

PROLARIS[®] BIOPSY TEST RESULT

ORDERING PHYSICIAN Bob Doctor MD 123 Grand Ave Anywhere, NV 89109 Jonathan Pathologist MD		CLINICOPATHOLOGIC FEATURES USED FOR ANALYSIS Patient Age at Diagnosis: 75 % Positive Cores: 10% (1/10) PSA Prior to This Biopsy: 35.0 Gleason Score: 3+3=6 Clinical T Stage: T1a AUA Risk: High	
SPECIMEN Specimen Type: Tissue Block Sample Received: Apr 17, 2017 Tissue: Prostate Accession Date: Apr 17, 2017 Biopsy Date: Mar 13, 2017 Report Date: Apr 20, 2017 TRF Received: Apr 17, 2017		PATIENT Name: Pt Last Name, Pt First Name Date of Birth: Jan 01, 1960 Accession #: 07000789-BLD Patient ID: Patient id Requisition #: 07000789 Gender: Male	

Block(s) Analyzed: **SC201601A**

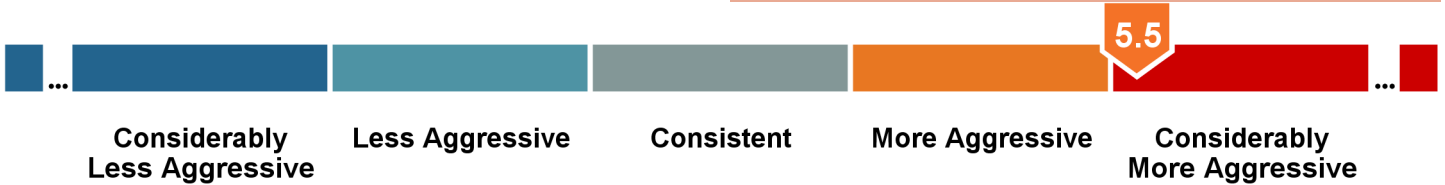
Considerably More Aggressive

Than Average AUA¹ High Risk

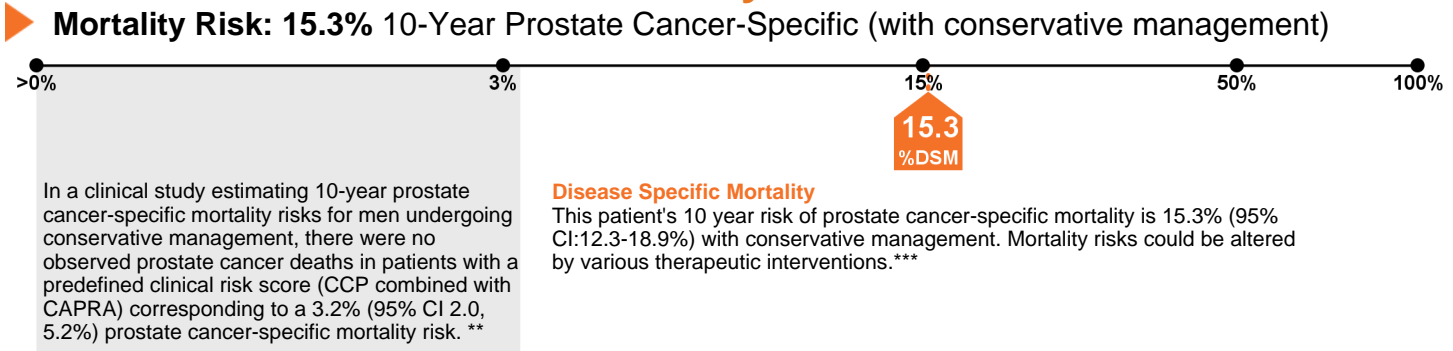
PROLARIS SCORE 5.5

US Distribution Percentile: 93%
(For AUA High Risk)

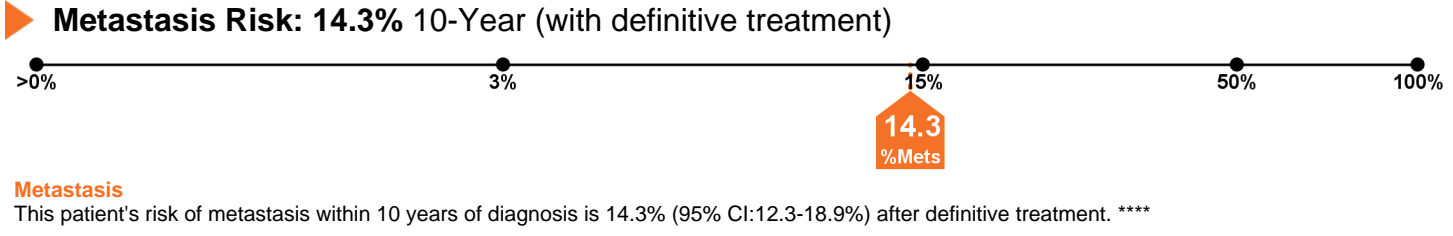
Interpretation: 93% of patients in the AUA High Risk* category have a lower Prolaris Score



