MAYO CLINIC LABORATORIES

Test Definition: PRKAF

Fibrolamellar Carcinoma, 19p13.1 (PRKACA) Rearrangement, FISH, Tissue

Overview

Useful For

Aid in the diagnosis of identifying *PRKACA* gene rearrangements of patients with fibrolamellar carcinoma

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
_PBCT	Probe, +2	No	No
_PADD	Probe, +1	No	No
_PB02	Probe, +2	No	No
_PB03	Probe, +3	No	No
_IL25	Interphases, <25	No	No
_I099	Interphases, 25-99	No	No
_I300	Interphases, >=100	No	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 fluorescence in situ hybridization test will be performed at an additional charge.

Appropriate ancillary probes may be performed at consultant discretion to render comprehensive assessment. Any additional probes will have the results included within the final report and will be performed at an additional charge.

Method Name

Fluorescence In Situ Hybridization (FISH)

NY State Available

Yes

Specimen

Specimen Type

Tissue

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

Specimen Type: Slides
Slides/Slide Count: Three consecutive, unstained, 5 micron-thick sections placed on positively charged slides, and 1 hematoxylin and eosin-stained slide
Additional Information: Broken or cracked unstained slides will be rejected. Stained slides that were broken and repaired (ie, double mounted) at the client site will not be rejected, as, in most cases, they can still be reviewed under the microscope. However, due to the double mounting, digital scanning cannot be performed.

Forms

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

Specimen Minimum Volume

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

Reject Due To

Broken or cracked unstained slides	Reject
Broken or cracked stained slides that cannot be repaired	Reject

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

DNAJB1-PRKACA fusion has been associated with a distinct subtype of hepatocellular carcinoma called fibrolamellar carcinoma. A break-apart strategy FISH probe has been developed to detect the rearrangement event that occurs in the *DNAJB1-PRKACA* fusion, specifically the loss of the 5' region labeled in red and retention of the 3' region labeled in green.

Reference Values

An interpretive report will be provided.

Interpretation

A positive result with the *PRKACA* probe is detected when the percent of cells with an abnormality exceeds the normal cutoff for the probe set.

A positive result of *PRKACA* suggests fusion of the *PRKACA* and *DNAJB1* genes at 19p13.1. A negative result suggests no fusion of the *PRKACA* and *DNAJB1* genes has occurred.

Cautions

This test is not approved by the US Food and Drug Administration, and it is best used as an adjunct to existing clinical and pathologic information.

Fixatives other than formalin (eg, Prefer, Bouin) may not be successful for FISH assays, however non-formalin 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.

Broken or cracked unstained slides are not compatible with the instrumentation used in our performing laboratories and will be rejected. Additional material may be requested.

Attempts will be made to repair broken or cracked stained slides; however, if they are unable to be repaired (ie, shattered in transit), they will be rejected and discarded due to safety concerns.

Supportive Data

FISH analysis was performed on 60 formalin-fixed paraffin-embedded specimens including 10 fibrolamellar carcinoma tissue samples, 25 non-fibrolamellar carcinoma liver tumor samples, and 25 noncancerous control specimens. The normal controls were used to generate the normal cutoff values. Structural alterations resulting in the rearrangement of the *PRKACA* gene region were identified and results correlated with pathology and previous FISH findings.

Clinical Reference

R Graham, L Jin, D Knutson, S Kloft-Nelson, et al: *DNAJB1-PRKACA* is specific for fibrolamellar carcinoma. Mod Path 2015;28:822-829

Performance

Method Description

This test uses a laboratory developed *PRKACA* (19p13.1) dual-color break-apart probe (BAP) strategy. 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 and 2 technologists analyze each probe set. Using the *PRKACA* 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
Mayo Clinic Laboratories - Rochester Main Campus

Fees & 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 account representative. For assistance, contact Customer Service.

Test Classification
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US 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
PRKAF	PRKACA, Rearrangement, FISH, Ts	104670-5

Result ID	Test Result Name	Result LOINC® Value
40669	Result Summary	50397-9
40670	Interpretation	69965-2
40671	Result	62356-1
40672	Reason for Referral	42349-1
40673	Specimen	31208-2
40674	Source	31208-2
40675	Tissue ID	80398-1
40676	Method	85069-3
40677	Additional Information	48767-8
40678	Disclaimer	62364-5
40679	Released By	18771-6