Test Definition: PROF

Prostate Tumor, FISH, Ts

Overview

Useful For

Identifying *PTEN* gene deletion or rearrangements in patients with prostatic adenocarcinoma

Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
_PBCT	Probe, +2	No, (Bill Only)	No
_PADD	Probe, +1	No, (Bill Only)	No
_PB02	Probe, +2	No, (Bill Only)	No
_PB03	Probe, +3	No, (Bill Only)	No
_IL25	Interphases,	No, (Bill Only)	No
_I099	Interphases, 25-99	No, (Bill Only)	No
_I300	Interphases, >=100	No, (Bill Only)	No

Testing Algorithm

This test does not include a pathology consultation. If a pathology consultation is requested, PATHC / Pathology Consultation should be ordered and the appropriate FISH test will be ordered and performed at an additional charge. This test includes a charge for application of the first probe set (2 FISH probes) and professional interpretation of results.

Additional charges will be incurred for all reflex probes performed. Analysis charges will be incurred based on the number of cells analyzed per probe set. If no cells are available for analysis, no analysis charges will be incurred.

Method Name

Fluorescence In Situ Hybridization (FISH)

NY State Available

Yes

Specimen

Specimen Type

Tissue

Shipping Instructions

Advise Express Mail or equivalent if not on courier service.

Necessary Information

1. A pathology report is required in order for testing to be performed. Acceptable pathology reports include working drafts, preliminary pathology or surgical pathology reports.

2. A reason for testing must be provided. If this information is not provided, an appropriate indication for testing may be entered by Mayo Clinic Laboratories.

Specimen Required

Submit only 1 of the following specimens:

Specimen Type: Tissue

Preferred: Tissue block

Container/Tube: Formalin-fixed, paraffin-embedded tumor tissue block

Acceptable: Slides

Slides: Three consecutive, unstained, 5 micron-thick sections placed on positively charged slides and 1 hematoxylin and eosin-stained slide

Forms

If not ordering electronically, complete, print, and send an Oncology Test Request (T729) with the specimen.

Specimen Minimum Volume

2 consecutive, unstained, 5 micron-thick sections placed on positively charged slides and 1 hematoxylin and eosin-stained slide

Reject Due To

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Tissue	Ambient (preferred)		
	Refrigerated		

Clinical and Interpretive

Clinical Information

The tumor suppressor gene *PTEN* is often altered in patients with prostate cancer. Patients with advanced tumors have a deletion of the *PTEN* gene locus. Rearrangement or separation may be another mechanism responsible for inactivation of the *PTEN* gene. FISH analysis allows for the detection of deletion, homozygous deletion, and rearrangement of the *PTEN* gene region.

Reference Values

An interpretive report will be provided.

Interpretation

A positive result with the *PTEN* probe is detected when the percent of cells with an abnormality exceeds the normal cutoff for the probe set. A positive result of PTEN suggests inactivating structural alterations of the *PTEN* gene region at 10q23. A negative result suggests no structural alterations of the locus.

Cautions

This test is not approved by the FDA and is best used as an adjunct to existing clinical and pathologic information.

Fixatives other than formalin (eg, Prefer, Bouin's) may not be successful for FISH assays, however nonformalin fixed samples will not be rejected.

Paraffin-embedded tissues that have been decalcified are generally unsuccessful for FISH analysis. The pathologist reviewing the hematoxylin and eosin-stained slide may find it necessary to cancel testing.

Supportive Data

FISH analysis was performed on 65 formalin-fixed paraffin-embedded specimens including 25 prostatic adenocarcinoma tissue samples, 15 prostatic adenocarcinoma needle biopsy and 25 noncancerous control specimens. The normal controls were used to generate the normal cutoff values. Structural alterations resulting in the inactivation of the *PTEN* were identified and results correlated with pathology and immunohistochemical findings.

Clinical Reference

1. Krohn A, Diedler T, Burkhardt L, et al: Genomic deletion of PTEN is associated with tumor progression and early PSA recurrence in ERG fusion-positive and fusion-negative prostate cancer. Am J Pathol 2012;181(2):401-412

2. Gao T, Mei Y, Sun H, et al: The association of Phosphatase and tensin homolog (PTEN) deletion and prostate cancer risk: A meta-analysis. Biomed Pharmacother 2016;83:114-121

3. Lotan TL, Carvalho FL, Peskoe SB, et al: PTEN loss is associated with upgrading of prostate cancer from biopsy to radical prostatectomy. Mod Pathol 2015;28:128-137

Performance

Method Description

This test uses a laboratory developed *PTEN* dual-color break-apart strategy probe (BAP). Formalin-fixed paraffin-embedded tissues are cut at 5 microns and mounted on positively charged glass slides. The selection of tissue and the identification of target areas on the hematoxylin and eosin (H and E)-stained slide are performed by a pathologist. Using the H and E-stained slide as a reference, target areas are etched with a diamond-tipped etcher on the back of the unstained slide to be assayed. The probes are hybridized to the appropriate target areas. Using the *PTEN* probe set, each technologist analyzes 50 interphase nuclei (100 total) and the results are expressed as the percent of abnormal nuclei.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

7 to 10 days

Specimen Retention Time

Slides and H&E used for analysis are retained by the laboratory in accordance to CAP and NYS requirements. Client provided paraffin blocks and extra unstained slides (if provided) will be returned after testing is complete.

Performing Laboratory Location

Rochester

Fees and Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification

This test was developed using an analyte specific reagent. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information

88271x2, 88291 - DNA probe, each (first probe set), Interpretation and report

88271x2 - DNA probe, each; each additional probe set (if appropriate)

88271x1 - DNA probe, each; coverage for sets containing 3 probes (if appropriate)

88271x2 - DNA probe, each; coverage for sets containing 4 probes (if appropriate)

88271x3 - DNA probe, each; coverage for sets containing 5 probes (if appropriate)

88274 w/modifier 52 - Interphase in situ hybridization, <25 cells, each probe set (if appropriate)

88274 - Interphase in situ hybridization, 25 to 99 cells, each probe set (if appropriate)

88275 - Interphase in situ hybridization, 100 to 300 cells, each probe set (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
PROF	Prostate Tumor, FISH, Ts	In Process

Result ID	Test Result Name	Result LOINC Value
38105	Result Summary	50397-9
38106	Interpretation	69965-2
38107	Result	62356-1
CG959	Reason for Referral	42349-1
38109	Specimen	31208-2
38110	Source	31208-2
38111	Tissue ID	80398-1
38112	Method	49549-9
38113	Additional Information	48767-8
38183	Disclaimer	62364-5

Result ID	Test Result Name	Result LOINC Value
38184	Released By	18771-6