Test Definition: UMM3F

Mono 3, Uveal Melanoma, FISH, Ts

Overview

Useful For

As an aid to prognosis in patients with uveal melanoma when used in conjunction with an anatomic pathology consultation

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.

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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

Uveal melanoma is the most common type of primary intraocular malignancy in adults, with an annual incidence of 6 per million. These melanomas arise within pigmented cells of the uveal tract of the eye, which consists of the choroid, ciliary body, and iris. Overall, mortality rates in patients with uveal melanoma are quite high (approximately 50%) and are due to metastatic disease. Identifying patients likely to develop metastasis is critical for establishing patient prognosis. Previous studies have demonstrated that monosomy 3 is highly correlated with the development of metastatic disease in patients with uveal melanoma.

Reference Values

An interpretive report will be provided.

Interpretation

A neoplastic clone is detected when the percent of cells with an abnormality exceeds the normal reference range for chromosome 3 probe set. A positive result is consistent with monosomy 3 and a higher risk for metastatic disease in uveal melanoma patients. A negative result suggests that aneuploidy of chromosome 3 is not present.

Cautions

This test is not approved by the U.S. 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 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 37 formalin-fixed, paraffin-embedded tissue samples, including 17 uveal melanomas and 20 noncancerous eye tissues (removed due to trauma or chronic eye disorders). The normal controls were used to generate a normal cutoff for this assay. Eleven of 17 (65%) uveal melanoma specimens demonstrated monosomy 3 in 29.5% to 80.5% of the nuclei (with a mean value of 63%). The remaining 6 specimens were considered normal.

Clinical Reference

1. Tschentscher F, Prescher G, Horsman DE, et al: Partial deletions of the long and short arm of chromosome 3 point to two tumor suppressor genes in uveal melanoma. Cancer Res 2001 Apr 15;61(8):3439-3442

2. Prescher G, Bornfeld N, Hirche H, et al: Prognostic implications of monosomy 3 in uveal melanoma. Lancet 1996 May 4;349(9010):1222-1225

3. Cross NA, Ganesh A, Parpia M, et al: Multiple locations onchromosome 3 are the targets of specific deletions in uveal melanoma. Eye 2006 Apr;20(4):476-481

4. Parrella P, Fazio VM, Gallo AP, et al: Fine mapping of chromosome 3 in uveal melanoma: identification of a minimal region of deletion on chromosomal arm 3p25.1-p25.2. Cancer Res 2003 Dec 1;63(23):8507-8510

5. Onken MD, Worley LA, Person E, et al: Loss of heterozygosity of chromosome 3 detected with single nucleotide polymorphisms is superior to monosomy 3 for predicting metastasis in uveal melanoma. Clin Cancer Res 2007 May 15;13(10):2923-2927

Performance

Method Description

The test is performed using a commercially available chromosome 3 centromere probe (D3Z1) and a laboratory-developed *BCL6* (3q27.2) probe. 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 is 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 probe set is hybridized to the appropriate target areas and 2 technologists each analyze 100 interphase nuclei (200 total) 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. to 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
UMM3F	Mono 3, Uveal Melanoma, FISH, Ts	In Process

Result ID	Test Result Name	Result LOINC Value
52195	Result Summary	50397-9
52197	Interpretation	69965-2
52196	Result Table	93356-4
54590	Result	86239-1
CG750	Reason for Referral	42349-1
52198	Specimen	31208-2
52199	Source	31208-2
52200	Tissue ID	80398-1
52201	Method	49549-9
55031	Additional Information	48767-8
53826	Disclaimer	62364-5
52202	Released By	18771-6