

Created by: Prolaris Biopsy Report Generator

Sample name: Sample 1A

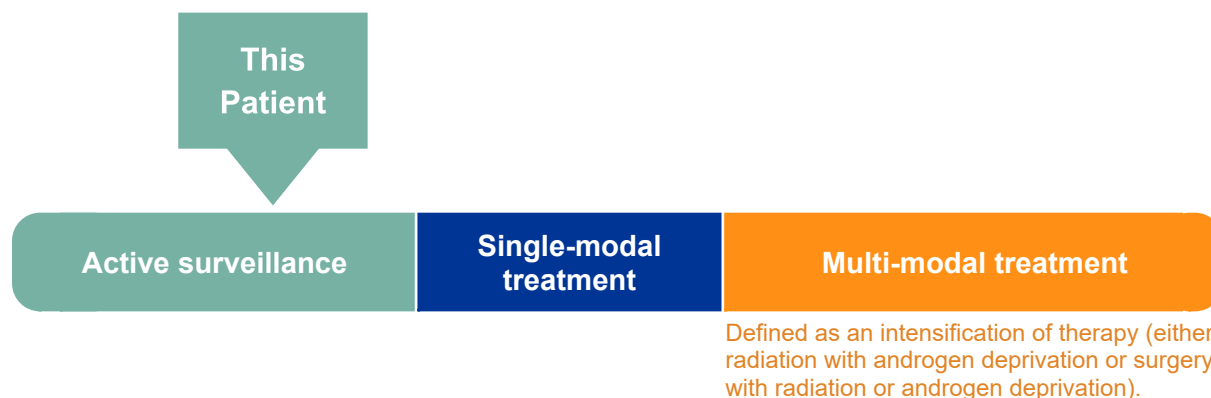
Additional ID: -

Report created: 2026-03-19

Validity of test: Passed

Prolaris test result summary

This patient has a Combined Clinical Risk Score (CCR) of 0.2. Based on the associated 10-year Disease Specific Mortality (DSM) risk of 2.0% with conservative management, this patient should be considered a candidate for Active Surveillance.



The Active Surveillance Threshold was validated in a cohort of conservatively managed men (n=585). Men with scores above the threshold had significantly different risk profiles compared to men at or below the threshold. No prostate cancer related deaths were observed in men with scores at or below the threshold within 10 years of diagnosis.⁴

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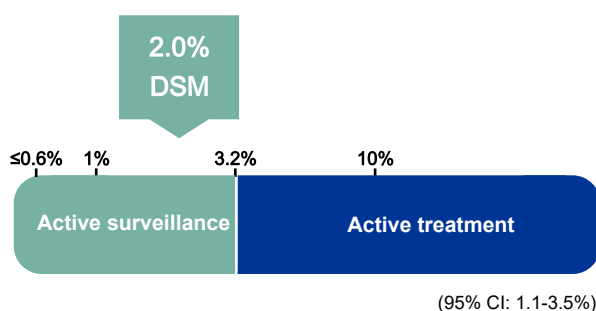
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Patient's risk assessment - two management scenarios

Prolaris Molecular Score and clinical variables **are combined** in a clinically validated, weighted algorithm.

Risk when considering active surveillance†

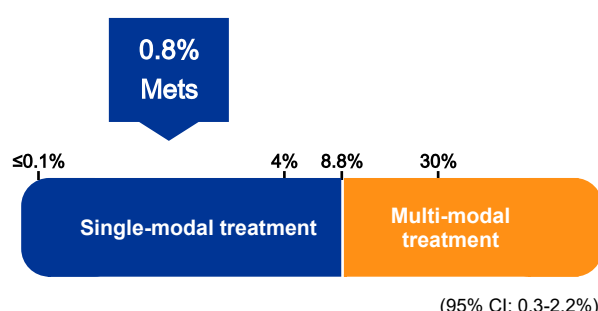
This patient's 10-year prostate cancer Disease Specific Mortality (DSM) risk with conservative management is:



Active Surveillance Threshold*: Patients with DSM at or below this threshold are considered to be candidates for conservative management.

