



## Background

- There have been misconceptions about the value of population-based PSA screening due to the potential of overdiagnosis of low-risk prostate cancer.
- The Canadian Urological Association (CUA) recommends PSA testing for men aged 50, or aged 45 with +family history.
- Recommend using adjunctive tools for men with high PSA.
- There is an opportunity to implement additional tools in the primary care setting to improve the early detection of prostate cancer to positively impact clinical outcomes.

## Methods

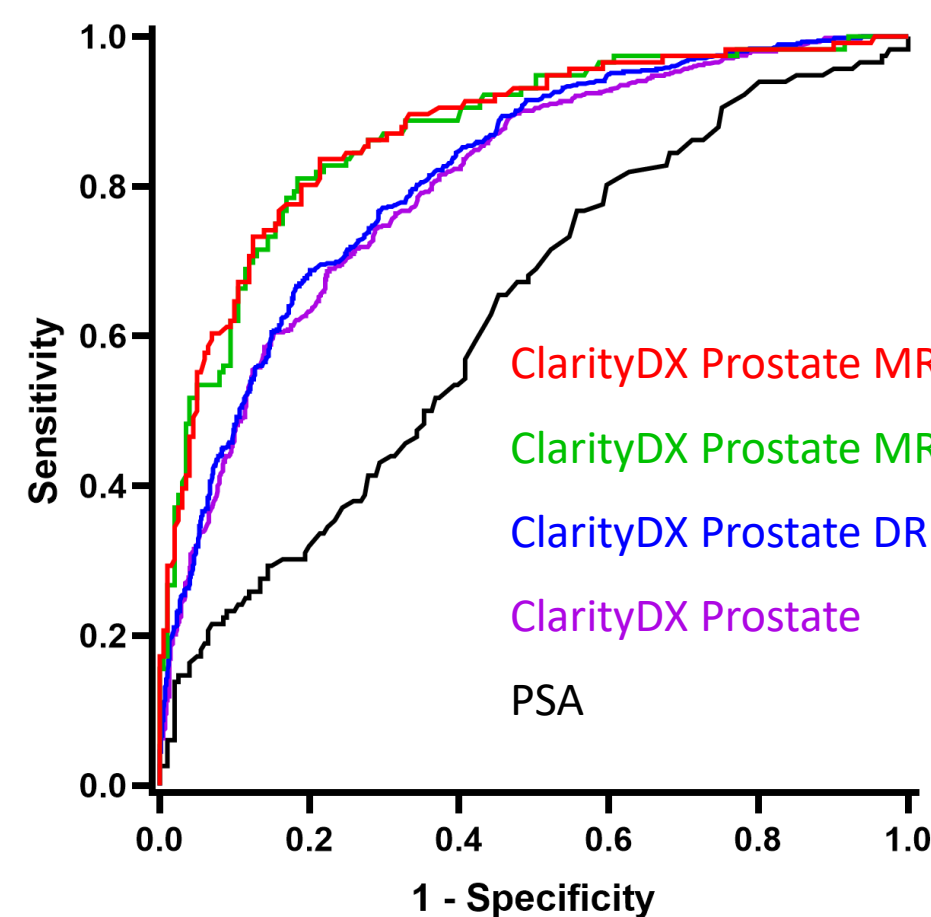
- Researchers at the University of Alberta and the Alberta Prostate Cancer Research Initiative (APCaRI) developed a risk calculator for clinically significant prostate cancer (grade group  $\geq 2$ ) that is up to ~4X more accurate than PSA alone.
- The risk calculator, called ClarityDX Prostate, aligns with the CUA recommendations as an easy-to-use test for primary care.

### International Study Sites

- ALBERTA PROSTATE CANCER RESEARCH INITIATIVE: Kipnes Urology Centre, Edmonton, CANADA
- ALBERTA PROSTATE CANCER RESEARCH INITIATIVE: Prostate Cancer Centre, Calgary, CANADA
- JOHNS HOPKINS MEDICINE: Johns Hopkins University, Baltimore, USA
- UCLA Health: UCLA Health, Los Angeles, USA
- THOMAYER UNIVERSITY HOSPITAL: Thomayer University Hospital, Prague, CZECHIA

