

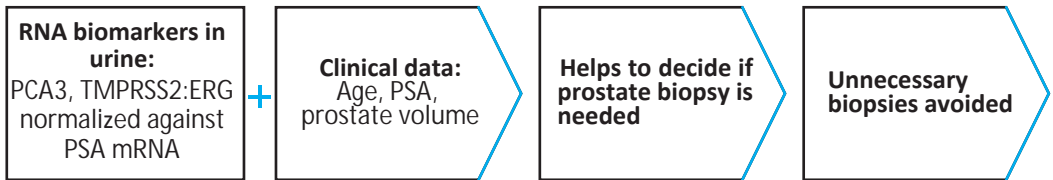


DIAGNOLITA'S NON-INVASIVE PROSTATE CANCER DIAGNOSTIC TEST

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Diagnolita's prostate cancer test is recommended for men when prostate cancer is suspected. Two prostate cancer specific RNA biomarkers are quantified in patients' urine using RT-qPCR method. The data is combined with clinical parameters to calculate the cancer risk scores. The test allows to estimate both the probability of prostate cancer and the likelihood of high grade prostate cancer.

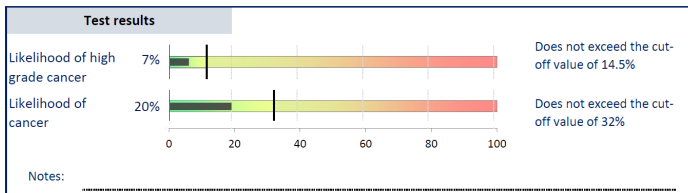


Features of the Diagnolita's diagnostic test

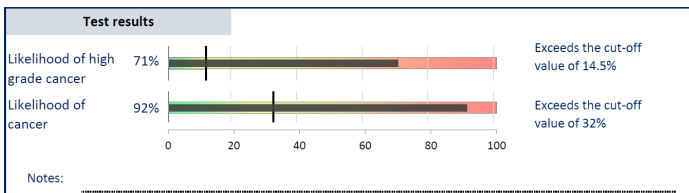
- Non-invasive** – patient's urine is used for analysis
- Universal** – can be performed with or without DRE
- Sensitive and specific** – based on detection of well-defined molecular biomarkers
- Efficient** – up to 45% of biopsies are saved

Examples of Diagnolita's test results

- The likelihood of high grade prostate cancer is evaluated. It shows the probability to detect Gleason's score of 7 or higher in the biopsy material (Grade group \geq G2; GS \geq 7). The likelihood of general prostate cancer is also calculated that shows the probability of positive biopsy.
- The cut-off values for both risk scores are provided in the test results, which helps the doctor together with the patient to make an informed decision on the necessity of biopsy.



If the likelihood of high grade cancer is below the cut-off value the biopsy can be avoided or postponed.



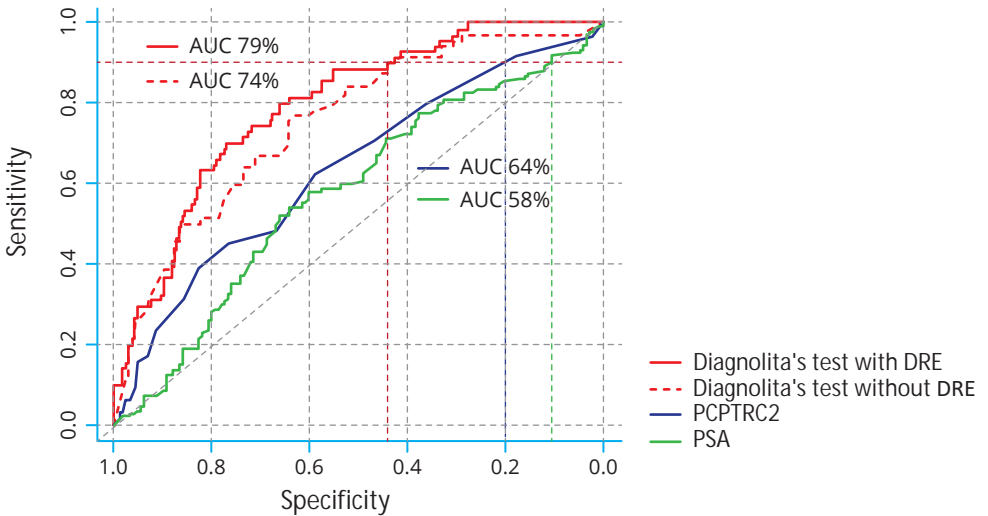
If the likelihood of high grade cancer exceeds the cut-off value the disease can be diagnosed at the early stage and cured efficiently.

