Prolaris® BIOPSY TEST RESULT

ORDERING PHYSICIAN	SPECIMEN		PATIENT	
Bob Doctor MS	Specimen Type:	**Tissue Block**	Last Name:	**Pt Last Name**
Institution	Tissue:	**Prostate**	First Name:	**Pt First Name**
123 Main St	Biopsy Date:	**Mar 13, 2018**	Date of Birth:	**Jan 7, 1944**
Anywhere, UT 84010	TRF Received:	**Jun 26, 2018**	Patient ID:	**Patient id**
	Sample Received:	**Jun 26, 2018**	Gender:	**Male**
Pathologist: Joey Pathologist MD	Report Date:	**Oct 2, 2018**	Accession #:	**07000134-BLD**
			Requisition #:	**07000134**

Block(s) Analyzed: Block-2

PROLARIS MOLECULAR SCORE

A measure of cell proliferation, independent of clinical variables.

5.7
Considerably More Aggressive* than patients in the same risk category

This Prolaris Score is at percentile >99 for NCCN Very Low/Low patients

DSM Risk exceeds the threshold for active surveillance**

VARIABLES USED FOR RISK ASSESSMENT

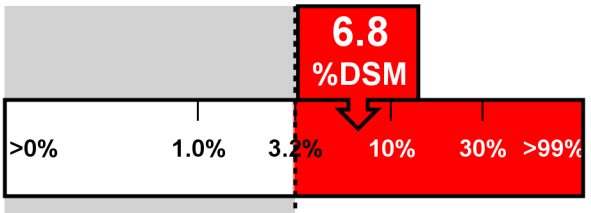
Prolaris Molecular Score:	5.7
Patient Age at Biopsy:	74
PSA Prior to This Biopsy:	6.79
Clinical T Stage:	T1c
% Postive Cores:	< 34%
Gleason Score:	3+3=6 (Group 1 ISUP[8])
NCCN Risk[1]:	Very Low/Low

PATIENT'S RISK ASSESSMENT

Prolaris Score and clinical variables are combined in a clinically validated weighted algorithm

When Considering Active Surveillance†

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

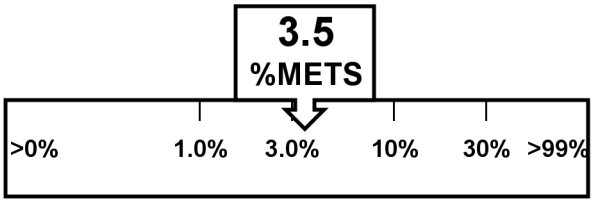


(95% CI:4.8-9.6%)

Active Surveillance Threshold:** DSM within the gray box may be considered appropriate for conservative management

When Considering Primary Radiation Therapy or Radical Prostatectomy‡

This patient's 10-Year Metastasis (METS) risk with definitive treatment is:



(95% CI:1.9-6.5%)

Mortality risks could be altered by various therapeutic interventions.

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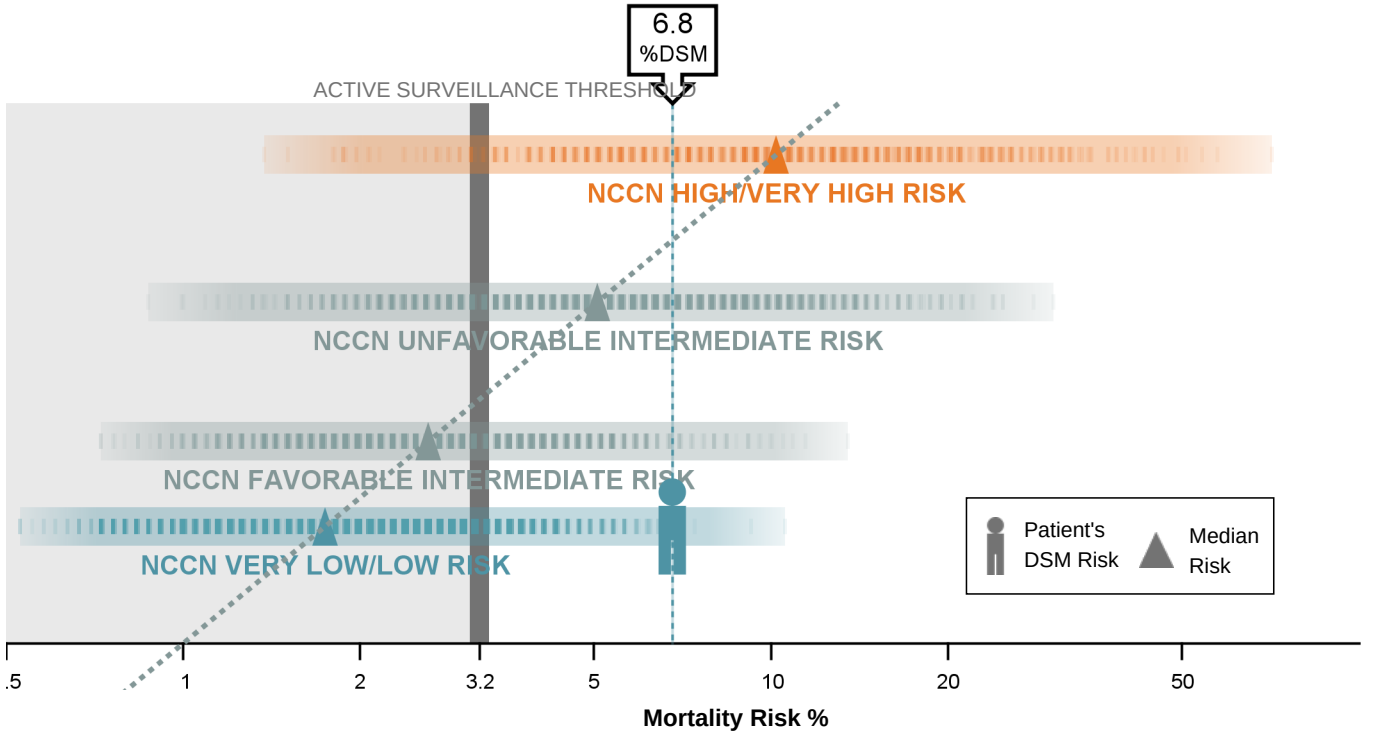
PATIENT'S PROLARIS MORTALITY RISK STRATIFICATION