## Performance of ClarityDX Prostate Models

### Predicting grade group $\geq 2$ prostate cancer



### Validation Data Summary

	AUC	Sensitivity	Specificity	PPV	NPV
ClarityDX Prostate MRI+DRE	0.87	95%	47%	51%	94%
ClarityDX Prostate MRI	0.87	95%	45%	50%	94%
ClarityDX Prostate DRE	0.82	95%	35%	54%	91%
ClarityDX Prostate	0.80	95%	32%	52%	89%
PSA	0.63	95%	12%	38%	80%

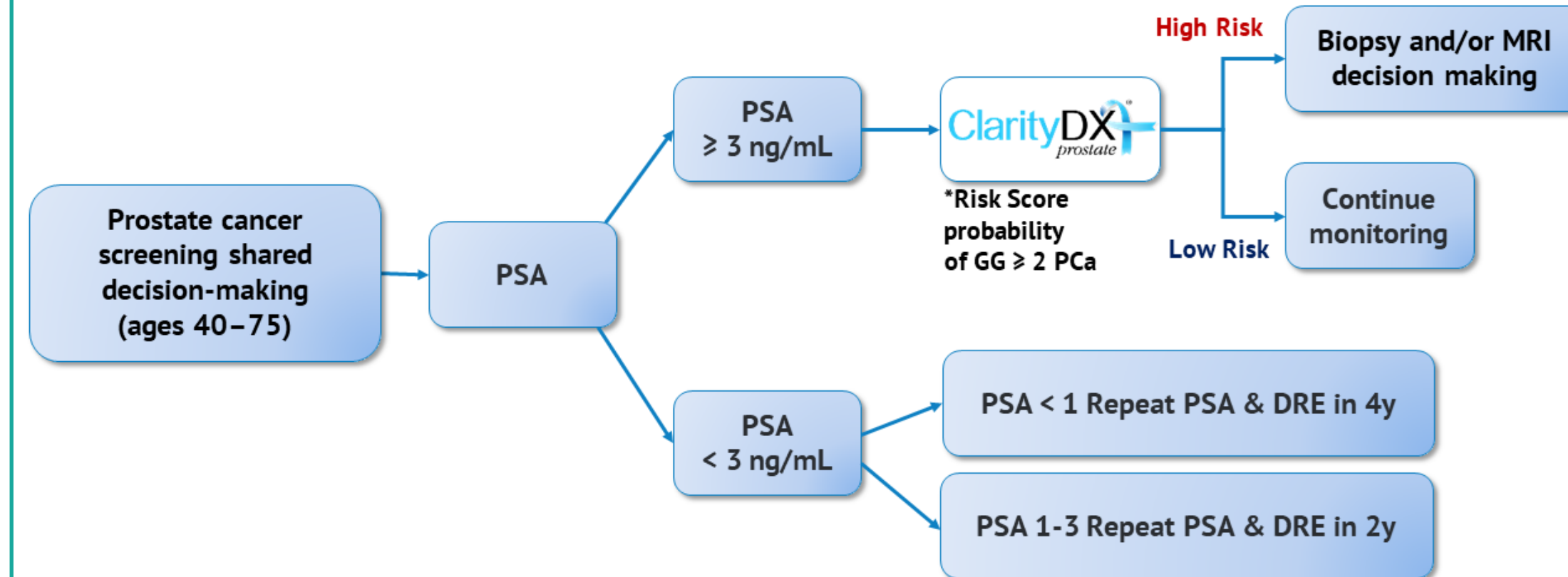
AUC: Receiver Operating Characteristic Area Under the Curve  
PPV: Positive Predictive Value NPV: Negative Predictive Value

- A 3,448-patient international clinical study demonstrated that using ClarityDX Prostate for men with elevated PSA reduced the number of unneeded biopsies:
  - 32% without a digital rectal exam (DRE) and without MRI data,
  - 35% with DRE and without MRI data,
  - 47% with DRE and MRI data.

