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OMNIINSIGHT™ PROSTATE CANCER PROGRAM

*A comprehensive, MENA-focused approach integrating **polygenic risk scores (PRS)**, **monogenic variant testing, clinical factors, and lifestyle** to deliver individualized prostate cancer prevention strategies.*

WHY PRS MATTERS

- Traditional genetic testing **alone is not enough.**
- PRS detects hidden high risk—**even in men with no mutations.**
- PRS modulates the penetrance of single-gene **mutations like BRCA,** meaning two patients with the same variant may have very different levels of risk.
- Uses a clinically validated multi-ancestry PRS, calibrated for diverse populations including the **MENA region.**

PERSONALIZED PREVENTION

Results are translated into **a clinically actionable care plan** aligned with best-practice guidelines, enabling personalized recommendations for **screening, lifestyle modification, medical interventions, and genetic counseling.**

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MONOGENIC RISK COVERAGE

Monogenic Risk Coverage Identifies high-impact pathogenic variants across NCCN-recommended prostate cancer genes, including: **BRCA1, BRCA2, ATM, PALB2, CHEK2, HOXB13, MLH1, MSH2, MSH6, PMS2.**

POWERED BY BLENDED GENOME EXOME

The innovative genomic technology is developed in collaboration **with Broad Clinical Labs at Harvard and MIT**, the program combines **95.5× Whole- Exome Sequencing (WES)** with **genome-wide lcWGS** to detect both rare mutations and polygenic risk with high precision.

Testing is performed through **CAP/CLIA-accredited laboratories,** with analytics support from **Allelica**, (MGB/LMM), and regional collaboration with **Novo Genomics.**

Equipped with most precise risk assessment available.

SCAN ME

Get started today

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THE CHALLENGE IN CURRENT PREVENTION

PSA & MRI miss significant cancers

- Traditional risk tools miss ~30–40%
- PSA & MRI miss significant cancers
- High genetic risk can exist with no family history of PC
- Current standard genetic tests (e.g., WES/WGS) detect only monogenic variants

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WHAT IS PC-PRS ?

A computational score derived from thousands to millions of genetic variants (SNPs)

- Estimates an individual's inherited riskfor common diseases such as Prostate Cancer
- Requires a single DNA test (blood or saliva); stable across life
- Independent of traditional risk factors
- Complements—does not replace—current clinical models

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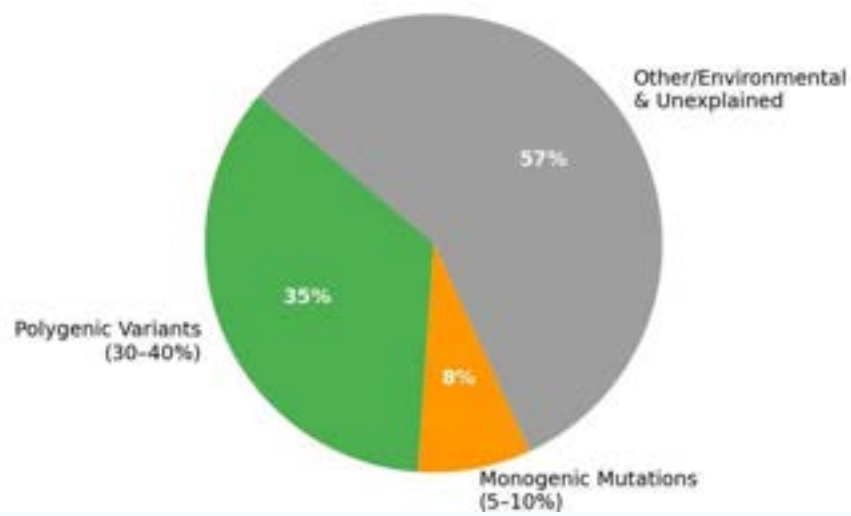
PC-PRS: A NEW PARADIGM

Traditional risk models miss ~30–40% of high-risk men—PRS captures these hidden risks

- Prostate cancer is one of the most heritable cancers (~57% genetic contribution)
- Rare high-risk mutations (monogenic): 10%
- Polygenic risk contributes 30–40%; far more than rare mutations (5-fold greater impact)

Distribution of Factors Contributing to PC Risk



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WHO SHOULD TAKE THIS TEST?

