# Cost analysis of ProsTAV®, a new telomere-based biomarker for the early detection of prostate cancer available in Europe

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## Objectives

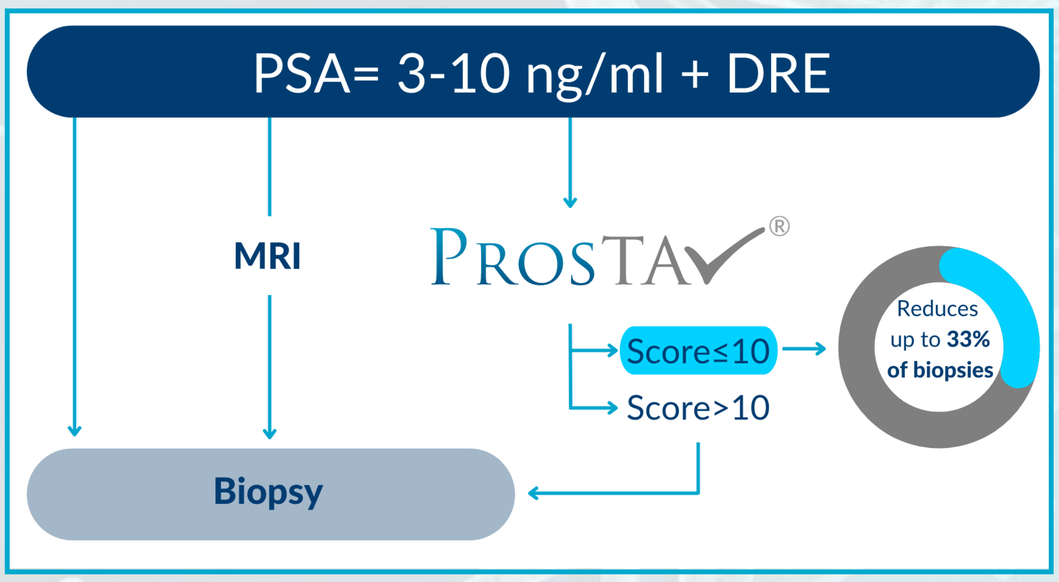
More than **1.4 million cases of prostate cancer (PCa)**, the second most common cancer in men, are diagnosed each year worldwide[1].

Patient's **risk stratification** is a crucial decision-making tool to identify clinically significant PCa, to avoid unnecessary biopsies, overdiagnosis and overtreatment.

**European Guidelines** indicate the need for new and improved biomarkers based in blood, urine or tissue.

**ProsTAV®** is a new *in vitro* blood test for the early detection of PCa authorised in Europe. It is also available in USA.

**Figure 1. New proposed diagnosis scheme**




**PSA:** prostate-specific antigen; **DRE:** digital rectal examination; **MRI:** magnetic resonance imaging

A cost analysis of ProsTAV® has been performed to determine the economic impact of its introduction in the Spanish healthcare system.

## Methods

The model was built under the following considerations:

| | |
|---|---|
| Perspective of the Spanish National Healthcare System | Population: 9.3 million (men >50 years) |
| One year time horizon | Number of annual biopsies in Spain: **57,568** |

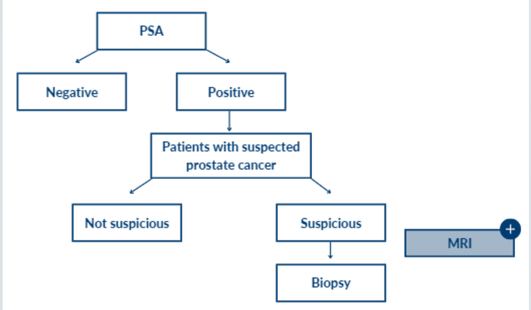
Direct costs (€, 2023[2]) derived from the consumption of resources required for the diagnosis of PCa:

- PSA determinations ..... *19,98 € /unit*
- Visits to urologist ..... *151,75 € /unit*
- Biopsies..... *623,78 € /unit*
- Complications arising from the performance of biopsies ..... Table 1

The model considered ProsTAV® parameters (90% sensitivity and 33% specificity)[3]

**Figure 2. Graphical representation of compared scenarios**

Scenario 1: Diagnosis in current clinical practice, WITHOUT availability of ProsTAV®




Scenario 2: Proposed diagnosis in clinical practice, WITH availability of ProsTAV®

