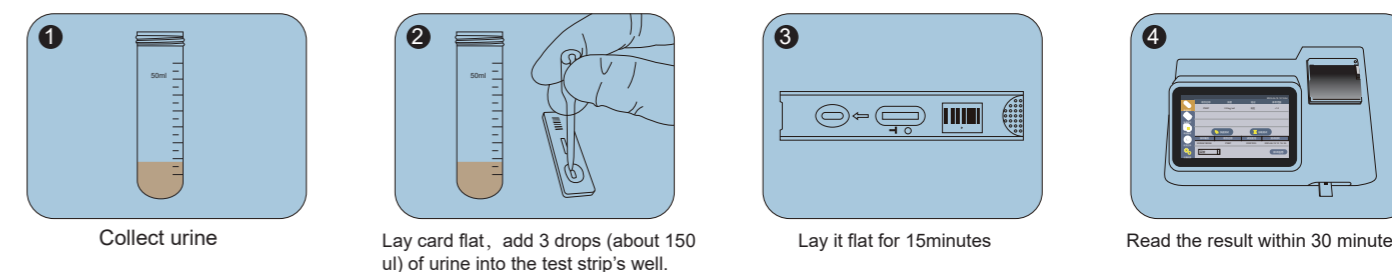
Features

- Non-invasive:** Urine based test, which is painless and physician friendly
- Objective:** Provide objective indication, diagnosis do not rely on physician's subject judgement
- Accurate and reliable:** With Sensitivity 87%, Specificity 93%
- High efficient:** Testing time for each sample is 15 minutes

Specification

- Applicable Instrument:** Colloidal gold immunochromatography analyzer
- Sample:** Random urine
- Cutoff value:** PSEP≤1.20ng/ml (normal), PSEP>1.20 ng/ml (indicative of CP/CPSP)

Test Procedure



Order Information

Product	Package Specifications	Storage Condition
Prostatic Exosomal Protein Diagnostic Kits (Fluorescence Immunochromatography)	25 tests / kit 50 tests / kit	2 - 30°C Away from light

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



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



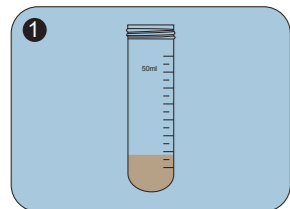
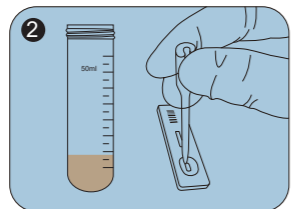
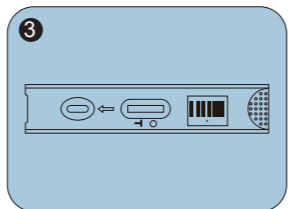
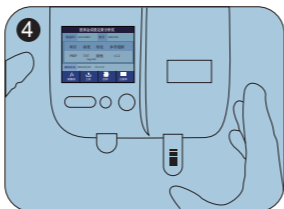
Features

- Non-invasive:** Urine based test, which is painless and physician friendly
- Objective:** Provide objective indication, diagnosis do not rely on physician's subject judgement
- Accurate and reliable:** With Sensitivity 94%, Specificity 93%
- High efficient:** Testing time for each sample is 15 minutes

Specification

- Applicable Instrument:** Colloidal gold immunochromatography analyzer
- Sample:** Random urine
- Cutoff value:** PSEP ≤ 1.20 ng/ml (normal), PSEP > 1.20 ng/ml (indicative of CP/CPSP)

Test Procedure

-  Collect urine
-  Lay card flat, add 3 drops (about 150 ul) of urine into the test strip's well.
-  Lay it flat for 15 minutes
-  Read the result within 30 minutes

Order Information

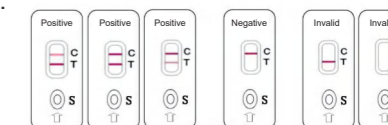
Product	Package Specifications	Storage Condition
Prostatic Exosomal Protein Diagnostic Kits (Colloidal Gold)	25 tests / kit	2 - 30°C Away from light

Features

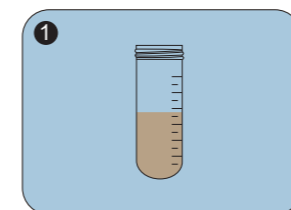
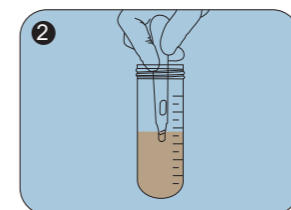
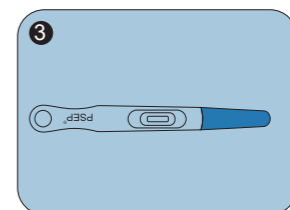
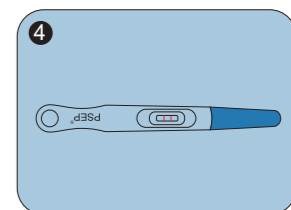
- Non-invasive:** Urine based test, which is painless and physician friendly
- Objective:** Provide objective indication, diagnosis do not rely on physician's subject judgement
- Accurate and reliable:** With Sensitivity 86%, Specificity 93%
- High efficient:** Testing time for each sample is 15 minutes
- Easy to use, no need analyzer**

Result Interpretation

- Negative:** A red line (control line-C line) appears in the test area, indicating a negative result
- Positive:** Two color bands (control line-C line and test line-T line) appear in the test area, indicating a positive result
- Invalid:** If the control line does not appear, this indicates test failure or reagent failure.



Test Procedure

-  Collect urine
-  Immerse the test section in the urine sample for about 10 seconds.
-  Lay it flat for 15 minutes
-  Read the result within 30 minutes

Order Information

Product	Package Specifications	Storage Condition
Prostatic Exosomal Protein Diagnostic Kits (Colloidal Gold)	1 test / kit	4 - 30°C Away from light