- Healthy Men aged 40 and above interested in understanding their genetic risk
- Men with a family history of prostate cancer (especially first-degree relatives)
- Men of African or Middle Eastern ancestry, who are at higher genetic risk and underrepresented in traditional screening tools
- Men with known monogenic mutations (e.g., BRCA1/2, HOXB13) seeking a more comprehensive risk assessment
- Men with elevated PSA levels or inconclusive biopsy results, as part of a broader risk evaluation

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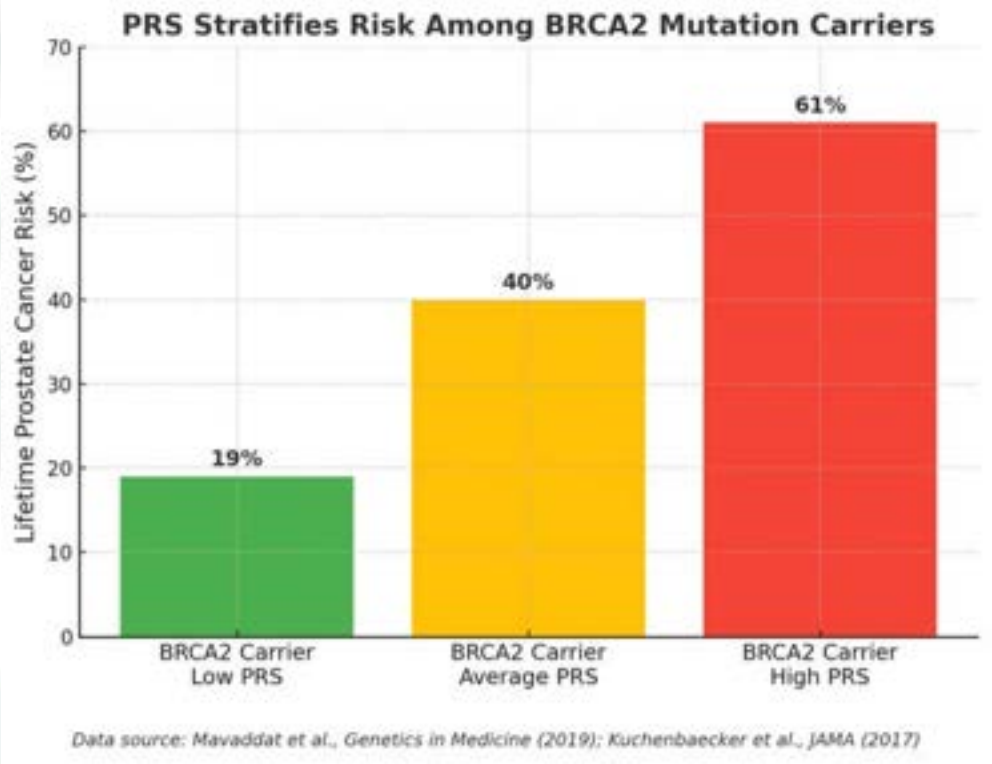
FROM GENETIC RISK TO PREVENTIVE ACTION

PRS can stratify risk even among men who carry a monogenic mutation for prostate



- Monogenic mutations confer a high baseline risk, however not all carriers develop cancer
- PRS further refines this risk—distinguishing those at highest vs lowest risk
- PRS refines screening, surveillance, and prevention for mutation carriers—shifting from one-size-fits-all to personalized risk management

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WHY PRS MATTERS FOR PROSTATE CANCER

Personalized Risk:

PRS provides an individualized estimate of lifetime prostate cancer risk based on common genetic variants.

Beyond Family History: It identifies risk in men without a known family history or monogenic mutation.

○Stronger Stratification:

PRS complements PSA and family history, helping distinguish between low-, intermediate-, and high-risk individuals.

Early Detection: Guides earlier and more frequent screening in high-risk individuals, potentially enabling timely diagnosis and treatment.

