Test Definition: FGF1F

FGFR1 (8p11.2) Amp, FISH, Ts

Overview

Useful For

Providing prognostic information and guiding treatment primarily for patients with squamous cell carcinoma of the lung, breast, esophagus, thymus, and other locations

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 consult. 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

A reason for referral and pathology report are required in order for testing to be performed. Send information with specimen. Acceptable pathology reports include working drafts, preliminary pathology or surgical pathology reports.

Specimen Required

Submit only 1 of the following specimens:

Specimen Type: Tissue

Preferred: Tissue block

Collection Instructions: Submit a formalin-fixed, paraffin-embedded (FFPE) tumor tissue block. Blocks prepared with alternative fixation methods may be acceptable; provide fixation method used.

Acceptable: Slides

Collection Instructions: Four 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

Two 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

Fibroblast growth factor receptor 1 (*FGFR1*) is a receptor tyrosine kinase. *FGFR1* overexpression or amplification in squamous cell carcinoma is associated with tumor growth. Studies have shown overexpression *or* amplification of *FGFR1* to be vulnerable to FGFR-tyrosine kinase inhibitors and *FGFR1* inhibitors maybe a promising therapeutic option and have shown tumors with *FGFR1* amplification may be sensitive to *FGFR1* tyrosine kinase inhibitors.

Reference Values

An interpretive report will be provided.

Interpretation

FGFR1 will be clinically interpreted as positive or negative.

The *FGFR1* locus is reported as amplified when the *FGFR1*:D8Z2 ratio is >2.0 or an average of 6 or more copies of

the *FGFR1* locus are observed per tumor nucleus.

A tumor with an *FGFR1*:D8Z2 ratio < or =2.0 and having an average of <6 copies of *FGFR1* per tumor nucleus is considered negative for amplification of the *FGFR1* locus.

Cautions

This test is not approved by the US Food and Drug Administration and 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 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 40 paraffin-embedded tissue samples from patients with various tumors. A series of normal control samples were used to generate the normal cutoffs. *FGFR1* amplification was detected in 2 of 40 (5%) of samples. Other abnormalities including aneusomy, duplication and deletion of *FGFR1* were also identified and may be observed in addition to *FGFR1* amplification in tumor samples.

Clinical Reference

1. Schultheis AM, Bos M, Schmitz K, et al: Fibroblast growth factor receptor 1 (FGFR1) amplification is a potential therapeutic target in small-cell lung cancer. Mod Pathol 2014 Feb;27(2):214-212

2. Heist RS, Mino-Kenudson M, Sequist LV, et al: FGFR1 amplification in squamous cell carcinoma of the lung. J Thorac Oncol 2012 Dec;7(12):1775-1780

3. Weis J, Sos ML, Seidel D, et al: Frequent and focal FGFR1 amplification associates with therapeutically tractable FGFR1 dependency in squamous cell lung cancer. Sci Transl Med 2010 Dec 15;2(62):62ra93

4. Craddock KJ, Ludkovski O, Sykes J, et al: Prognostic value of fibroblast growth factor receptor 1 gene locus amplification in resected lung squamous cell carcinoma. J Thorac Oncol 2013 Nov;8(11):1371-1377

5. Schildhaus HU, Heukamp LC, Merkelbach-Bruse S, et al: Definition of a fluorescence in-situ hybridization score identifies high- and low-level FGFR1 amplification types in squamous cell lung cancer. Mod Pathol 2012 Nov;25(11):1473-1480

Performance

Method Description

This test uses a commercially available *FGFR1* dual-color enumeration probe strategy probe set. 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 each analyze 30 interphase nuclei (60 total) with the results expressed as a ratio of *FGFR1* to centromere 8 signals.(Unpublished Mayo method)

PDF Report

No

Day(s) and Time(s) Test Performed

Samples processed Monday through Sunday.

Results reported Monday through Friday; 8 a.m.-5 p.m.

Analytic Time

7 days

Maximum Laboratory Time

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 Ã¢â‚¬â€œ DNA probe, each (first probe set), Interpretation and report

88271x2 Ã¢â‚¬â€œ DNA probe, each; each additional probe set (if appropriate)

88271x1 Ã¢â‚¬â€œ DNA probe, each; coverage for sets containing 3 probes (if appropriate)

88271x2 Ã¢â‚¬â€œ DNA probe, each; coverage for sets containing 4 probes (if appropriate)

88271x3 Ã¢â‚¬â€œ DNA probe, each; coverage for sets containing 5 probes (if appropriate)

88274 w/modifier 52 Ã¢â‚¬â€œ Interphase in situ hybridization, <25 cells, each probe set (if appropriate)

88274 Ã¢â‚¬â€œ Interphase in situ hybridization, 25 to 99 cells, each probe set (if appropriate)

88275 Ã¢â‚¬â€œ Interphase in situ hybridization, 100 to 300 cells, each probe set (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
FGF1F	FGFR1 (8p11.2) Amp, FISH, Ts	78915-6

Result ID	Test Result Name	Result LOINC Value
55213	Result Summary	50397-9
55214	Interpretation	69965-2
55216	Result	78915-6
CG939	Reason for Referral	42349-1
55217	Specimen	31208-2
55218	Source	31208-2
55219	Tissue ID	80398-1
55220	Method	49549-9
55221	Additional Information	48767-8
55222	Disclaimer	62364-5
55225	Released By	18771-6