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Medical Director

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TEST NAME: ProMark TM

PATIENT INFORMATION

Name: John Q. Sample
DOB: 1/1/1955
EMR: 14-121-006

Clinical Indication: Risk Assessment

SAMPLE INFORMATION

Date of Collection: 2/9/2015
Date Received: 2/9/2015
Date of Report: 00/00/00

Sample Type: Prostate biopsy core sections (X4), FFPE

PHYSICIAN INFORMATION

Ordering Physician:
Edward P. Sample

RESULT

ProMark Risk Score = 30

ANALYTIC INTERPRETATION

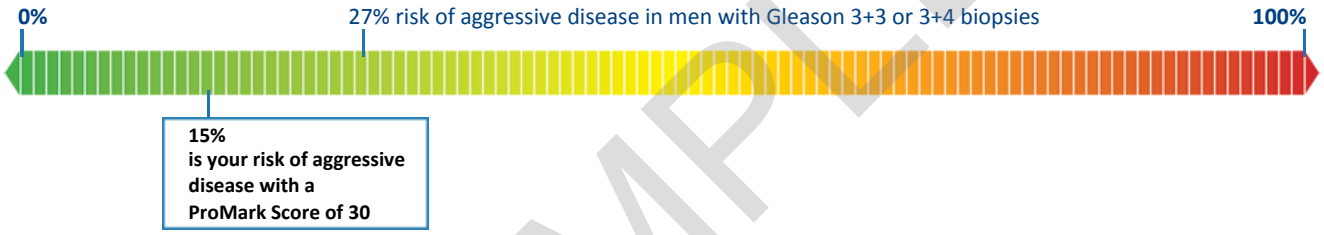
A ProMark Risk Score of 30 predicts the risk of aggressive disease at 15%.

CLINICAL INTERPRETATION

You have a 15% chance of:

- Unfavorable pathology in your prostate
- And/or Tumor spread beyond prostate gland (T3a or T3b)
- And/or Nodal (N1) or Distant Metastasis (M1)

Your risk of 15% is a 45% reduction from the risk predicted from biopsy pathology alone.



Additional clinical information can alter your risk of aggressive disease.

If your NCCN risk category is	Your risk of aggressive disease with a ProMark Score of 30 would be
VERY LOW	8.2%
LOW	16.9%
INTERMEDIATE	23.7%

Test Methology: The ProMark Risk Score is calculated from quantitative immunofluorescence of eight cellular proteins in the submitted specimen (1-5). These markers are DERL1, HSPA9, CUL2, FUS, SMAD4, PDSS2, pS6, and YBX1. Images were measured with the Vectra Intelligent Slide Analysis Systems (PerkinElmer), and then analyzed using custom software implemented in Definiens Developer (Definiens AG). The risk of aggressive disease is the probability that a patient with this protein expression pattern will show upon prostatectomy a Gleason Score >3+4, and/or tumor spread beyond the prostate (T3a, T3b, N, or M). The calculated risk incorporates data from disease prevalence from a U.S. Institutional Prostate Cancer Database from 2004-2014 (2,3,6). In this population of 9305 men with biopsy Gleason Scores 3+3 or 3+4, 27% were found to have aggressive disease in their prostate upon radical prostatectomy.

Disclaimer: This test was developed and its performance characteristics determined by Metamark Genetics. It has not been cleared or approved by the US Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. This laboratory is CAP accredited and CLIA certified to perform high complexity testing.

Signed-out By: Metamark Pathologist, 3/20/2015

REFERENCES
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2. Choudhury S. et al. Evaluation of early clinical experience of a novel prognostic proteomics prostate cancer biopsy test. ASCO 2015 Genitourinary Cancers Symposium.
3. Dunyak, J. et al. Data on file at Metamark (2014)
4. Shipitsin, M. et al. Identification of proteomic biomarkers predicting prostate cancer aggressiveness and lethality despite biopsy-sampling error. British Journal of Cancer 111, 1201-1212, (2014).
5. Shipitsin, M. et al. Automated quantitative multiplex immunofluorescence in situ imaging identifies phospho-S6 and phospho-PRAS40 as predictive protein biomarkers for prostate cancer lethality.Proteome Science 12, 40, (2014).
6. Epstein, J. I., Feng, Z., Trock, B. J. & Pierorazio, P. M. Upgrading and downgrading of prostate cancer from biopsy to radical prostatectomy: incidence and predictive factors using the modified Gleason grading system and factoring in tertiary grades.European Urology 61, 1019-1024, (2012).

ProMark
PROTEOMIC PROGNOSTIC TEST
for PROSTATE CANCER