

Gender: M Age: 65
 Social Security Number:
 Patient ID/Case Number:

Urology Group
 Doe, John MD
 1 Main Street
 New York, NY 10022
 (000) 000-0000



CBLPATH

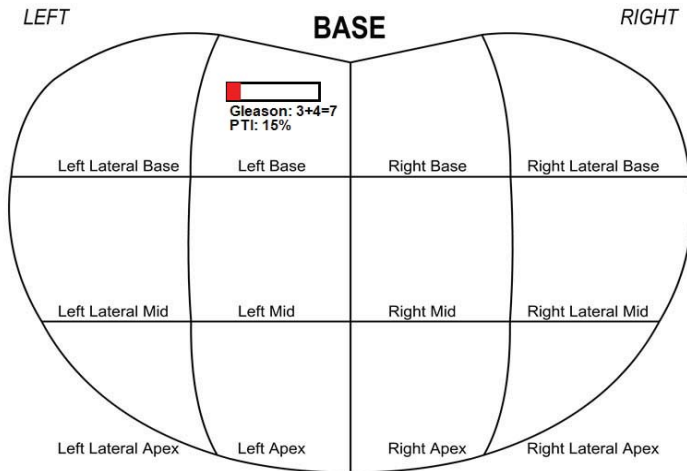
A Sonic Healthcare Company

Date of Procedure: 00/00/0000
 Date Received: 00/00/0000

Clinical Information: Prostate Histology
 PSA 5.81

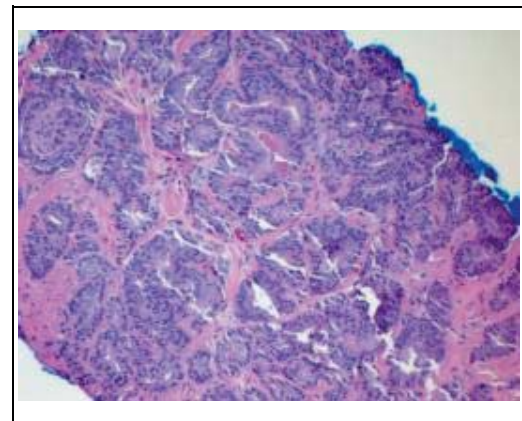
Urologic Pathology Report

Diagnostic Map



Photomicrograph

Specimen 4 Left Base



Microscopic Description:

Gleason 3+4=7

Malignant: █ ASAP Suspicious: █ HGPIN: █
 PTI: Percent Tumor Involvement

DIAGNOSTIC SUMMARY

Adenocarcinoma in specimen(s) 4. Highest Gleason Score is 3+4=7. Highest PTI is 15%

FINAL DIAGNOSIS:

- 4: **Left Base: Adenocarcinoma , Gleason's Score 3+4=7, involving 1 of 2 cores, approximately 15% of the total tissue.**
- 1: **Left Lateral Base: Benign prostatic tissue with mild chronic inflammation and atrophy.**
- 2: **Left Lateral Mid: Benign prostatic tissue with mild atrophy.**
- 3: **Left Lateral Apex: Benign prostatic tissue.**
- 5: **Left Mid: Benign prostatic tissue with mild atrophy and concretions.**
- 6: **Left Apex: Benign prostatic tissue with mild atrophy.**
- 7: **Right Base: Benign prostatic and seminal vesicle tissue.**
- 8: **Right Mid: Benign prostatic tissue with mild atrophy and basal cell hyperplasia.**

9:	Right Apex: Benign prostatic tissue.
10:	Right Lateral Base: Benign prostatic tissue.
11:	Right Lateral Mid: Benign prostatic tissue with mild atrophy.
12:	Right Lateral Apex: Benign prostatic tissue with mild atrophy.

Gross Description

No.	Media	Location	Specimen	Color	Length	Cassette
4	Formalin	Left Base	2 Cores	light tan	0.5, 0.9	1
1	Formalin	Left Lateral Base	1 Cores	light tan	1.3	1
2	Formalin	Left Lateral Mid	1 Cores	light tan	1.4	1
3	Formalin	Left Lateral Apex	1 Cores	light tan	0.5	1
5	Formalin	Left Mid	2 Cores	light tan	0.7, 1.2	1
6	Formalin	Left Apex	1 Cores	light tan	1.7	1
7	Formalin	Right Base	2 Cores	light tan	0.4, 0.7	1
8	Formalin	Right Mid	2 Cores	light tan	0.4, 1.3	1
9	Formalin	Right Apex	1 Cores	light tan	1.2	1
10	Formalin	Right Lateral Base	1 Cores	light tan	1.4	1
11	Formalin	Right Lateral Mid	1 Cores	light tan	1.2	1
12	Formalin	Right Lateral Apex	1 Cores	light tan	1.5	1

Comments

Immunohistochemical stains with PTEN / ERG (by FISH - see separate report), Ki67, p53, 34BE12, p63, and P504S were performed to aid the prognosis / diagnosis on part #4

Staining for p63 and HMWCK is positive in the basal layer of benign glands and negative in malignant glands. P504S shows positive cytoplasmic staining in malignant glands.

PTEN	Abnormal	At Risk
ERG	Abnormal	At Risk
Ki67	Positive	At Risk
P53	Positive	At Risk

Gleason Score 3+4=7. CA in 1 of 16 cores, 15% of one biopsy. Gleason Prognostic Group (GPG) 2 of 5*.

IHC pattern is HIGH RISK* of tumor progression / aggressive CA behavior.

Case reviewed in conference. Clinical correlation recommended.