Precision Prevention: Informs lifestyle counseling and preventive strategies tailored to genetic risk.

Better Resource Use: Helps reduce over-screening in low-risk men and focus healthcare resources on those most at risk.

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EARLY DETECTION GUIDED BY THE PRS PREVENTS PROSTATE CANCER AND SAVES LIVES

Predicting Medical Events Anticipating
health issues before they occur

Preventing Prostate Cancer
Reducing risk through early intervention.

Identifying High-Risk Individuals
Early detection of at-risk patients

Polygenic Risk Score (PRS)
Precision medicine approach to prevention

Disclaimer:
Educational material only; PRS must be interpreted by qualified healthcare professionals within clinical context

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PRS outperforms PSA/MRI, with >70% of clinically significant cancers missed by the current UK pathway, based on elevated PSA and positive MRI

ORIGINAL ARTICLE

Assessment of a Polygenic Risk Score in Screening for Prostate Cancer

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ABSTRACT

BACKGROUND

The incidence of prostate cancer is increasing. Screening with an assay of prostate-specific antigen (PSA) has a high rate for false positive results. Genomewide association studies have identified common germline variants in persons with prostate cancer, which can be used to calculate a polygenic risk score associated with risk of prostate cancer.

METHODS

We recruited persons 55 to 69 years of age from primary care centers in the United Kingdom. Using germline DNA extracted from saliva, we derived polygenic risk scores from 130 variants known to be associated with an increased risk of prostate cancer. Participants with a polygenic risk score in the 90th percentile or higher were invited to undergo prostate cancer screening with multiparametric magnetic resonance imaging (MRI) and transperineal biopsy, irrespective of PSA level.

RESULTS

Among 40,292 persons invited to participate, 8953 (22.2%) expressed interest in participating and 6393 had their polygenic risk score calculated; 745 (11.7%) had a polygenic risk score in the 90th percentile or higher and were invited to undergo screening. Of these 745 participants, 468 (62.8%) underwent MRI and prostate biopsy; prostate cancer was detected in 187 participants (40.0%). The median age at diagnosis was 64 years (range, 57 to 73). Of the 187 participants with cancer, 103 (55.1%) had prostate cancer classified as intermediate or higher risk according to the 2024 National Comprehensive Cancer Network (NCCN) criteria, so treatment was indicated; cancer would not have been detected in 74 (71.8%) of these participants according to the prostate cancer diagnostic pathway currently used in the United Kingdom (high PSA level and positive MRI results). In addition, 40 of the participants with cancer (21.4%) had disease classified as unfavorable intermediate risk or as high or very high risk according to NCCN criteria.

CONCLUSIONS

In a prostate cancer screening program involving participants in the top decile of risk as determined by a polygenic risk score, the percentage found to have clinically significant disease was higher than the percentage that would have been identified with the use of PSA or MRI. (Funded by the European Research Council Seventh Framework Program and others; BARCODE1 ClinicalTrials.gov number, NCT03857477.)

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Avigena OmniInsight™ (AVI-OI™) - Prostate Cancer Genomics-guided prostate cancer risk prediction and prevention

	Test Name	Description
Avigena OmniInsight™ - Prostate Cancer (AVI-OI-PC™) IPC: AVI-OI-PC-02	Comprehensive Prostate Cancer Genomic Risk Stratification (PRS + Monogenic Analysis)	Designed for pre-disease risk assessment to guide personalized screening start age and interval.
	Polygenic Risk Score (PRS)	**Included Genes**
	Genome-wide polygenic susceptibility assessment Prostate Cancer PRS: 644,819 variants	BRCA1, BRCA2, ATM, PALB2, CHEK2, HOXB13, MLH1, MSH2, MSH6, PMS2

Clinical Intent: Not intended for the diagnosis of prostate cancer. Designed for genetic risk prediction and preventive management. Supports risk-based screening using polygenic risk scores (PRS). ***Technology:*** Blended Genome-Exome™ sequencing (95.5× WES + genome-wide lcWGS), performed in a CAP/CLIA-certified laboratory in collaboration with the Broad Institute (MIT/Harvard). ***Clinical Output:*** Integrates PRS, monogenic variants, clinical and lifestyle factors to generate an integrated genomic report, personalized prevention roadmap, and virtual genetic counseling via the Avigena OmniInsight™ platform. Used to guide PSA screening intensity and preventive strategies.