Mortality Risk



Metastasis Risk



Myriad Genetic Laboratories, Inc.
 320 Wakara Way, Salt Lake City, Utah 84108 | 800.469.7423 | Fax 801.584.3615
prolaris.com

CONFIDENTIAL



MMM75222

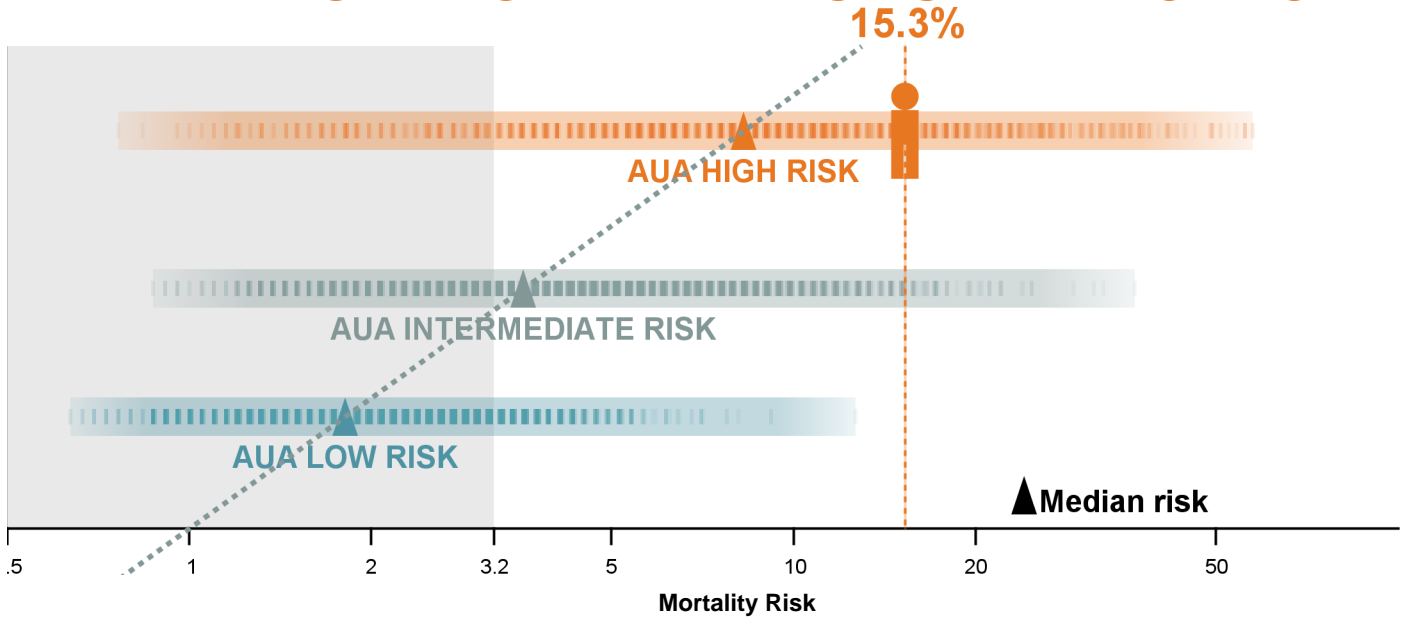
Myriad, the Myriad logo, Prolaris and the Prolaris logo are either trademarks or registered trademarks of Myriad Genetics, Inc. in the United States and other jurisdictions. © 2017

