Overview

Useful For
Confirming the presence or absence of minimal residual disease in patients with known chronic lymphocytic leukemia who are either postchemotherapy or post-bone marrow transplantation

Reflex Tests

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>FCINT</td>
<td>Flow Cytometry Interp, 2-8 Markers</td>
<td>No, (Bill Only)</td>
<td>No</td>
</tr>
</tbody>
</table>

Additional Tests

<table>
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<th>Reporting Name</th>
<th>Available Separately</th>
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<tbody>
<tr>
<td>FIRST</td>
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<td>Yes</td>
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<tr>
<td>ADD1</td>
<td>Flow Cytometry, Cell Surface, Addl</td>
<td>No, (Bill Only)</td>
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</table>

Testing Algorithm
When this test is ordered, flow cytometry interpretation, 2 to 8 markers will be performed at an additional charge.

Method Name
Immunophenotyping

NY State Available
Yes

Specimen

Specimen Type
Varies

Advisory Information
The preferred test for evaluating any tissue biopsy for a potential lymphoproliferative disorder is LLPT / Leukemia/Lymphoma Immunophenotyping, Flow Cytometry, Tissue.

The preferred test for a first-time evaluation of a patient with lymphocytosis is a routine flow cytometric assay (LCMS / Leukemia/Lymphoma Immunophenotyping, Flow Cytometry, Varies).

Additional Testing Requirements
If cytogenetic tests are also desired, when collecting for this test an additional specimen should be submitted. It is important that the specimen be obtained, processed, and transported according to instructions for the other required
Test Definition: CLLMV
CLL Monitoring MRD Detection, V

Specimen Required
Submit only 1 of the following specimens:

Specimen Type: Blood

Container/Tube:
Preferred: Yellow top (ACD solution A or B)
Acceptable: Sodium heparin, EDTA

Specimen Volume: 10 mL

Slides: Include 5- to 10-unstained blood smears, if possible.

Collection Instructions: Do not transfer blood to other containers.

Specimen Type: Bone Marrow

Container/Tube:
Preferred: Yellow top (ACD solution A or B)
Acceptable: Sodium heparin, EDTA

Specimen Volume: 1-5 mL

Slides: Include 5- to 10-unstained bone marrow aspirate smears, if possible.

Collection Instructions:
1. Submission of bilateral specimens in not required.
2. Label specimen appropriately (bone marrow)

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

Specimen Minimum Volume
Blood: 4 mL
Bone Marrow: 1 mL

Reject Due To

<table>
<thead>
<tr>
<th>Condition</th>
<th>Action</th>
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<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject</td>
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<tr>
<td>Gross lipemia</td>
<td>OK</td>
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</table>
Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Varies</td>
<td>Ambient (preferred)</td>
<td>72 hours</td>
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</tr>
<tr>
<td></td>
<td>Refrigerated</td>
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Clinical and Interpretive

Clinical Information

Chronic lymphocytic leukemia (CLL) is a low-grade, B-cell neoplasm that is the most common leukemia detected in the western world. It is a disease primarily of adults and may present as a lymphocytosis, be detected as part of a lymphadenopathy evaluation, or be found incidentally in an otherwise asymptomatic patient. The diagnosis of CLL is based on a combination of morphologic features showing primarily small lymphoid cells with coarse chromatin and scant cytoplasm and an immunophenotype of clonal B-cells with dim immunoglobulin, dim CD20, and coexpression of CD5 and CD23.

New therapeutic approaches in CLL have been increasingly successful with some patients showing no or only very minimal residual disease (MRD) in their peripheral blood or bone marrow specimens following a therapeutic course. Immunophenotyping studies are necessary as morphologic features are not sufficient to detect MRD. The absence of MRD is an important prognostic indicator in these patients.

Reference Values

An interpretive report will be provided.

This test will be processed as a laboratory consultation. An interpretation of the immunophenotypic findings and correlation with the morphologic features will be provided by a hematopathologist for every case.

Interpretation

An interpretive report for presence or absence of minimal residual disease (MRD) for chronic lymphocytic leukemia (CLL) is provided.

Individuals without CLL should not have detectable clonal B cells in the peripheral blood or bone marrow.

Patients who have detectable MRD by this assay are considered to have residual CLL disease.

Cautions

This test is only appropriate for patients who have a previously confirmed diagnosis of chronic lymphocytic leukemia.

Supportive Data

This assay has been used in several clinical trials at Mayo Clinic evaluating response to therapies in chronic lymphocytic leukemia (CLL). In total, 421 specimens have been analyzed for CLL minimal residual disease (MRD) with this assay; 316 had MRD present and 105 had no detectable MRD. Of the 316 with MRD, 136 had less than 1.0% MRD with 18 at 0.01% detectable MRD (assay sensitivity). Of the 136, 123 had direct correlations with the routine clinical flow cytometric screening assay. Of those 123 cases, 63 had similar findings by both techniques, while 60 had detectable clonal B cells only with the CLL MRD assay.

Clinical Reference

2. Varghese AM, Rawstron AC, Hillmen P: Eradicating minimal residual disease in chronic lymphocytic leukemia: should this be the goal of treatment? Curr Hematol Malig Rep 2010;5:35-44


**Performance**

**Method Description**

Flow cytometric immunophenotyping (high sensitivity) of peripheral blood and bone marrow is performed to evaluate the presence or absence of chronic lymphocytic leukemia minimal residual disease using the following antibodies:


**PDF Report**

No

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

Specimens are processed and reported Monday through Saturday

**Analytic Time**

1 day

**Maximum Laboratory Time**

4 days

**Specimen Retention Time**

4 days

**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
88184-Flow cytometry; first cell surface, cytoplasmic or nuclear marker
88185 x 7-Flow cytometry; additional cell surface, cytoplasmic or nuclear marker (each)
88187-Flow Cytometry Interpretation, 2 to 8 markers

LOINC® Information

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<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tr>
<td>CLLMV</td>
<td>CLL Monitoring MRD Detection, V</td>
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