The clinical efficiency of the Diagnolita’s prostate cancer diagnostic test has been proved in a multi-center study with a large cohort of patients

Number of patients	Urine collected w/o DRE	Urine collected after DRE
Total number of patients	355	366
Patients with positive biopsy	177	185
Patients with negative biopsy	178	181



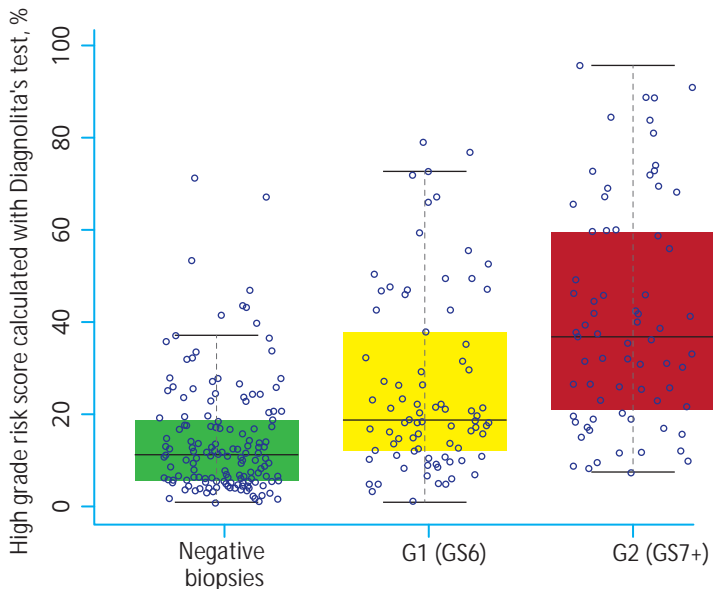
The specificity of Diagnolita’s test is much higher than that of the PSA test



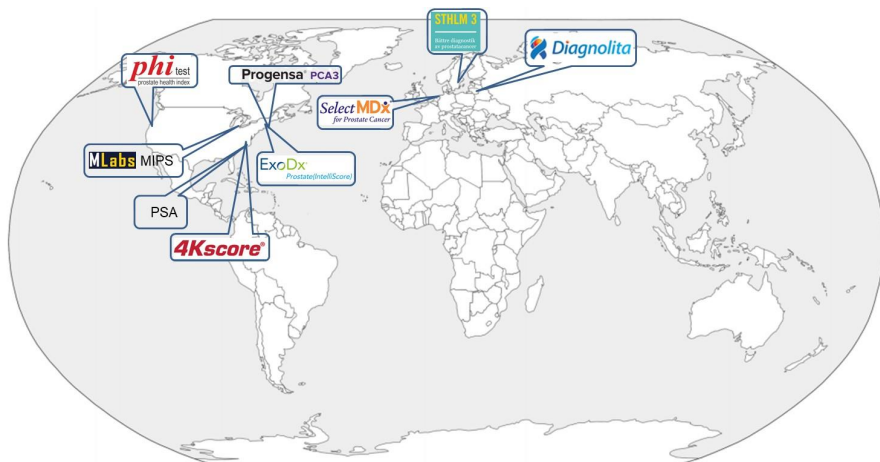
High grade prostate cancer prediction by Diagnolita’s test in a cohort of patients with PSA 2-10 ng/ml. PCPTRC2 – prostate cancer risk calculator (<http://riskcalc.org/PCPTRC/>). Data used for PCPTRC2 calculation: PSA, age, family history, results of digital rectal examination (DRE), results from previous biopsies.

At same 90% sensitivity the specificity of Diagnolita’s test demonstrates higher specificity (43%) than the PSA test (9%) or the PCPTRC2.





The risk of high grade cancer calculated using Diagnolita's test correlates with the prostate cancer Grade group



Diagnolita's test is one of the few prostate cancer tests developed in Europe



Comparison of commercial urine prostate cancer tests

Test	 Diagnolita	 Select MDx™	 MLabs MIPS	 ExoDx™ <i>Prostate(IntelliScore)</i>
Biomarkers	PCA3, TMPRSS2:ERG	DLX1, HOXC6	PCA3, TMPRSS2:ERG	PCA3, ERG
Normalizing gene	KLK3 (PSA)	KLK3 (PSA)	KLK3 (PSA)	SPDEF
Clinical parameters	Age, PSA, prostate volume	Age, PSA, prostate volume, DRE results	PSA	Not used
Recommendations	PSA 2-10 ng/ml*	Any PSA concentration	PSA 3-10 ng/ml	PSA 2-10 ng/ml, age over 50 years
Possibility to take the test without DRE	YES	NO	NO	Only without DRE

* Recommendations are based on European Urology Society guidelines. Results can be also reported for cases where PSA is beyond the recommended range and if clinical data is incomplete.

Comparison of diagnostic parameters of prostate cancer tests

Comparison of diagnostic parameters for high grade prostate cancer (GS \geq 7; G \geq 2)

Company, test	DRE	AUC	Sensitivity	Specificity	NPV	PPV	Avoided Biopsies
Diagnolita , Prostate cancer diagnostic test	NO	74%	90%	43%	93%	33%	35%
Exosome Diagnostics , IntelliScore, EPI ¹	NO	70%	90%	39%	89%	40%	30%
Diagnolita , Prostate cancer diagnostic test	YES	79%	89%	55%	94%	38%	45%
MIabs , MIPS (Michigan University) ²	YES	78%	92%	42%	96%	26%	36%
MdxHealth , Select Mdx ³	YES	82%	89%	53%	95%	34%	44%

Comparison of diagnostic parameters for prostate cancer (B+)

