Helping you to **find** significant prostate cancer

The problem

PSA has a low specificity for detecting (high-grade) prostate cancer.
As a result, many men having a prostate biopsy are diagnosed with clinically insignificant disease. This may in turn lead to overtreatment.
Also, many men have a negative biopsy and are unnecessarily exposed to associated anxiety, pain and risk of complications.
One of the major challenges is how to identify men who harbour an increased risk of having clinically significant prostate cancer. Finding these men at high risk of significant cancer is essential as they will mostly benefit from earlier diagnosis and treatment. At the same time, it is important to reduce the number of unnecessary invasive biopsies in men without (clinically significant) cancer.

The solution

SelectMDx helps you to find clinically significant cancer.
It is a new generation biomarker test that distinguishes men at increased risk for significant prostate cancer from those at very low risk.
SelectMDx aids to guide the decision for biopsy.

About SelectMDx

SelectMDx is a non-invasive, urine-based test that measures the expression of 2 mRNA cancer-related biomarkers (HOXC6 and DLX1). This is combined with PSA, PSA density, DRE, age and family history of prostate cancer into a risk score.
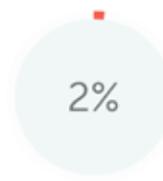
Prostate **MDx**

Brochure for healthcare practitioners

Benefits of SelectMDx

1. **SelectMDx identifies men at high risk of having clinically significant cancer.** These men may benefit from earlier diagnosis and treatment.

2. **Very high negative predictive value (NPV): 98%.** This means that if the test is negative, the patient can be 98% sure that he doesn't have clinically significant (Gleason score ≥7) prostate cancer. The risk of missing high-grade (Gleason score ≥7) prostate cancer is only 2%. This provides reassurance for your patients. Of note, SelectMDx has a NPV of 99.6% for Gleason score ≥8 cancer.

3. **Very high predictive accuracy for high-grade prostate cancer (AUC 0.87).**
   This was statistically significantly better than the PCPT risk calculator version 2 (AUC 0.77; *P*=0.015) [1].

4. **Non-invasive, urine-based test.**
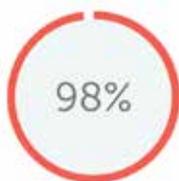
98% NPV (98% certainty of no clinically significant prostate cancer with a negative test result)

2% Risk of missing high-grade prostate cancer

SelectMDx has a superior performance compared to other biomarker tests

Indirect comparison	Gleason score ≥7 cancer				Overall cancer	
	SelectMDx [1,2]	4Kscore (cut-off 7.5%) [3,4]	ConfirmMDx [5]	MiPS [6]	PCA3 (cut-off 20-35) [7-9]	PHI [10,11]
Negative predictive value (NPV,%)	98	95	96	–	88-90	67-92
Risk of missing prostate cancer (%)	2	5	4	–	10-12	8-33
AUC	0.87	0.82	0.74	0.77	0.66-0.69	0.70-0.77

SelectMDx improves patient selection for biopsy

SelectMDx helps distinguish men with a high likelihood for high-grade prostate cancer upon biopsy from the men at very low risk (with a 98% NPV).

- Men at high risk may benefit from biopsy, early detection and treatment

- Men at very low risk may avoid unnecessary invasive biopsy procedures and the associated risk of anxiety, pain and complications

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Patient: Elevated PSA      SelectMDx          Increased Risk      Consider          Biopsy
and/or Abnormal DRE                           for ≥ GG2 PCa       mpMRI

                                              Very Low Risk       Routine PSA
                                              for ≥ GG2 PCa       follow-up
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SelectMDx patient report

The patient report indicates the likelihood of detecting prostate cancer in the biopsy, including the probability of high-grade (Gleason score ≥7) prostate cancer.

PATIENT		SPECIMEN		ACCOUNT	
Patient's name:	John Sample	Specimen#:		Physician:	John Smith, MD
Date of birth:	03-Mar-1962	Collection Date:	14-Mar-2017	Account:	Urology Associates
MRN/Patient:		Received Date:	14-Mar-2017	Address:	Geert Grooteplein Zuid 34
Prostate Volume:	30cc	Report Date:	14-Mar-2017	City:	GA Nijmegen
Family History:	Not Provided	Specimen Type:	Urine		
PSA: 7 ng/mL	DRE: normal				

Patient Result:

The SelectMDx test result for this patient indicates a 57% likelihood of detecting prostate cancer, with a 50% probability for Gleason score ≥7, when performing a standard 12-core TRUS guided biopsy.

57% Likelihood of prostate cancer upon biopsy

50% Likelihood of Gleason score ≥7 prostate cancer upon biopsy

EXAMPLE

Development and validation of SelectMDx

SelectMDx was developed and validated in a prospective, multicenter study using 2 independent cohorts of men scheduled for prostate biopsy [1]:

- Before biopsy, post-DRE urine was collected and mRNA levels of several biomarkers were measured. The combination of HOXC6 and DLX1 had the highest predictive accuracy (AUC 0.76) for high-grade prostate cancer (Gleason score ≥7). From a previous study, it was also shown that these biomarkers have a higher predictive accuracy for high-grade prostate cancer than PCA3 [11].

- Subsequently, logistic regression models were developed and validated combining the biomarkers with clinical variables (PSA, PSA density, DRE, age, family history and noprior biopsy).

- SelectMDx had a very high predictive accuracy (AUC 0.87) for high-grade prostate cancer.

More information about diagnostic biomarkers in prostate cancer?

You will find all the essential and up-to-date information in one easy-to-use slide format, freely available for download: **http://prostatemdx.org/download**

Try out SelectMDx test kit for free

Are you a healthcare professional in one of the EMEA countries? MDxHealth kindly offers you a free SelectMDx test kit to try in your own practice. The test will give you an indication of your patient's risk of (high-grade) prostate cancer and helps you find significant prostate cancer.
Get your first clinical experience with SelectMDx!

Subscribe now at: http://prostatemdx.org/free-kit

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