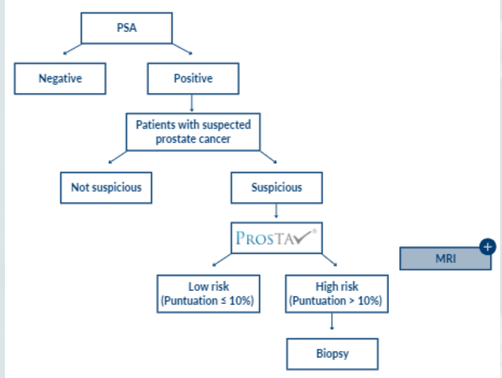



**Table 1. Complications of transrectal biopsy**

| Benett et al. (2015)[4] | Weiner et al. (2020)[5] | Forsvall et al. (2021)[6] | Sahin et al. (2021)[7] | Bokhorst et al. (2016)[8] | *COSTS (€)[2]* |
|---|---|---|---|---|---|
| Infection: 3.50% | Infection: 6.40% | Infection: 5.37% | Infection: 5.80% | Infection: 2.30% | *4,897€* |
| Sepsis: 0.70% | | Sepsis: 0.75% | Sepsis: 0.50% | | *7,782€* |
| | Hematuria: 4.20% | | | Hematuria: 12.70% | *5,100€* |
| Hospitalization: 0.90% | Hospitalization: 1.90% | | | | *1,018€ (per day)* |

**The use of ProsTAV®** is associated with a reduction in the number of urologist visits, avoiding 21.28% of patients with suspected PCa having to undergo a biopsy.

**33 %** — **ProsTAV® reduce by 33% t**he number of biopsies that would end up confirming the absence of PCa.

## Results

The introduction of ProsTAV® into the PCa diagnostic process in Spain has a neutral impact on the Health System, showing a range from savings (-0.18%) to a small increase (0.21%) compared to current costs (Figure 3).

**Figure 3. Results of cost analysis**


The introduction of ProsTAV® into the PCa diagnostic process has a neutral impact on the Spanish Health System.

## Conclusion

ProsTAV® does not increase the costs associated with the diagnosis of PCa.

ProsTAV® is linked with a reduction in the number of biopsies and the visits to the Urology Department.

ProsTAV® is linked with the avoidance of biopsies in patients without risk of PCa.

ProsTAV®, therefore, promotes evident benefits for patients.

The use of the new **ProsTAV®** biomarker represents a very useful innovation in the early diagnosis of Prostate Cancer for European Health Systems

(1) https://www.wcrf.org/cancer-trends/prostate-cancer-statistics/[[last accessed 24/09/2023]
(2) Oblike Consulting (2023) [[last accessed 08/05/2023]
(3) Gómez, E. G., Castiñeira, R. C., Burgos, J., Antolín, A. R., Miles, B. J., Salamanca, J. I. M., Bianco, F., Fernández, L., Calmarza, I., Pastor, J., Butler, R. G., & Pedro, N. de.(2023). ProsTAV, a novel blood-based test for biopsy decision management in significant prostate cancer. The Prostate. https://doi.org/10.1002/PROS.24594
(4) Bennett, H.Y. et al. (2015) 'The global burden of major infectious complications following prostate biopsy', Epidemiology and Infection, 144(8), pp. 1784–1791. doi:10.1017/s0950268815002885.
(5) Weiner, A.B. et al. (2020) 'The cost of prostate biopsies and their complications: A summary of data on all Medicare fee-for-service patients over 2 years', Urology Practice, 7(2), pp. 145–151. doi:10.1097/upj.0000000000000072.
(6) Forsvall, A. et al. (2021) 'Rate and characteristics of infection after transrectal prostate biopsy: A retrospective observational study', Scandinavian Journal of Urology, 55(4), pp. 317–323. doi:10.1080/21681805.2021.1933169.
(7) Şahin, C. et al. (2021) Las complicaciones infecciosas después de biopsia próstata transrectal están incrementadas en Pacientes Con Estreñimiento crónico idiopático., Dialnet. Available at: https://dialnet.unirioja.es/servlet/articulo?codigo=8083343 (Accessed: 11 May 2023).
(8) Bokhorst, L.P. et al. (2016) 'Complications after prostate biopsies in men on active surveillance and its effects on receiving further biopsies in the prostate cancer research international: Active surveillance (PRIAS) study', BJU International, 118(3), pp. 366–371. doi:10.1111/bju.13410.

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