MAYO CLINIC LABORATORIES

Test Definition: SLL

Small Lymphocytic Lymphoma, FISH, Tissue

Overview

Useful For

Detecting a neoplastic clone associated with the common chromosome abnormalities seen in patients with small lymphocytic lymphoma (SLL) and other low-grade B-cell lymphomas

Distinguishing patients with 11;14 translocations who have mantle cell lymphoma from patients who have SLL

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
_PRAG	Probe, Each Additional (SLL)	No, (Bill Only)	No

Testing Algorithm

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

Mayo Hematopathology Consultants are involved in both the pre-analytic (tissue adequacy and probe selection, when applicable) and post-analytic (interpretation of FISH results in context of specific case, when applicable) phases.

A charge and CPT code is applied for each probe set hybridized, analyzed, and reported.

If the patient is being tracked for known abnormalities, indicate which probes should be used.

Panel includes testing for the following abnormalities using the probes listed:
6q-, D6Z1/MYB
11q-, D11Z1/ATM
+12, D12Z3/MDM2
13q-, D13S319/LAMP1
17p-, TP53/D17Z1
t(11;14), CCND1/IGH

When an *IGH* rearrangement is identified, reflex testing with the t(14;19)(q32;q13*)* IGH/BCL3 FISH probe will be performed.

Highlights

This assay detects chromosome abnormalities observed in paraffin-embedded tissue samples from patients with small lymphocytic lymphoma.

Method Name

Fluorescence In Situ Hybridization (FISH)

NY State Available
Yes

Specimen

Specimen Type
Tissue

Ordering Guidance
This test is not appropriate for testing blood and bone marrow from patients with chronic lymphocytic leukemia. See CLLDF / Chronic Lymphocytic Leukemia (CLL), Diagnostic FISH, Varies or CLLMF / Chronic Lymphocytic Leukemia (CLL), Specified FISH, Varies.

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: Lymph node
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: For each probe set ordered, 2 consecutive, unstained, 5 micron-thick sections placed on positively charged slides, and 1 hematoxylin and eosin-stained slide.

Specimen Type: Solid tumor
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: For each probe set ordered, 2 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 a Hematopathology/Cytogenetics Test Request (T726) with the

specimen.

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
Small lymphocytic lymphoma (SLL) is the nonleukemic form of chronic lymphocytic leukemia (CLL), the most common adult leukemia in North America. The most common cytogenetic abnormalities detected in CLL are deletions of 6q, 11q, 13q, and 17p, trisomy 12, and the occasional occurrence of *IGH* translocations at 14q32. Cytogenetics has proven to be a reliable predictor of outcome for patients with CLL. It is unknown if SLL has the same prognostic significance when these genetic abnormalities are observed.

This FISH test detects an abnormal clone in approximately 65% of patients with SLL. Patients with t(11;14)(q13;q32) associated with *CCND1/IGH* fusion, have mantle cell lymphoma which can be distinguished from SLL and other B-cell lymphomas with this assay. Patients with t(14;19)(q32;q13.3) associated with *IGH/BCL3* fusion, may have an atypical form of SLL or another low-grade B-cell lymphoma.

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 any given probe.

A positive result is not diagnostic for small lymphocytic lymphoma, but may provide relevant prognostic information.

The absence of an abnormal clone does not rule out the presence of a neoplastic disorder.

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

Each probe was independently tested on a set of 62 formalin-fixed, paraffin-embedded tissue specimens from patients diagnosed with small lymphocytic lymphoma, splenic marginal zone lymphoma, or lymphoplasmacytic lymphoma and a set of noncancerous lymph node specimens. Normal cutoffs were calculated based on the results from 25 normal specimens. For each probe set, a series of chromosomally abnormal specimens were evaluated to confirm each probe set detected the anomaly it was designed to detect.

Clinical Reference

1. WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues. Swerdlow SH, Campo E, Harris NL eds. IARC; 2017
2. Shanafelt TD: Predicting clinical outcome in CLL: how and why. Hematology Am Soc Hematol Educ Program. 2009;421-429
3. Van Dyke DL, Werner L, Rassenti LZ, et al: The Dohner fluorescence in situ hybridization prognostic classification of chronic lymphocytic leukaemia (CLL): the CLL Research Consortium experience. Br J Haematol. 2016;173:105-113

Performance

Method Description

This test is performed using commercially available and laboratory-developed probes. Deletion of chromosomes 6q, 11q, 13q, and 17p, and trisomy of chromosome 12 are detected using enumeration strategy probes. A dual-color, dual-fusion (D-FISH) strategy probe set is used to detect *CCND1/IGH* rearrangements and for reflex testing to identify *BCL3/IGH* rearrangements. 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. For each probe set, the probes are hybridized to the appropriate target areas and 2 technologists each analyze 50 interphase nuclei (100 total) with the results expressed as the percent 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&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

88377-if 1 probe set
88377 x 2-if 2 probe sets
88377 x 3-if 3 probe sets
88377 x 4-if 4 probe sets
88377 x 5-if 5 probe sets
88377 x 6-if 6 probe sets
88377 x 7-if 7 probe sets
88377 x 8-if 8 probe sets

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
SLL	SLL, FISH, Tissue	In Process

Result ID	Test Result Name	Result LOINC® Value
603129	Result Summary	50397-9
603130	Interpretation	69965-2
603131	Result Table	93356-4
603132	Result	62356-1
GC038	Reason for Referral	42349-1
603133	Specimen	31208-2
603134	Source	31208-2
603135	Tissue ID	80398-1
603136	Method	85069-3
603137	Additional Information	48767-8
603138	Disclaimer	62364-5

603139	Released By	18771-6