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## Prostatic exosomal protein (PSEP) ELISA method for detecting chronic prostatitis

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There is increasing evidence that men with prostate cancer are associated with prostatitis and/or benign prostatic hyperplasia. Therefore, early and reliable diagnosis and treatment of prostatitis may reduce or even prevent prostate cancer progression. Chronic prostatitis/Chronic pelvic pain syndrome (CP/CPPS) is a multifactorial medical condition, which affects adult males of all ages and demographics. Recent studies have shown that the prevalence of prostatitis is approximately 2-10% among unselected men in North America, Europe and Asia. Traditionally, diagnoses have included clinical symptoms and signs, a routine urine test, or culture as well as the expressed prostatic secretion (EPS) during rectal exams. But there is no standard diagnostic test for non-bacterial CP/CPPS, which makes effective treatments more challenging. As a result, it is quite important to equip urologists with a useful tool for the diagnosis of CP/CPPS. We isolated PSEP from the urine of CP/CPPS patients and used it as the immunogen to generate mouse monoclonal antibodies. Purified antibodies were used to establish an indirect ELISA method and study a total of 140 urine samples of CP/CPPS and 60 normal control urine samples. The amount of PESP in the urine of CP/CPPS patients ( $3.013 \pm 2.199$  ng/ml) was significantly higher than that in the group of normal control urine samples ( $0.734 \pm 0.574$  ng/ml). There were statistically significant differences between the two groups ( $Z=10.74$ ,  $P<0.05$ ). The cut-off value obtained in this study was about 1.2 ng/ml. The sensitivity was 88.57% in the 140 urine samples of CP/CPPS patients and the specificity was 90% in the normal urines. Comparing the results of PSEP test kits to the traditional clinical standard, Kappa was 0.75 (95% CI=0.652 to 0.848) with  $P<0.01$ . In this study, PSEP ELISA kit showed high sensitivity and specificity. Additionally, its detection outcomes were highly consistent with those of the clinical observation. Thus we suggest that PSEP ELISA application can support reliable CP/CPPS diagnosis.

### Biography

Yan Zeng obtained her Medical Degree and Master's Degree from Shanghai Second Military University in China. She completed her Postdoctoral research at the Brody School of Medicine of East Carolina University, USA in 2007. She was the Director of Pathology Department of Jinan General Hospital, before that she was the Director of the R&D department of OCBT, Ltd., a Bio-Medical technology company based in Jiangsu, China.

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