

# Exosomal miRNAs in seminal plasma as non-invasive markers of prostate cancer diagnosis

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## HIGHLIGHTS

- ✓ More specific biomarkers for malignant prostate cancer (PCa) detection
- ✓ Method to avoid unnecessary biopsies of benign disease
- ✓ Novel miRNA-based classifier for PCa

## TECH STATUS

- ✓ TRL: Technology validated in lab
- ✓ IP: Patent on draft

## Problem to be solved

The prediction of PCa in the early stage of the disease is one of the most important objectives in male urology. A significant decrease in deaths due to PCa has been associated with the use of serum PSA test for nearly 30 years. Although specific for prostatic tissue, PSA has low cancer specificity. Thus, PSA screening has resulted in an over-diagnosis of PCa, and in many unnecessary biopsies of benign disease

Additionally, serum PSA levels do not correlate with tumor aggressiveness, survival, or response to pharmacological treatments leading to over-treatment of indolent tumors and in many unnecessary biopsies of benign disease. Given this context more specific non-invasive diagnostic biomarkers, either alone or in addition to PSA marker, that could identify PCa patients would be very welcomed indeed.

## Background

Prostate cancer (PCa) is the most prevalent type of malignant male cancer in Western countries and a major cause of cancer-related deaths. Detection is mainly carried out by the determination of levels of prostate-specific antigen (PSA) in blood and/or by physical examination of the prostate gland (digital rectal examination –DRE-). However, the deficiencies of serum PSA as a biomarker are well documented. Although specific for prostatic tissue,

PSA has low cancer specificity. Thus, suspicious results are evaluated in prostate tissue samples (transrectal or transperineal biopsy), essential to confirm the diagnosis and in which the severity or degree of affectation will be determined by means of the modified Gleason Score (GS).

Since its application in clinical practice, and although, the PSA-based screening of PCa has allowed better detection of the disease, in the early stages, it has resulted in an over-diagnosis of PCa, and in many unnecessary biopsies of benign disease.

## Technology

We have evaluated and assessed the expression levels of miRNAs contained in semens' exosomes from malignant and benign prostate disease. Besides, undergone vasectomy patients were taken into account for the accurate interpretation of the results.

Our findings demonstrated that clinically relevant, quantitative changes in the transcript levels of miRNAs can be detected in the semen exosomes of reproductive cancer patients. Thus, miRNA signature from the exosome-associated fraction of semen improve the efficiency of detection of PCa and of determining the severity/aggressiveness of

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PCa. The miRNA signature is helpful as molecular tests complementing and/or improving the efficiency of PSA screening as PCa diagnosis/prognosis biomarkers.

## Applications

Identified miRNAs, from the exosome-fraction of semen, could be used as non-invasive biomarkers that contribute in the diagnosis/prognosis of malignant PCa.

Moreover, identified miRNA combined with PSA have higher predictive accuracy than PSA alone as a prognostic value.

Proposed diagnostics is recommended to:

- Patients with a PSA result “in the grey zone” as to assess the need for a biopsy.
- Patients with negative biopsy but in whom it is still suspected that there may be a prostate cancer.
- Patients with positive biopsy, in order to know the aggressiveness of cancer.
- Patients with prostate cancer at early stages (GS6) to monitor active surveillance and determine if the cancer progresses.
- Men with a family history of prostate cancer.

## Technology status

We demonstrated that clinically relevant, quantitative changes in the transcript levels of miRNAs can be detected in the semen exosomes of reproductive cancer patients. Our findings showed a miRNA signature from the exosome-associated fraction of semen as a molecular classifier to improve the efficiency of detection of PCa and of determining the severity/aggressiveness of PCa at the time of diagnosis

## Market Opportunity

PCa is the most prevalent type of malignant male cancer in Western countries. It may not cause signs or symptoms in its early stages. Every year, more than 2,30,000 men are diagnosed with prostate cancer, 25,000 in Spain.

The global cancer diagnostics market is witnessing a rapid transformation owing to several technological advancements in diagnostic platforms. The market is expected to reach \$13.1 Billion by 2020 from \$7.1 Billion in 2015, and is poised to grow at a CAGR of 12.9% during the forecast period. Yet, specific prostate cancer diagnostics market is estimated to expand at a CAGR of 12.3% to reach USD 5.5 billion by 2025

## Business Opportunity

Co-development or license agreement

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