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 probe application, analysis, and professional interpretation of results for one probe set (2 individual fluorescence in situ hybridization probes). Analysis charges are based on the number of cells analyzed per probe. No analysis charges apply if there are insufficient representative cells for evaluation.

Appropriate ancillary probes may be performed at the consultant's 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 requested, order PATHC / Pathology Consultation, and appropriate testing will be added at the discretion of the pathologist and performed at an additional charge.

This test is **not appropriate** for distinguishing tissue from the same sex, 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 pathology report is required for testing to be performed. If not provided, appropriate testing and/or interpretation may be compromised or delayed. Acceptable pathology reports include working drafts, preliminary pathology, or surgical pathology reports.
2. The following information must be included in the report provided:
-Patient name
-Block number - **must be on all blocks, slides, and paperwork**
-Collection date
-Tissue source
3. 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.
4. If a transplant has been performed, provide organ (ie, bone marrow, heart, lung, kidney, etc) and sex of donor information when sending the specimen.

Specimen Required

Submit only 1 of the following specimens:

Preferred:
Specimen Type: Tissue block (fresh tissue is **not acceptable**)
Collection Instructions:
1. Submit a formalin-fixed, paraffin-embedded tumor tissue block.
2. Blocks prepared with alternative fixation methods (eg, Prefer, Bouin's) will be attempted but are less favorable for successful results. Provide fixation method used.
Additional Information:
1. Paraffin-embedded specimens can be from any anatomic location (skin, soft tissue, lymph node, etc).
2. Decalcified paraffin-embedded specimens will have testing attempted; however, the success rate is approximately 50%. **Testing may be canceled** if sufficient tumor tissue is not present.
3. **Submitted fresh tissue specimens will be canceled upon receipt**. If only fresh tissue is available, embed in paraffin prior to sending.

Acceptable:
Specimen Type: Tissue slides
Slides: 1 Hematoxylin and eosin-stained and 4 unstained

Collection Instructions: Submit 1 slide stained with hematoxylin and eosin and 4 consecutive unstained, positively charged, unbaked slides with 5-micron thick sections of the tumor tissue.
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

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:
-Informed Consent for Genetic Testing (T576)
-Informed Consent for Genetic Testing-Spanish (T826)

Specimen Minimum Volume

Slides: 1 Hematoxylin and eosin-stained and 2 unstained

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

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 US Food and Drug Administration, and it is best used as an adjunct to existing clinical and pathologic information.

This test is intended to be used for sex chromosome identification.

This fluorescence in situ hybridization (FISH) assay does not rule out other chromosome abnormalities.

Fixatives other than formalin (eg, Prefer, Bouin's) may not be successful for FISH assays. Non-formalin fixed specimens will not be rejected.

Paraffin-embedded tissues that have been decalcified may not be successful for FISH analysis. The success rate of FISH studies on decalcified tissue is approximately 50%, but FISH will be attempted if sufficient tumor is present for analysis.

fluorescence in situ hybridization studies will be attempted if sufficient tumor is present for analysis. The pathologist reviewing the hematoxylin and eosin-stained slide may find it necessary to cancel testing if insufficient tissue/tumor is available for testing.

If no FISH signals or a lack of sufficient tumor tissue are observed post-hybridization, the case will be released indicating a lack of FISH results.

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;120(3):227-233
2. Riopel MA, Yu IT, Hruban RH, Lazenby AJ, Griffin CA, Perlman EJ. Ideas in pathology. Whose tumor is this? FISHing for the answer. Mod Pathol. 1995;8(4):456-457
3. College of American Pathologists, 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;130(8):1106-1113

Performance

Method Description

The test is performed using a commercially available enumeration strategy fluorescence in situ hybridization probe set for the X centromere (DXZ1) and Y centromere (DYZ3). Paraffin-embedded tissue samples 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 engraving tool 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 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 and E used for analysis are retained by the laboratory in accordance with regulatory requirements. Client provided paraffin blocks and extra unstained slides 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
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