## Conclusions

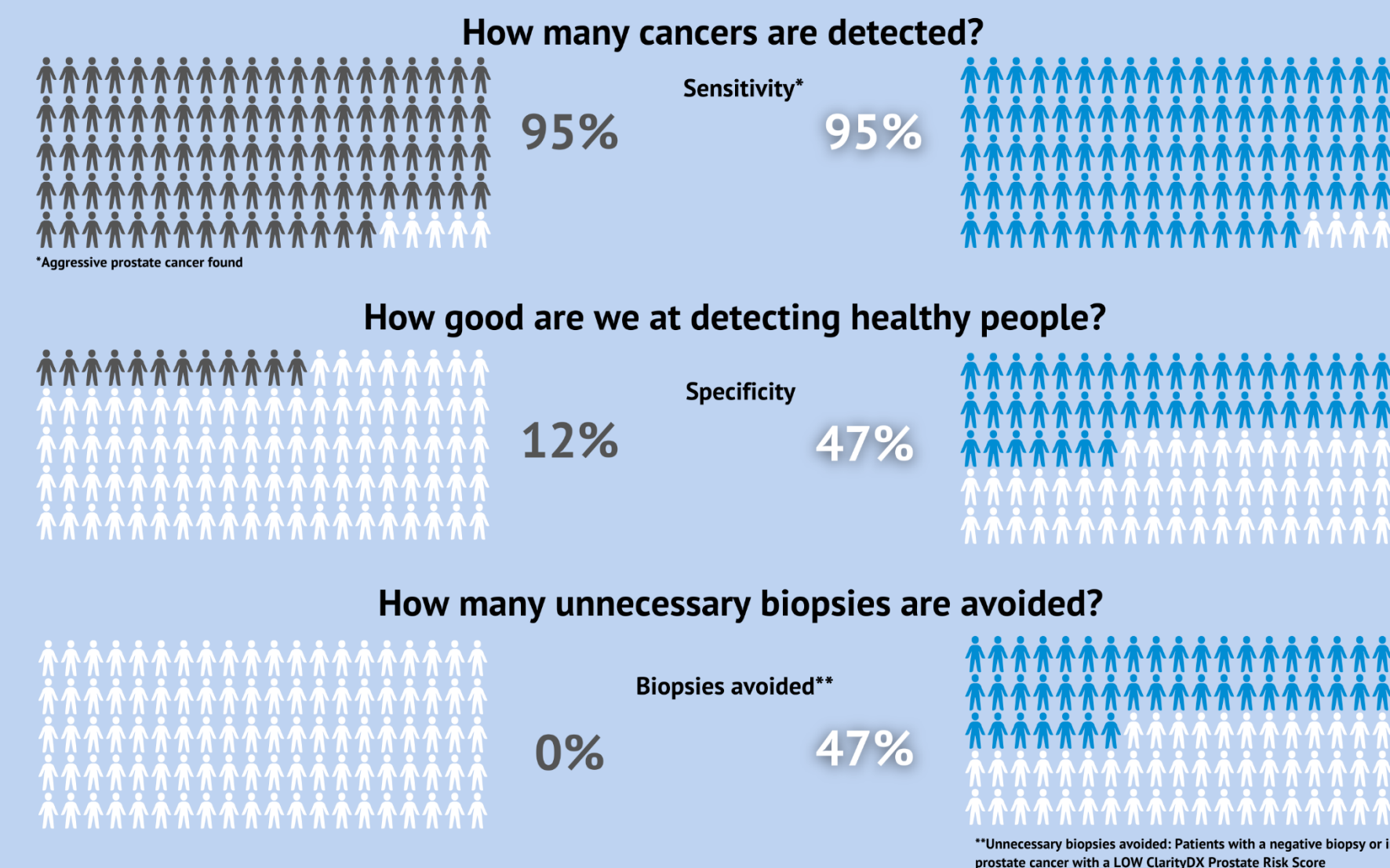
- We validated ClarityDX Prostate which uses common clinical features, standard blood-based biomarkers, and machine learning to create an easy-to-understand risk score to refine the prediction of clinically significant prostate cancer.
- The model was designed to fit into the current standard of care as a reflex test for men with elevated levels of PSA to help physicians identify patients needing a prostate biopsy.
- Clinical Care Pathways are predicted to include machine learning algorithms and precision medicine approaches to an ever-increasing extent.
- The adoption of ClarityDX Prostate into the continuum of care will reduce healthcare costs and improve patient outcomes.

## Clinical Care Pathway



## Take Home Message

### PSA TEST



## Acknowledgments

Funding: NRC-IRAP, Alberta Innovates ASBIRI, Bird Dogs/Alberta Cancer Foundation: Prostate Cancer Research Plan, TELUS Ride For Dad/Prostate Cancer Fight Foundation, Prostate Cancer Canada. JDL holds Bird Dogs Chair in Translational Oncology, funded ACF.

## Disclosures

RP, DP, CV, AF, MEH, CW, PB, SS, TM and JDL are Nanostics employees, IP holders, and/or leadership. AA is a Nanostics Board Member. AK and CPP have no relationships to disclose.