PROLARIS® BIOPSY TEST RESULT

ORDERING PHYSICIAN Bob Doctor MD 123 Grand Ave Anywhere, NV 89109 Jonathan Pathologist MD		CLINICOPATHOLOGIC FEATURES USED FOR ANALYSIS Patient Age at Diagnosis: 75 % Positive Cores: 10% (1/10) PSA Prior to This Biopsy: 35.0 Gleason Score: 3+3=6 Clinical T Stage: T1a AUA Risk: High	
SPECIMEN Specimen Type: Tissue Block Tissue: Prostate Biopsy Date: Mar 13, 2017 TRF Received: Apr 17, 2017	Sample Received: Apr 17, 2017 Accession Date: Apr 17, 2017 Report Date: Apr 20, 2017	PATIENT Name: Pt Last Name, Pt First Name Date of Birth: Jan 01, 1960 Patient ID: Patient id Gender: Male	Accession #: 07000789-BLD Requisition #: 07000789

Block(s) Analyzed: SC201601A

INDIVIDUAL MORTALITY RISK STRATIFICATION



INDIVIDUALIZED TREATMENT PLAN NOTES



Myriad Genetic Laboratories, Inc.
 320 Wakara Way, Salt Lake City, Utah 84108 | 800.469.7423 | Fax 801.584.3615
prolaris.com

CONFIDENTIAL



MMM75222

Myriad, the Myriad logo, Prolaris and the Prolaris logo are either trademarks or registered trademarks of Myriad Genetics, Inc. in the United States and other jurisdictions. © 2017

PROLARIS® BIOPSY TEST RESULT

SPECIMEN		PATIENT	
Specimen Type: Tissue Block	Sample Received: Apr 17, 2017	Name: Pt Last Name, Pt First Name	
Tissue: Prostate	Accession Date: Apr 17, 2017	Date of Birth: Jan 01, 1960	Accession #: 07000789-BLD
Biopsy Date: Mar 13, 2017	Report Date: Apr 20, 2017	Patient ID: Patient id	Requisition #: 07000789
TRF Received: Apr 17, 2017		Gender: Male	

Block(s) Analyzed: SC201601A

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.²⁻⁵

*The thresholds between the "Considerably Less Aggressive", "Less Aggressive", "Consistent", "More Aggressive", and "Considerably More Aggressive" intervals are two units of Prolaris Score apart, with the "Consistent" interval centered at the median Prolaris Score as of April 10, 2013. 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 two units of Prolaris Score is 1.9 (95% CI 1.3, 2.8).^{2,3} 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

***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.^{2,4}

****Patients undergoing definitive 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.^{2,6}

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

References

- 1) American Urological Association. Guideline for the management of clinically localized prostate cancer: 2007 update.
- 2) Data on file. Myriad Genetics, Inc.
- 3) 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.
- 4) 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):382-389, 2015
- 5) 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.
- 6) 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):409-414.

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.

Authorized Signature:

Benjamin B. Roa, Ph.D.
Diplomate ABMG
Laboratory Director

Johnathan M. Lancaster, M.D. Ph.D.
Chief Medical Officer
Myriad Genetic Laboratories, Inc.

Karla R. Bowles, Ph.D.
Diplomate ABMG
Laboratory Director Pharmacogenetics

Hillary Z. Kimbrell, M.D.
Diplomate FCAP
Laboratory Director Anatomic Pathology

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.

AUA LOW

PSA less than or equal to 10, Gleason score less than or equal to 6, and clinical stage T1c-2a

AUA INTERMEDIATE

PSA between 10 and 20, Gleason score 7, or clinical stage T2b

AUA HIGH

PSA more than 20, Gleason score between 8 and 10, or clinical stage T2c



Prolaris®

Myriad Genetic Laboratories, Inc.

320 Wakara Way, Salt Lake City, Utah 84108 | 800.469.7423 | Fax 801.584.3615

prolaris.com

Myriad, the Myriad logo, Prolaris and the Prolaris logo are either trademarks or registered trademarks of Myriad Genetics, Inc. in the United States and other jurisdictions. © 2017