Commercial data on file. Myriad Genetics Laboratories.

PATIENT'S RESULTS INTERPRETATION

▲ Prior to Prolaris Testing, this patient's prostate cancer was categorized as Very Low/Low risk.

After Prolaris Risk Assessment, this patient's risk of DSM is above the median DSM risk for the typical NCCN Very Low/Low patient. This patient's risk exceeds the defined active surveillance range.

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Test Description:
Prolaris utilizes quantitative PCR analysis to measure the mRNA expression levels of 31 cell cycle progression genes and 15 control genes from which a molecular score is calculated. Prolaris Scores are initially calculated as previously described and then adjusted by +4 units for the patient result. The Prolaris Score is combined with a patient's CAPRA score, resulting in a personalized 10 year prostate cancer-specific mortality risk (DSM).[2,4-6]

* The thresholds between the "Considerably Less Aggressive", "Less Aggressive", "Consistent", "More Aggressive", and "Considerably More Aggressive" intervals are one unit of Prolaris Score apart, with the "Consistent" interval centered at the median Prolaris Score for samples collected between May 12, 2016 to Feb 8, 2018. These intervals are based upon Prolaris Scores observed among patients tested at Myriad and may be adjusted in the future to reflect additional observations. The hazard ratio for death from prostate cancer for one unit of Prolaris Score is 1.9 (95% CI 1.3, 2.8).[2,4] The aggressiveness intervals are intended to help refine risk assessment. Specific therapeutic decisions should take into account all relevant clinical parameters including a patient's age, overall health, etc.

** Active Surveillance Study: The Prolaris Score distribution was determined in a training cohort of men (N=505) who, based on clinical parameters (Gleason score ≤ 3+4; PSA < 10 ng/ml; < 25% cores positive; and clinical stage ≤ T2a), might be considered for active surveillance. A predefined combined clinical risk score (CCP score + CAPRA) 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 deaths in patients with lower scores. This predefined clinical risk score was associated with a 3.2% (95% CI: 2.0, 5.2) 10-year risk of prostate cancer-specific mortality in the combined cohort.[2-5]

† Patients with similar clinicopathologic features, as defined by their CAPRA score, have the same a priori 10-year prostate cancer-specific mortality risk. The addition of the Prolaris Score further differentiates this risk.[2-5]

‡ 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* risk of developing metastases. The addition of the Prolaris Score further differentiates this risk.[2,7]

Please contact Myriad Medical Services at 1-800-469-7423 x3850 to discuss any questions regarding this result.

References

1) NCCN Clinical Practice Guidelines in Oncology; Prostate Cancer. Version 3. 2018.
2) Data on file. Myriad Genetics, Inc.
3) Lin, DW, et al. Identification of men with low-risk biopsy-confirmed prostate cancer as candidates for active surveillance. Urologic Oncology: Seminars and original investigations. 2018 Jun;36(6):310.e7-310.e13.
4) Cuzick, J *et al.* Prognostic value of a cell cycle progression signature for prostate cancer death in a conservatively managed needle biopsy cohort. Br J Cancer. 106(6):1095-9, 2012.
5) Cuzick, J *et al.* Validation of an RNA cell cycle progression score for predicting death from prostate cancer in a conservatively managed needle biopsy cohort. Br J Cancer. 113(3):382-9, 2015.
6) Cooperberg MR *et al.* Risk assessment for prostate cancer metastasis and mortality at the time of diagnosis. J Natl Cancer Inst. 101(12):878-87, 2009.
7) Bishoff Jay T, *et al.* Prognostic utility of the cell cycle progression score generated from biopsy in men treated with prostatectomy. J Urol. 2014;192(2):409-14.
8) Epstein, JI, *et al.* The 2014 International Society of Urological Pathology (ISUP) Consensus Conference on Gleason Grading of Prostatic Carcinoma: Definition of Grading Patterns and Proposal for a New Grading System. Am J Surg Pathol. 2016 Feb;40(2):244-52.

Note: Myriad deems information provided on the Test Request Form to be definitive, and to supersede information provided in any other form (e.g., pathology report). Clinicopathologic parameters provided by the healthcare provider(s), in whatever form, have not been verified by Myriad.

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The Technical Specifications summary (available at myriadpro.com) describes the analysis, method, performance characteristics, nomenclature, and interpretive criteria of this test. This test may be considered investigational in some states. This test was developed and its performance characteristics determined by Myriad Genetic Laboratories. It has not been reviewed by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.

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