MAYO CLINIC LABORATORIES

Test Definition: SCTF

Sex Chromosome Determination, FISH, Tissue

Overview

Useful For

Identifying the sex chromosome complement in paraffin-embedded tissues

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, <25	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 includes a charge for application of the first probe set (2 fluorescence in situ hybridization 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.

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.

Special Instructions

- Informed Consent for Genetic Testing
- Informed Consent for Genetic Testing (Spanish)

Method Name

Fluorescence In Situ Hybridization (FISH)

NY State Available

Yes

Specimen

Specimen Type

Tissue

Ordering Guidance

This test does not include a pathology consultation. If a pathology consultation is required, order PATHC / Pathology Consultation and the appropriate fluorescence in situ hybridization (FISH) test will be ordered and performed at an additional charge.

This testing is not appropriate for distinguishing tissue from the same gender, as in a same-sex transplant or potential tissue mix-up between 2 male patients or 2 female patients.

This evaluation can be more complicated in a post-transplant neoplastic evaluation and may not produce a confirmatory result.

Shipping Instructions

Advise Express Mail or equivalent if not on courier service.

Necessary Information

1. A reason for testing and a 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.

2. If a transplant has been performed, provide organ (ie, bone marrow, heart, lung, kidney, etc) and gender of donor information when sending the specimen.

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 (H and E)-stained slide.

Forms

New York Clients-Informed consent is required. Document on the request form or electronic order that a copy is on file.
The following documents are available in Special Instructions:
-Informed Consent for Genetic Testing (T576)
-Informed Consent for Genetic Testing-Spanish (T826)

Specimen Minimum Volume

See Specimen Required

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 & Interpretive

Clinical Information

Genotypically normal females possess 2 X chromosomes (XX); genotypically normal males possess 1 X chromosome and 1 Y chromosome (XY). Determining the sex chromosome complement in a tissue specimen can be used to:
-Identify opposite sex-donor cells post-transplant
-Help resolve cases of suspected sample mix-up

Reference Values

An interpretive report will be provided.

Interpretation

An interpretive report will be provided.

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's) 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.

Supportive Data

Fluorescence in situ hybridization analysis was performed on a series of formalin-fixed, paraffin-embedded specimens. Specimens with known sex chromosome aneusomy were correctly identified.

Clinical Reference

1. Nakhleh RE, Zarbo RJ: Surgical pathology specimen identification and accessioning: A College of American Pathologists Q-Probes study of 1,004,115 cases from 417 institutions. Arch Pathol Lab Med. 1996 Mar;120:227-233
2. Riopel MA, Yu IT, Hruban RH, Lazenby AJ, Griffin CA, Perlman EJ: Whose tumor is this: FISHing for the answer. Mod Pathol. 1995;8:456-457
3. Valenstein PN, Raab SS, Walsh MK: Identification errors involving clinical laboratories: a College of American Pathologists Q-Probes study of patient and specimen identification errors at 120 institutions. Arch Pathol Lab Med. 2006 Aug;130(8):1106-1113

Performance

Method Description

The test is performed using a commercially available enumeration strategy probe set for the X centromere (DXZ1) and Y centromere (DYZ3). Formalin-fixed, paraffin-embedded tissues are cut at 5 microns and mounted on positively charged glass slides. The selection of tissue and the 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 50 interphase nuclei (100 total) with the results expressed as the percent of XX (female) or XY (male) nuclei.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

7 to 10 days

Specimen Retention Time

Slides and H and 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 & 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 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 US Food and Drug Administration.

CPT Code Information

88271 x 2, 88291-DNA probe, each (first probe set), Interpretation and report
88271 x 2-DNA probe, each; each additional probe set (if appropriate)
88271-DNA probe, each; coverage for sets containing 3 probes (if appropriate)
88271 x 2-DNA probe, each; coverage for sets containing 4 probes (if appropriate)
88271 x 3-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
SCTF	Sex Chromosome, FISH, Ts	87436-2

Result ID	Test Result Name	Result LOINC® Value
52077	Result Summary	50397-9
52079	Interpretation	69965-2
52078	Result	87436-2
CG733	Reason for Referral	42349-1
CG734	Specimen	31208-2
52080	Source	31208-2
52081	Tissue ID	80398-1
52082	Method	85069-3
54575	Additional Information	48767-8
52083	Released By	18771-6
53840	Disclaimer	62364-5