Risk when considering definitive treatment‡

This patient's 10-year prostate cancer metastasis (Mets) risk with single-modal treatment is:



Multi-Modal Threshold:** Patients with Mets at or below this threshold are considered to be candidates for single-modal treatment.

Prolaris Molecular Score

2.3

A measure of cell proliferation, independent of clinical variables.

Clinical range
1.8 - 8.7

Combined Clinical Risk Score

0.2

A measure of cell proliferation, combined with clinicopathologic factors.

Clinical range
-0.1 - 3.8

Variables used for risk assessment

Prolaris Molecular Score:	2.3
Patient age at biopsy:	65
PSA prior to this biopsy:	7.3 ng/ml
Clinical T stage:	T2a
% positive cores:	17%
Gleason score:	3+4=7 (Group 2 ISUP ¹)
NCCN risk ² :	Favorable intermediate

NCCN, National Comprehensive Cancer Network® (NCCN®)

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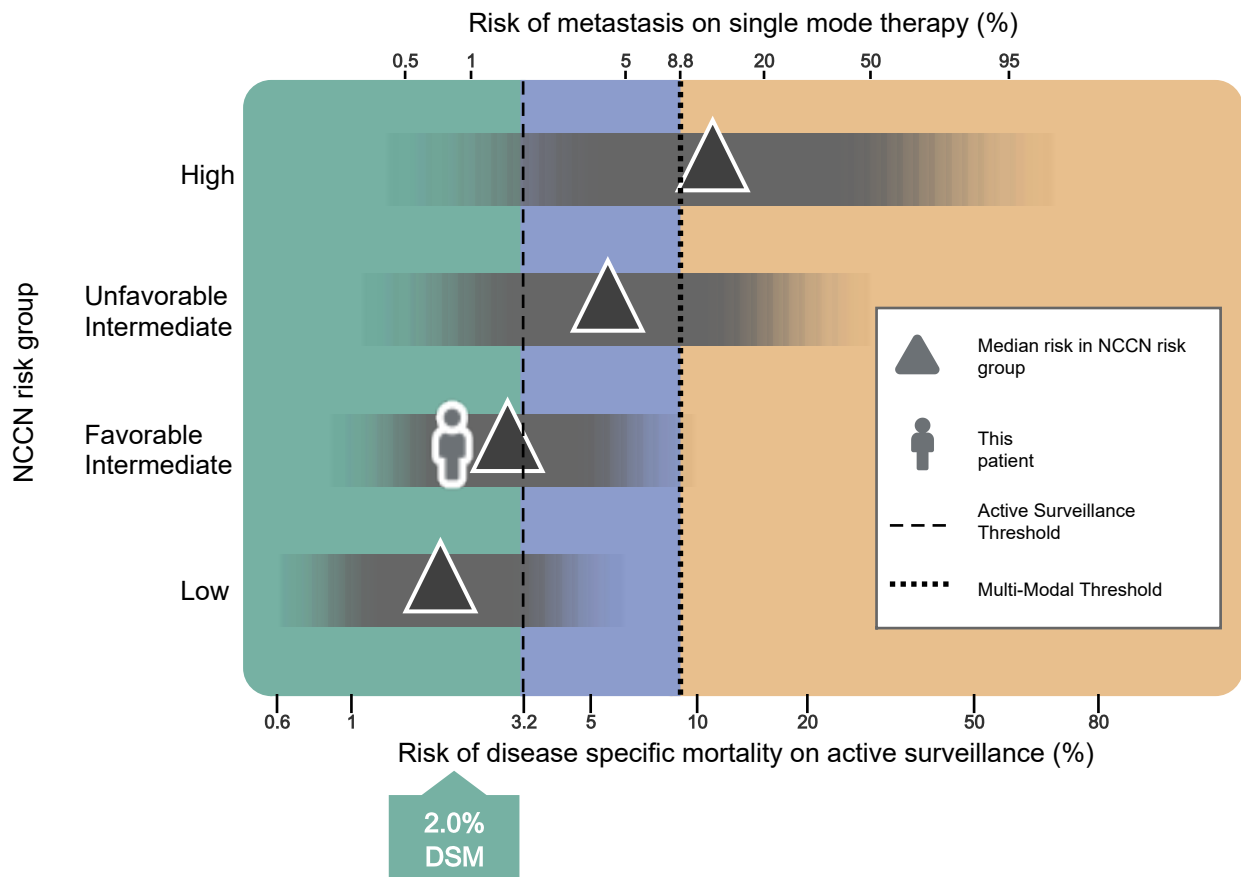
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Supplementary information: Risk stratification graph

