6555 Sanger Rd. Suite 232 Orlando, FL 32827
CLIA ID #: 10D2192649 | PA Lab ID#: 39259
CA State ID: CDS-90005103

Medical Director:
Anthony Magliocco, MD FCAP

PROTEAN MAPS™

PROTEAN BIODIAGNOSTICS

Customer Support: 1 (754) 242-9682
support@proteanbiodx.com

Patient Information

Name: Doe, Jane	Pathologist: First Last MD
DOB: 00/00/0000	Date Collected: 00/00/0000
Protean ID #: P0-00001	Date Received: 00/00/0000
Physician(s): First Last MD	Date Reported: 00/00/0000
External ID#: 100000	Report Status: Completed

Medical History

The patient is a male diagnosed with stage IIB (T2B, N0, M0) prostatic adenocarcinoma. The patient had an elevated PSA of 19.6 and was started on bicalutamide and had a radical prostatectomy in 2021. The prostate contained invasive Gleason grade 3+4 adenocarcinoma which involved the left posterior apex resection margin. Pelvic lymph nodes were free of malignancy.

Recommendations

This tumor is expected to be responsive to adjuvant anti-androgen therapy for minimal residual disease.

Experimental treatments that target Hedgehog are currently emerging, and may also be considered.

Radiotherapy could also be a consideration for any residual disease in the pelvis. The presence of CTCs and cfDNA mutations in the blood could be used for serial monitoring of treatment response along with repeated PSA analysis. This analysis may be appropriate at 3-to-6-month intervals. Bone scans and blood tests for ALP can assist in the monitoring of bone health.

PROTEAN MAPS™

Tissue Analysis Histology, IHC, and ISH	Molecular Analysis Comprehensive Genomic Profiling
Risk MAPS Hereditary Cancer Testing	Liquid Biopsy Circulating Tumor Cells & Cell Free DNA

Tissue Analysis

PDL1 SP142 – Negative; PDL1 SP263 – Low Positive
P53 – Negative; Ki67 – Low (10% or less); ER – Positive in stroma

The pathology review confirmed the presence of invasive prostatic adenocarcinoma, Gleason Grade 3+4. The tumor involved resection margins, presenting some concern for residual disease at the surgical site. The pelvic lymph nodes were negative, making metastatic disease less likely. PDL1 SP263 was weakly positive. When high, this marker can identify tumors that may respond to immunotherapy. Ki67 was low, indicating that this tumor has a low growth rate. ER was positive in the stroma, which is a finding of uncertain significance.

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Liquid Biopsy

FollowIT – ERBB2 R811W identified 2.2%
CTC enumeration – 1 CTC identified per 7.5 mL

Liquid biopsy is used to evaluate presence of residual cancer. In this case there was evidence of low amounts of residual cancer with 1 CTC per 7.5 ml and 2.2% mutant ERBB2 in the blood. Patients with less than 5CTCs generally have a good prognosis. The liquid biopsy can be repeated at 3-to-6-month intervals to monitor the amount of residual disease and its response to ongoing treatment.

Molecular Analysis

MSI (microsatellite instability): NEGATIVE
Protean 600+: TMPRSS2-ERG fusion identified, MSI stable, TMB low

The molecular findings included testing for MSI, which can be used to identify tumors which respond to immune therapy. The MSI in this case was stable, making it unsuitable for such therapy. Protean 600+ identified TMPRSS2-ERG fusion, a common alteration in prostate cancer.

Risk MAPS

Germline Testing: SERPIN1 germline mutation identified

The genetic analysis identified a SERPIN1 inherited mutation. Mutations in this gene can cause deficiency in the circulating α(1)-Antitrypsin, which can contribute to emphysema and liver disease in certain patients. It is uncertain if SERPINA1 has any role in prostate or other cancers. A subset of prostate cancers are associated with inherited mutations in BRCA1, 2 and other members of homologous recombination pathway. The genetic analysis did not identify mutations in BRCA1, BRCA2, or other genes associated with HRD. Prostate cancers with HRD gene mutations may have response to PARP inhibitor therapy.

Additional Comments

This tumor is expected to be responsive to adjuvant anti-androgen therapy for minimal residual disease.

Experimental treatments that target Hedgehog are currently emerging, and may also be considered. Radiotherapy could also be a consideration for any residual disease in the pelvis. The presence of CTCs and cfDNA mutations in the blood could be used for serial monitoring of treatment response along with repeated PSA analysis. This analysis may be appropriate at 3-to-6-month intervals. Bone scans and blood tests for ALP can assist in the monitoring of bone health.

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Case Materials Received

1. LYMPH NODES, RIGHT PELVIC: Received three H&Es
2. LYMPH NODES, LEFT PELVIC: Received four H&Es
3. LEFT POSTERIOR LATERAL MARGIN: Received one H&E
4. POSTERIOR BLADDER NECK MARGIN: Received one H&E
5. PROSTATE, RADICAL RESECTION: Received one FFPE block

References

N/A

Medical Director Signature

Signed by Anthony M. Magliocco, MD

Finalization Date