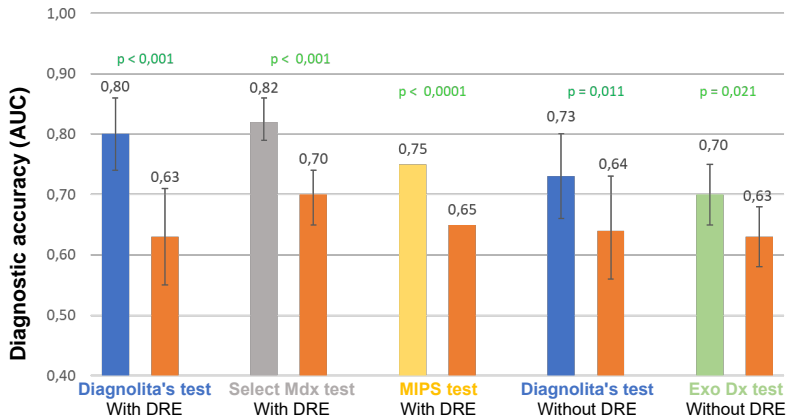
Company, test	DRE	AUC	Sensitivity	Specificity	NPV	PPV	Avoided Biopsies
Diagnolita , Prostate cancer diagnostic test	NO	71%	90%	33%	78%	57%	21%
Diagnolita , Prostate cancer diagnostic test	YES	78%	90%	43%	81%	62%	26%
MIabs , MIPS (Michigan University) ²	YES	76%	92%	32%	85%	50%	22%
Hologic , Progensca PCA3 ⁴ (for repeated biopsies)	YES	71%	78%	57%	90%	34%	50%

¹ - McKiernan J. Et al (2018); ² - Tomlins S. A. et al (2016) ; ³ - Haese A. et al. (2019); ⁴ – FDA database.

The diagnostic parameters of Diagnolita's test are comparable to those of molecular diagnostic tests based on the same biomarkers.

Comparison of added values of prostate cancer diagnostic tests

According to the San Francisco convention (Cooperberg MR, et al, Eur Urol (2019)), diagnostic tests or biomarkers should be estimated according to the accuracy that they add to the multi-variant clinical information (in this case the PCPTRC2 – Prostate Cancer Prevention Trial Risk Calculator Version 2)



Added value	0,16	0,12	0,10	0,10	0,07
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- Diagnolita's test¹
- Select Mdx test²
- MIPS test^{3,4}
- ExoDx Prostate(IntelliScore) - EPI⁵
- PCPTRC2⁶

¹ - to match the PCPTRC2 criteria only patients over 55 years old have been included;

² - According to Haese A. et al (2019) <https://doi.org/10.1097/JU.0000000000000293>;

³ - According Tomlins S. A. et al (2016) ; <https://dx.doi.org/10.1016%2Fj.eururo.2015.04.039>;

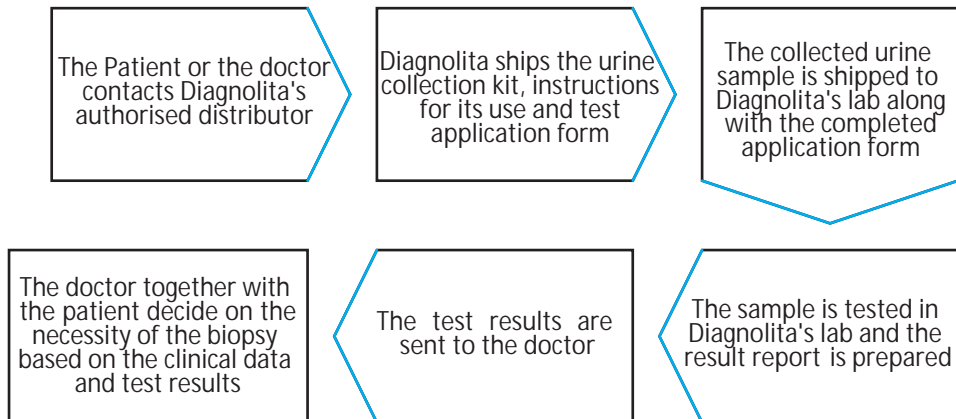
⁴ - Patients' PSA was in the range of 3-10 ng/ml;

⁵ - According to McKiernan J. et al (2018); <https://doi.org/10.1016/j.eururo.2018.08.019>

⁶ - PCPTRC2 - Prostate Cancer Prevention Trial Risk Calculator Version 2.0 (<http://riskcalc.org/PCPTRC/>)

The added value of Diagnolita's test for high grade prostate cancer is similar to those of competitor's tests.

How to accomplish the Diagnolita's prostate cancer diagnostic test?



Where to order the test?

JSC "Diagnolita", phone +370-688-12972, e-mail: tyrimas@diagnolita.lt

Authorised distributors in Lithuania:

medicina
practisa
medicinių tyrimų laboratorija

Alémelio KLINIKA

SYNLAB

DC MEDICINOS DIAGNOSTIKOS
IR GYDYMO CENTRAS

ANTĖJA
laboratorija

 **Invitro diagnostika**

