MAYO CLINIC LABORATORIES

Test Definition: CLLMF

Chronic Lymphocytic Leukemia, Specified FISH, Varies

Overview

Useful For

Detecting a neoplastic clone associated with the common chromosome abnormalities seen in patients with chronic lymphocytic leukemia (CLL)

Identifying and tracking known chromosome abnormalities in patients with CLL and tracking response to therapy

Distinguishing patients with 11;14 translocations who have leukemic phase of mantle cell lymphoma from patients who have CLL

Detecting patients with atypical CLL or other forms of lymphoma associated with translocations between *IGH* and *BCL3*

Reflex Tests

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

Testing Algorithm

This test includes a charge for the probe application, analysis, and professional interpretation of results for one probe set (2 individual fluorescence in situ hybridization probes). Additional charges will be incurred all reflex or additional probe sets performed.

Indicate which probes from the selection below should be performed:
6q-, *D6Z1/MYB*
11q-, *D11Z1/ATM*
+12, *D12Z3/MDM2*
13q-, *D13S319/LAMP1*
17p-, *TP53/D17Z1*
t(11;14), *CCND1/IGH*
t(14;19), *IGH/BCL3*

This assay detects abnormalities observed in the blood and bone marrow of patients with chronic lymphocytic leukemia (CLL). If a paraffin-embedded tissue sample is received, this test will be cancelled and SLL / Small Lymphocytic Lymphoma, FISH, Tissue will be added and performed as the appropriate test.

Method Name

Fluorescence In Situ Hybridization (FISH)

NY State Available

Yes

Specimen

Specimen Type
Varies

Ordering Guidance
If testing a paraffin-embedded tissue specimen for patients with chronic lymphocytic leukemia (CLL) is desired, order SLL / Small Lymphocytic Lymphoma, FISH, Tissue.

Shipping Instructions
Advise Express Mail or equivalent if not on courier service.

Necessary Information
1. Provide a reason for testing with each specimen. The laboratory will not reject testing if this information is not provided, but appropriate testing and interpretation may be compromised or delayed.
2. A pathology and/or flow cytometry report may be requested by the Genomics Laboratory to optimize testing and aid in interpretation of results.

Specimen Required
Submit only 1 of the following specimens:

Specimen Type: Blood
Container/Tube:
Preferred: Yellow top (ACD)
Acceptable: Green top (sodium heparin), purple top (EDTA)
Specimen Volume: 6 mL
Collection Instructions: Invert several times to mix blood.

Specimen Type: Bone marrow
Container/Tube:
Preferred: Yellow top (ACD)
Acceptable: Green top (sodium heparin), purple top (EDTA)
Specimen Volume: 1-2 mL
Collection Instructions: Invert several times to mix bone marrow.

Forms
If not ordering electronically, complete, print, and send a Hematopathology/Cytogenetics Test Request (T726) with the specimen.

Specimen Minimum Volume
Blood: 2 mL
Bone Marrow: 1 mL

Reject Due To

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Ambient (preferred)		
	Refrigerated		

Clinical & Interpretive

Clinical Information

Chronic lymphocytic leukemia (CLL) is the most common leukemia in North America. The most common cytogenetic abnormalities in CLL involve chromosomes 6, 11, 12, 13, and 17. These are detected and quantified using the CLL fluorescence in situ hybridization (FISH) panel.

Use of CpG-oligonucleotide mitogen will identify an abnormal CLL karyotype in at least 80% of cases. This mitogen is added to cultures when chromosome analysis is ordered and the reason for testing is a B-cell disorder (CHRBM / Chromosome Analysis, Hematologic Disorders, Bone Marrow and CHRHB / Chromosome Analysis, Hematologic Disorders, Blood).

This FISH test detects an abnormal clone in approximately 70% of patients with indolent disease and greater than 80% of patients who require treatment. At least 5% of patients referred for CLL FISH testing have translocations involving the *IGH* locus. Fusion of *IGH* with *CCND1* is associated with t(11;14)(q13;q32), and fusion of *IGH* with *BCL3* is associated with t(14;19)(q32;q13.3). Patients with t(11;14) usually have the leukemic phase of mantle cell lymphoma. Patients with t(14;19) may have an atypical form of B-CLL or the leukemic phase of a lymphoma.

The prognostic associations for chromosome abnormalities detected by this FISH assay are, from best to worst: 13q-, normal, +12, 6q-, 11q-, and 17p-.

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 set.

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.

Supportive Data

Each probe was independently tested and verified on unstimulated peripheral blood and bone marrow specimens. Normal cutoffs were calculated based on the results of at least 25 normal specimens. For each probe set a series of chromosomally abnormal specimens were evaluated to confirm each probe set detected the abnormality it was designed to detect.

Clinical Reference

1. Dewald GW, Brockman SR, Paternoster SF, et al: Chromosome anomalies detected by interphase FISH: correlation with significant biological features of B-cell chronic lymphocytic leukemia. Br J Haematol. 2003;121:287-295
2. Dohner H, Stilgenbauer S, Benner A, et al: Genomic aberrations and survival in chronic lymphocytic leukemia. N Engl J Med. 2000 Dec;343(26):1910-1916
3. Van Dyke DL, Shanafelt TD, Call TG, et al: A comprehensive evaluation of the prognostic significance of 13q deletions in patients with B-chronic lymphocytic leukaemia. Br J Haematol. 2010;148:544-550
4. Shanafelt TD: Predicting clinical outcome in CLL: how and why. Hematology Am Soc Hematol Educ Program. 2009;421-429
5. 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 Apr;173(1):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 fluorescence in situ hybridization (D-FISH) strategy probe set is used to detect *CCND1/IGH* rearrangements and for reflex testing to identify *IGH*/*BCL3* rearrangements. For enumeration strategy probe sets, 100 interphase nuclei are scored; 200 interphase nuclei are scored when D-FISH probes are used. Two technologists analyze each probe set and all results are 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

4 weeks

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
88275 x 1
88291 - FISH Probe, Analysis, Interpretation; 1 probe set
88271 x 2 (if appropriate)
88275 x1 - FISH Probe, Analysis; each additional probe set (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CLLMF	CLL, Specified FISH	101920-7

Result ID	Test Result Name	Result LOINC® Value
610725	Result Summary	50397-9
610726	Interpretation	69965-2
610727	Result Table	93356-4
610728	Result	62356-1
GC091	Reason for Referral	42349-1
GC092	Specimen	31208-2
610729	Source	31208-2
610730	Method	85069-3
610731	Additional Information	48767-8
610732	Disclaimer	62364-5
610733	Released by	18771-6
GC093	Probes Requested	78040-3