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 BCL2, BCL3, or other partner genes

Reflex Tests

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<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
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Testing Algorithm

This test includes a charge for application of the first probe set (2 FISH probes) and professional interpretation of results. Additional charges will be incurred 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. See the Method Description for specific details.

Indicate if the entire panel is to be performed. The entire panel is suggested for patients with a new diagnosis of chronic lymphocytic leukemia (CLL). If the patient is being tracked for known abnormalities or disease progression, 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 will be performed to identify the translocation partner. Probes include identification of t(14;18)(q32;q21) **IGH/BCL2** and t(14;19)(q32;q13) **IGH/BCL3**.

This assay detects abnormalities observed in the blood and bone marrow of patients with 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

**Advisory Information**
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 referral 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**: Green top (sodium heparin)

**Specimen Volume**: 7-10 mL

**Collection Instructions**: Invert several times to mix blood.

**Specimen Type**: Bone marrow

**Container/Tube**: Green top (sodium heparin)

**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

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<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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Clinical and Interprete

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 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 referral 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; approximately 66% of these patients have translocations that result in fusion of IGH/CCND1, IGH/BCL2, or IGH/BCL3. Fusion of IGH and CCND1 is associated with t(11;14)(q13;q32), IGH and BCL2 with t(14;18)(q32;q21), and IGH and BCL3 with t(14;19)(q32;q13.3). Patients with t(11;14)(q13;q32) usually have the leukemic phase of mantle cell lymphoma. Patients with t(14;18) or 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**


**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 IGH/BCL2 and IGH/BCL3 rearrangements. For enumeration strategy probe sets, 200 interphase nuclei are scored; 500 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. 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

**PDF Report**

No

**Day(s) and Time(s) Test Performed**

Specimens are processed Monday through Sunday.

Results reported Monday through Friday, 8 a.m.-5 p.m.

**Analytic Time**
Test Definition: CLLF
CLL, FISH

7 days

Maximum Laboratory Time
10 days

Specimen Retention Time
4 weeks

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
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 x 1-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

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