This patient has a Disease Specific Mortality (DSM) risk below the median for his NCCN risk group² of Favorable intermediate.



The risk stratification plot is based primarily on US patients and NCCN risk classification.

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Test description:

The Prolaris® Prostate Cancer Prognostic Test kit utilizes quantitative RT-PCR analysis to measure the RNA expression levels of 10 cell cycle progression genes and 6 housekeeper genes to generate a cell-cycle-progression score (CCP Score) from FFPE biopsy. This score is adjusted by adding 4 units to achieve the Prolaris® Molecular Score for the patient result. The CCP Score is combined with the patient's CAPRA Score to provide a Combined Clinical Risk Score (CCR Score), which is associated with a personalized 10-year prostate cancer Disease Specific Mortality (DSM) risk with conservative management and 10-year metastasis (Mets) risk with definitive treatment.^{3-7,11,12} Prolaris® instruction manual contains information on the equivalence study.

* Active Surveillance (AS) Threshold validation analysis: The Prolaris Score distribution was determined in a training cohort of patients (N=505) who, based on clinical parameters (Gleason score \leq 3+4; PSA < 10 ng/ml; <25% cores positive; and clinical stage \leq T2a), might be considered for active surveillance (NCCN recommendations). A predefined combined clinical risk score was selected such that 90% of the men in the training cohort had lower scores. Two independent cohorts of conservatively managed men (N=765) were evaluated and there were no observed prostate cancer-specific deaths in patients with lower scores. This predefined clinical risk score (absolute value = 0.8) was associated with a 3.2% 10-year risk of prostate cancer-specific mortality in the combined cohort.³⁻⁶

** Multi-Modal Threshold validation analysis: The Combined Clinical Risk (CCR) score and a predefined CCR-based threshold were evaluated in two independent studies of men with NCCN intermediate- or high-risk localized disease (N=718¹¹ and N=741¹²) who received either single or multimodality therapy with known outcomes. Multi-modality therapy was defined as either radiation or surgery with androgen deprivation, or surgery with adjuvant radiation. Single-modality therapy included surgery or radiation therapy. Median follow-up in the combined cohorts was about 5.3 years. A predefined multi-modality threshold was selected such that the number of men who would be above the threshold would be similar to the number considered high-risk by NCCN clinicopathologic risk stratification. The predefined CCR threshold (absolute value = 2.112) was associated with an 8.8% (95% CI: 5.3, 14.7) 10-year risk of metastasis for men receiving single mode therapy (N=912, subset of combined cohorts).^{3,11,12}

† Patients with similar clinicopathologic features, as defined by their CAPRA Score, have the same a priori 10-year prostate cancer-specific mortality risk according to NCCN guidelines risk stratification. The addition of the Prolaris® Score further differentiates this risk.³⁻⁶

‡ Patients undergoing definitive therapy, defined as radical prostatectomy or primary radiation therapy with or without androgen deprivation therapy, with similar clinicopathologic features, as defined by their CAPRA Score, have the same a priori 10-year risk of developing biochemical recurrence/metastasis according to NCCN guidelines risk stratification. The addition of the Prolaris® Score further differentiates this risk.^{3,8-10}

Please contact Eurobio Scientific Professional Support at kitsupport@eurobio-scientific.de to discuss questions regarding this result.

References:

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2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.1.2022. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed [November 19, 2021]. To view the most recent and complete version of the guideline, go online to <https://www.nccn.org/>. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.
3. Data on file. Myriad Genetics, Inc.
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