CONFIDENTIAL

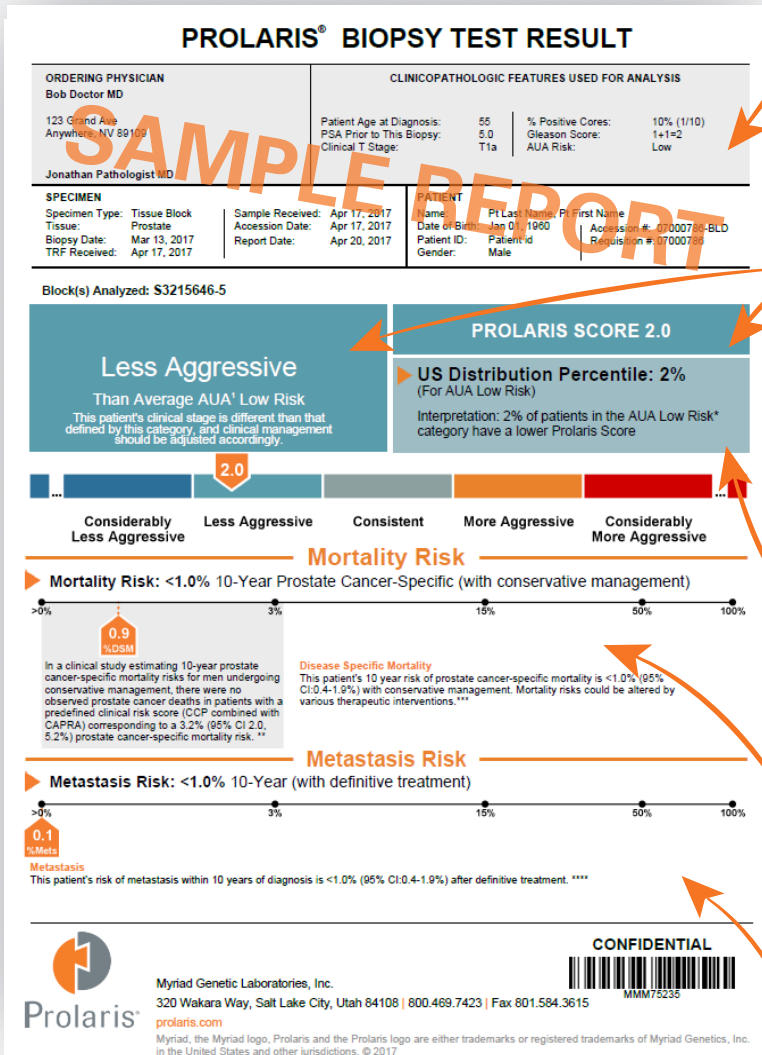


MMM75222

PROLARIS® BIOPSY TEST RESULT // Explaining the Score

The Prolaris® report provides an analysis of the individual tumor aggressiveness as well as a clinically validated prostate cancer-specific mortality risk. The Prolaris Score™ is calculated by directly measuring the biology of the tumor through the expression of cell cycle progression genes. The report itself is designed to provide easy to understand and clinically actionable information to assist with disease management decisions.

At the top of the report you'll see a summary of the clinical and pathological features provided to Myriad when ordering Prolaris. These values are used in combination with the Prolaris Score™ to calculate a patient's 10-year prostate cancer-specific mortality risk when managed conservatively.



In the center of the page is the easy to read Prolaris Score along with the Relative Risk. The Prolaris Score reveals the aggressiveness of the individual's prostate cancer while the relative risk shows how a patient's score compares to the average score in their American Urological Association (AUA) risk category. The majority of Prolaris Scores will fall between 0 and 10^{1,2} with a higher score indicating a more aggressive cancer. For every 1 unit increase in the Prolaris Score, the patient's risk doubles.

The US Distribution Percentile provides the patient's relative risk, or how his tumor compares to those in the same AUA risk group. For the patient shown, 2% of patients, or 2 out of 100, AUA low risk patients would have a lower score.

The patient's 10-year prostate cancer-specific mortality risk, is calculated by combining the Prolaris Score with the patient's clinical and pathological features. A recent study showed there were no observed prostate cancer-specific deaths in men whose Mortality Risk was below the threshold of 3.2%.¹ Therefore, a score falling below this threshold may indicate a more conservative disease management is possible.

The patient's 10-year risk of developing metastasis after definitive treatment, is also calculated by combining the Prolaris Score with the patient's clinical and pathological features.



FOR MORE INFORMATION, VISIT www.Prolaris.com
OR CALL MYRIAD AT 855.469.7765

REFERENCES

- Cuzick J, Berney DM, Fisher G, et al; Transatlantic Prostate Group. Prognostic value of a cell cycle progression signature for prostate cancer death in a conservatively managed needle biopsy cohort. *Br J Cancer*. 2012;106(6):1095-1099.
- Data on file. Salt Lake City, UT: Myriad Genetic Laboratories, Inc..
For information on technical specifications that describe test methodology and analysis, visit www.MyriadPro.com.

Myriad, the Myriad logo, Prolaris, Prolaris Score and the Prolaris logo are either trademarks or registered trademarks of Myriad Genetics, Inc. in the United States and other jurisdictions. ©2017 Myriad Genetic Laboratories, Inc. PRBRSLGD/02-17

Myriad Genetic Laboratories, Inc.
Prolaris.com

