

**PATIENT INFORMATION**

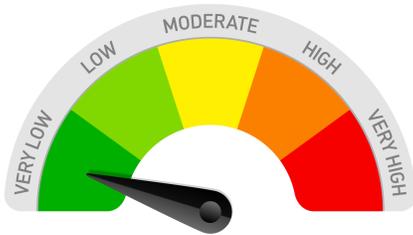
Name: XXXXXXX  
DOB: X/XX/XXXX  
Patient #: XXXXXX

**SPECIMEN ID #: XXXXXXXX**

Date Collected: 4/10/2015  
Date Received: 4/24/2015  
Date Reported: 4/28/2015

**PHYSICIAN**

Primary Physician: XXXXXX  
Client: XXXXXX  
Client #: XXXXXX



**This Patient is in the VERY LOW RISK Category.**

This result places this cancer in a category of VERY LOW RISK and predicts the shortest time to biochemical recurrence. Clinical intervention is a decision best left to the clinician and the patient.

These findings should be considered as an adjunct to other clinico-pathological findings including but not limited to Gleason score and number of cores involved by carcinoma.

**DIAGNOSIS - PTEN**

PTEN deletion not observed in this sample.  
Limited interpretation due to over fixed tissue resulting in poor hybridization

**DIAGNOSIS - TMRSS/ERG**

Fusion Not Detected

Both PTEN and TMRSS/ERG, fluorescent in situ hybridization tests were developed and their performance characteristics determined by Metamark. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. Metamark is certified under Clinical Laboratory Improvements Amendments of 1988 (CLIA) as qualified to perform high complexity clinical laboratory testing.

**GROSS DESCRIPTION**

Source	Blocks / Slides	Biopsy ID
Tissue	XXXXXXXX	3: Right Medial Apex; 5: Right Lateral Mid

**COMMENTS**

FISH assay results may not be informative if the specimen quality and/or specimen slide preparation is inadequate. A rigorous quality check should be performed when selecting slides for FISH.

Genetic mutations of PTEN are observed in up to 60% of prostate cancers 1-3. Loss of PTEN is a significant prognostic marker that has been shown to be associated with poor clinical outcome as measured with biochemical recurrence. Homozygous deletion (loss of both copies of the PTEN gene) demonstrates a shorter time to recurrence when compared to hemizygous deletion (loss of one of two gene copies of the PTEN gene).

There is a statistically significant association between TMRSS2:ERG fusions and prostate cancer specific metastases or death. In a Multivariate analysis, having TMRSS2:ERG fusion with a concomitant PTEN loss appears to be an additional determinant of the phenotype that governs a more aggressive tumor phenotype. 4

- Carver, B., Tran, J., Gopalan, A., Chen, Z., Shaikh, S., Carracedo, A., Alimonti, A., Nardella, C., Varmeh, S., Scardino, P., Cordon-Cardo, C., Gerald, W., Pandolfi, P. (2009). Aberrant ERG expression cooperates with loss of PTEN to promote cancer progression in the prostate. Nature Genetics 41:619-24, 2009.
- Rubin MA, Gerstein A, Reid K, Bostwick DG, Cheng L, Parsons R, Papadopoulos N. (2000) 10q23.3 loss of heterozygosity is higher in lymph node-positive (pT2-3,N+) versus lymph node-negative (pT2-3,N0) prostate cancer. Hum Pathol. 2000 Apr;31(4):504-8.
- Yoshimoto M, Cunha IW, Coudry RA, Fonseca FP, Torres CH, Soares FA, Squire JA. (2007) FISH analysis of 107 prostate cancers shows that PTEN genomic deletion is associated with poor clinical outcome. Br J Cancer. 2007 Sep 3;97(5):678-85. Epub 2007 Aug 14.
- Yoshimoto M, Joshua AM, Cunha IW, Coudry RA, Fonseca FP, Ludkovski O, Zielenska M, Soares FA, Squire JA. (2008) Absence of TMRSS2:ERG fusion and PTEN

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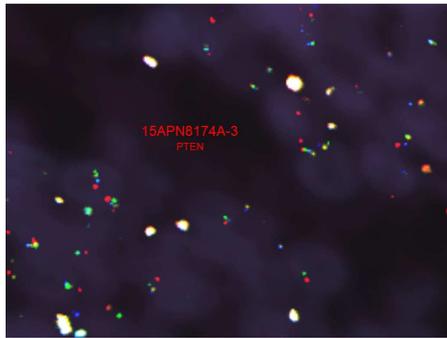
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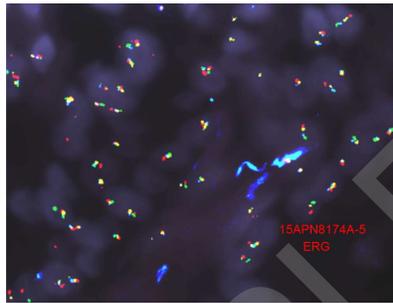
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losses in prostate cancer is associated with a favorable outcome. Mod Pathol. Dec;21(12):1451-61. Epub 2008 May 23.

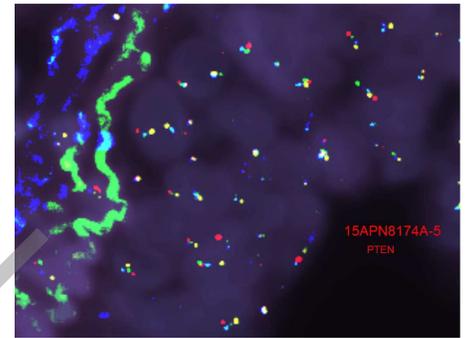
**CASE MICROGRAPHS**



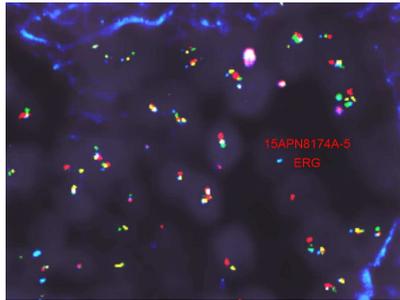
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Final Report Electronically Signed on 4/28/2015 at 8:44 AM