Clinical Indications

Population	Description
Men ⩾40years presenting for screening	For personalized prostatecancerrisk assessment. Use PRS as a risk-based screening tool.
Men of African or Middle Eastern ancestry or with a family history of prostate cancer	Higher inherited susceptibility and underrepresented in traditional risk tools.
Men with known monogenic variants (e.g., BRCA1/2, HOXB13)	PRS modifies penetrance of monogenic variants, resulting in different absolute risks among carriers of the same variant and refining risk stratification.
Men with elevated PSA or an inconclusive biopsy	Adjunctive risk stratification to guide management decisions.

ClinicalEvidence: Large prospective studies demonstrate that PRS-guided screening improves the detection of clinicallysignificant prostate cancer compared with conventional risk-based screening strategies (NEJM, 2025).

Sample Collection: Non-invasive saliva collection kit. Turnaround Time: 6-8 weeks Laboratory: CAP/CLIA-certified laboratory in collaboration with the Broad Institute (MIT/Harvard) CPT Codes: 81599, 96040

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Academic medical center	Location (USA)	PRS delivery model	Main PRS focus / use
Mass General Brigham/Harvard	Boston,MA	Clinical test via LMM+ translational programs	Cardiovascular PRS(clinical); other common diseases (research/implementation)
Massachusetts General Hospital/ Harvard	Boston,MA	Preventive genomics clinics	Cardiovascular and common disease PRS
Brigham and Women's Hospital	Boston,MA	Preventive genomics & clinical genetics programs	Cardiometabolic and common disease PRS
Harvard /Mayo Clinic	Rochester, MN	Genome-Informed Risk Assessment)	Cardiovascular, cancer, diabetes
Northwestern Medicine	Chicago, IL	Research-to-care implementation (eMERGE site)	Cardiometabolic and common diseases
Vanderbilt University Medical Center	Nashvill TN	Translational implementation (precision medicine programs)	Cardiovascular, metabolic and cancer PRS
University of Chicago Medicine	Chicago, IL	Clinical genomics programs	Cancer PRS (especially breast cancer)
Baylor College of Medicine	Houston, TX	Clinical genomics framework with PRS partners	Multi-ancestry PRS for common diseases
Penn Medicine	Philadelphia, PA	Biobank-driven research-to-care programs	Cancer and cardiometabolic PRS
Cleveland Clinic	Cleveland, OH	Genomic medicine programs	Cardiovascular and common diseases PRS

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Shipment Logistics Instructions

A. Shipment Address (via DHL or other courier services)

Broad Clinical Labs Receiving Lab 132 27 Blue Sky Drive Burlington,
MA 01803, USA Attention: Nick Argiro Phone: +1 617-714-8952

B. Sample Labeling Requirements

Product: DNA Genotek saliva collection kits (ORAgene)

All samples must include **two unique identifiers** clearly visible on the collection tube:

1. Barcode (Primary Identifier):
The barcode is pre-printed onthetube andmustremain clearly visible.
Do not cover or obscure the barcode.

2. Patient Identifier (Secondary Identifier):

A label including **the patient's full name and date of birth must be affixed to the tube.**

Ensure that the label does not cover or obscure the barcode or kit code.

Samples may be rejected if:

- The barcode is covered or unreadable
- Patient identifiers are missing or incomplete

C. Required Documentation (to be shared electronically)

Please submit the following documents via email, WhatsApp, or the Clinic Portal:

- Barcode (as printed on the saliva collection
- tube) Patient full name and date of birth
- Signed Consent Forms Completed Patient
- Intake Forms DHL shipment details and tracking information

Handling Instructions:

Store samples at room temperature. Avoid exposure to extreme heat.
Forassistance, pleasecontact:

• Email: info@avigena.com • WhatsApp (Avigena Boston): +1 (617) 412-5580