

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

Test Id	Reporting Name	Available Separately	Always Performed
FCINT	Flow Cytometry Interp, 2-8 Markers	No, (Bill Only)	No

Additional Tests

Test Id	Reporting Name	Available Separately	Always Performed
FIRST	Flow Cytometry, Cell Surface, First	No, (Bill Only)	Yes
ADD1	Flow Cytometry, Cell Surface, Addl	No, (Bill Only)	Yes

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

Ordering Guidance

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.

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 is 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

Gross hemolysis	Reject
Gross lipemia	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Ambient (preferred)	72 hours	
	Refrigerated	72 hours	

Clinical & 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

1. Hallek M, Cheson BD, Catovsky D, et al: Guidelines for the diagnosis and treatment of chronic lymphocytic leukemia: a report from the International Workshop on chronic lymphocytic leukemia updating the National Cancer Institute-Working Group 1996 guidelines. *Blood* 2008;111:5446-5456
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
3. Shanafelt TD: Predicting clinical outcome in CLL: how and why. *Hematology Am Soc Hematol Educ Program* 2009;421-429
4. Sayala HA, Rawstron AC, Hillmen P: Minimal residual disease assessment in chronic lymphocytic leukaemia. *Best Pract Res Clin Haematol* 2007;20:499-512
5. Rawstron AC, Villamor N, Ritgen M, et al: International standardized approach for flow cytometric residual disease monitoring in chronic lymphocytic leukaemia. *Leukemia* 2007;21:956-964
6. Moreton P, Kennedy B, Lucas G, et al: Eradication of minimal residual disease in B-cell chronic lymphocytic leukemia after alemtuzumab therapy is associated with prolonged survival. *J Clin Oncol* 2005;23:2971-2979

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: CLLM Panel: CD5, CD19, CD20, CD23, CD38, CD45, and kappa and lambda light chains. (Flow Cytometry in Clinical Diagnosis. Fourth edition. Edited by P Keren, JP McCoy Jr, J Carey. ASCP Press, Chicago, IL, 2007)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

1 to 4 days

Specimen Retention Time

4 days

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 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 US 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

Test ID	Test Order Name	Order LOINC® Value
CLLMV	CLL Monitoring MRD Detection, V	In Process

Result ID	Test Result Name	Result LOINC® Value
CK141	Final Diagnosis	50398-7
CK142	Special Studies	30954-2
CK143	Microscopic Description	22635-7
CK140	CLLMV Result	No LOINC Needed