Test Definition: MELF

Melanoma, FISH, Ts

Overview

Useful For

An aid in the differentiation of benign from malignant melanocytic lesions when used in conjunction with clinical and pathologic information

Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
_I099	Interphases, 25-99	No, (Bill Only)	No
_I300	Interphases, >=100	No, (Bill Only)	No
_IL25	Interphases,	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
_PBCT	Probe, +2	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: Seven consecutive, unstained, 5 micron-thick sections placed on positively charged slides, and 1 hematoxylin and eosin (H and E) stained slide.

Forms

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

Specimen Minimum Volume

Three consecutive, unstained, 5 micron-thick sections placed on positively charged slides and 1 (H&E) 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

Melanocytic tumors arising in the skin can present a significant diagnostic challenge. While many lesions can be easily classified as benign nevi or malignant melanoma based on histologic features alone, there is a significant subset of lesions that cannot be clearly defined as either benign or malignant. Because the course of treatment for malignant melanoma relative to benign lesions varies significantly from the time of diagnosis, accuracy, and expediency of the diagnosis are of paramount importance. A FISH-based test panel has been developed that can be used as a diagnostic aid in the differentiation of malignant from benign melanocytic lesions.

This test is intended to be used in conjunction with clinical and pathologic information to aid the pathologist in the differentiation of benign from malignant melanocytic lesions.

Reference Values

An interpretive report will be provided.

Interpretation

The panel test is considered abnormal if certain parameters are met that have been shown to be observed in malignant melanocytic lesions and within normal limits if these parameters are not met.

An abnormal result is not diagnostic of malignancy, nor does a normal result exclude malignancy.

The results are intended to be interpreted in the context of the pathologic and clinical findings.

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. Although FISH testing will not be rejected due to non-formalin fixation, results may be compromised.

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 55 formalin-fixed, paraffin-embedded tissue samples, including 29 samples from patients suspected or diagnosed with melanoma and 26 histologically nonmalignant nevi (normal). The normal controls were used to generate a normal cutoff for this assay. Of the 29 suspected or diagnosed cases with melanoma, 26 were abnormal for at least 1 of the probes tested and at least 50% of the nuclei exhibited the abnormality. Three cases were considered equivocal since the abnormality was identified in <50% of nuclei.

Clinical Reference

1. Gerami P, Zembowicz A: Update on fluorescence in situ hybridization in melanoma: state of the art. Arch Pathol Lab Med 2011;135:830-837

2. Gerami P, Mafee M, Lurtsbarapa T, et al: Sensitivity of fluorescence in situ hybridization for melanoma diagnosis using RREB1, MYB, Cep6, and 11q13 probes in melanoma subtypes. Arch Dermatol 2010;146:273-278

3. Morey AL, Murali R, McCarthy SW, et al: Diagnosis of cutaneous melanocytic tumours by four-colour fluorescence in situ hybridisation. Pathology 2009;41(4):383-387

4. Gammon B, Beilfuss B, Guitart J, et al: Enhanced detection of spitzoid melanomas using fluorescence in situ hybridization with 9p21 as an adjunctive probe. Am J Surg Pathol 2012; 36(1):81-88

5. Gerami P, Jewell S, Pouryazdanparast P, et al: Copy number gains in 11q13 and 8q34 are highly linked to prognosis in cutaneous malignant melanoma. J Mol Diagn 2011;13(3):352-358

6. Pouryazdanparast P, Cowen D, Beilfuss B, et al: Distinctive clinical and histologic features in cutaneous melanoma with copy number gains in 8q24. Am J Surg Pathol 2012;36(2):253-264

Performance

Method Description

This test is performed using 3 commercially available enumeration strategy probes sets: a) *RREB1*/D6Z1/*MYB/CCND1*, b) *CDKN2A*/D9Z1, and c) D8Z2/*MYC*. 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 each analyze 25 interphase nuclei each (50 cells total for each probe set) with the results expressed as the percent of abnormal nuclei.(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. CST.

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
MELF	Melanoma, FISH, Ts	In Process

Result ID	Test Result Name	Result LOINC Value
52123	Result Summary	50397-9
52125	Interpretation	69965-2
52124	Result	62356-1
CG741	Reason for Referral	42349-1
52126	Specimen	31208-2
52127	Source	31208-2
52128	Tissue ID	80398-1
52129	Method	49549-9
54581	Additional Information	48767-8
53834	Disclaimer	62364-5
52130	Released By	18771-6