*Biochemical Disease-Free 5Y survival s/p RP@Johns Hopkins; (BJU 2013):
GPG1= 94.6%, GPG2= 82.7%, GPG3= 65.1%, GPG4= 63.1%, GPG5= 34.5%

Disclaimer

The immunohistochemical stains were developed and their performance characteristics determined by CBLPath. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing.

IHC

Date/Time of Sample Collection:
00/00/0000 00:00:00 PM

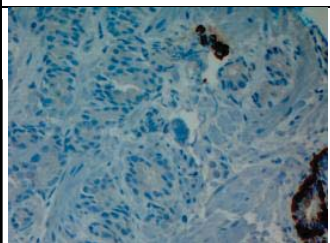
Date/Time Sample Received:
00/00/0000 00:00:00 PM

Submitted Diagnosis / Diagnosis Under Consideration:

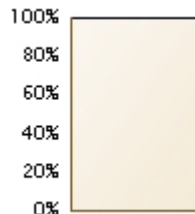
Specimen Type: Formalin Fixed Tissue **Specimen Site:** Left Base

Immunohistochemical (IHC) Results:

Antibodies	Clone	Results/Comments
P504S (IHC)	Polyclonal	Negative
Ki67	MIB-1	Positive
P53	DO-7	Positive

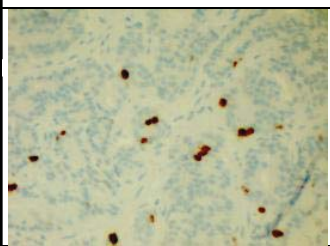


P504S (IHC)

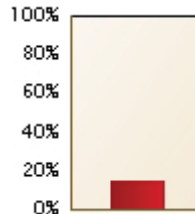


NEGATIVE

PCA Triple Immunostain
Negative p63 & CK903

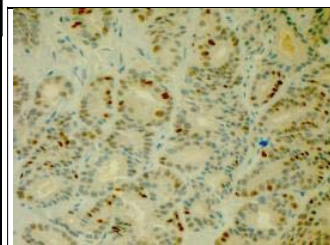


Ki67

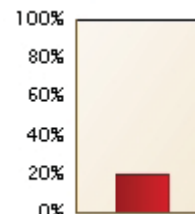


POSITIVE

normal = 3%



P53



POSITIVE

normal < 12 / hpf

Electronically signed out by:

Dr. Joseph Benson
Department of UroPathology

(877) 258-93100

00/00/0000

Images included in this report are for information only and are not intended for diagnosis. Some tests performed at CBLPath Inc have not been cleared or approved for specific uses by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. In accordance to CLIA '88 requirements, this laboratory has verified the validity and accuracy of these tests for clinical purposes. CBLPath is regulated under the Clinical Improvement Amendments Acts of 1988 (CLIA) as qualified to perform high complexity testing.

End of Report

Sample, Patient H

DOB: 00/00/0000

Accession #: XF14NY1-00000000

Gender: M Age: 65
Social Security Number:
Patient ID/Case Number: 12345

Date of Procedure: 00/00/0000
Date Received: 00/00/0000

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1 Main St.
New York, NY 10022
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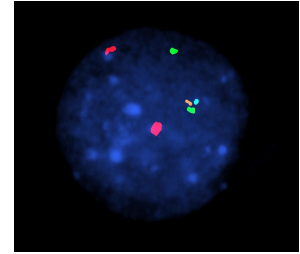
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Fluorescence in situ Hybridization (FISH) Report*

Interpretation: Positive Prostate Panel: Abnormal PTEN & Abnormal ERG

TEST	Probe Results
Prostate Panel (FISH)	This specimen exceeded the cut-off limit for the Prostate Panel by FISH (PTEN, TMRSS2:ERG) for the following criteria: Deletion of the PTEN gene was observed in 50 out of 100 (50%) nuclei analyzed.. This represents an abnormal PTEN result. TMRSS2:ERG gene rearrangement was observed in 50 out of 100 (50%) nuclei analyzed. This represents an Abnormal ERG result.
	ISCN: NA



PTEN

Specimen Type/Site: Formalin Fixed, Paraffin-Embedded Tissue, Prostate

Gross Description: Received 4 slides,1 stained,3 unstained, labeled with patients name . Forwarded to FISH for Prostate Panel (FISH).

Methodology: Fluorescence in situ hybridization analysis was performed on nuclei derived from this Prostate sample using the Prostate Panel (FISH) (manufactured by Cymogen Dx.). A test is considered positive if the normal cut off value established at CBLPath, Inc. are exceeded in value. A sample is considered positive if any of the following criteria are met: (A) Percentage of nuclei with PTEN loss >20% OR (B) Percentage of nuclei with PTEN homozygous loss >30% OR (C) Percentage of nuclei with TMRSS2:ERG rearrangement >10%. A sample is considered negative if none of the above criteria are met.

Case screened by: Cristina Steele, CG(ASCP)

Electronically signed out by:

Dr. Dongsheng Xu

(877) 258-9310

00/00/0000

Department of Molecular Pathology

FISH analysis can only identify abnormalities that are within the specific locus of the probe(s) used and may not detect small clonal populations of aberrant cells below the normal cut-off values; therefore, FISH results should be interpreted in the context of the patient's full clinical history and under most circumstances, in conjunction with histomorphological and/or cytogenetic evaluation. Images included in this report are for information only and are not intended for diagnosis. Some tests performed at CBLPath Inc have not been cleared or approved for specific uses by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. In accordance to CLIA '88 requirements, this laboratory has verified the validity and accuracy of these tests for clinical purposes. CBLPath is regulated under the Clinical Improvement Amendments Acts of 1988 (CLIA) as qualified to perform high complexity testing.

End of Report