

Notification Date: February 14, 2023 Effective Date: March 28, 2023

Chronic Lymphocytic Leukemia (CLL) Monitoring Minimal Residual Disease Detection, Flow Cytometry, Varies

Test ID: CLLMD

Useful for:

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

Methodology:

Immunophenotyping for Minimal Residual Disease (MRD)

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.

Specimen Requirements:

Submit only 1 of the following specimens:

Specimen Type: Whole Blood

Container/Tube:

Preferred: Yellow top (ACD solution A or B)

Acceptable: Lavender top (EDTA)

Specimen Volume: 6 mL

Slides: If possible, include 5- to 10-unstained blood smears labeled with two unique identifiers

Collection Instructions:

- 1. Send whole blood specimen in original tube. Do not aliquot.
- 2. Label specimen as blood.

Specimen Type: Bone Marrow

Container/Tube:

Preferred: Yellow top (ACD solution A or B)

Acceptable: Lavender top (EDTA)

Specimen Volume: 6 mL

Slides: If possible, include 5 to 10 unstained bone marrow aspirate smears labeled with two unique identifiers.

Collection Instructions:

- 1. Submission of bilateral specimens is not required.
- 2. Send bone marrow specimen in original tube. Do not aliquot.
- 3. Label specimen as bone marrow.

Specimen Stability Information:

Specimen Type	Temperature	Time
Varies	Ambient (preferred)	4 days
	Refrigerated	4 days

Method Description:

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

CLL, MRD Panel: CD5, CD19, CD20, CD22, CD38, CD43, CD45, CD200, and kappa and lambda light chains.

The sensitivity of this assay is 0.002% (2 x 10[-5]) based on 1,000,000 total events collected and an abnormal cell immunophenotype detected in a cluster of at least 20 cells. The assay sensitivity meets or exceeds the 0.01-0.001% (10[-4]-10[-5]) level of detection by flow cytometry, as recommended by the current ERIC method and NCCN guidelines for MRD analysis in CLL.(Keren P, McCoy Jr JP, Carey J eds: Flow Cytometry in Clinical Diagnosis. 4th ed. ASCP Press; 2007; NCCN Clinical Practice Guidelines in Oncology [NCCN Guidelines] Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, Version 3.2022. Updated June 3, 2022)

Cautions

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

CPT Code:

88184-Flow cytometry; first cell surface, cytoplasmic or nuclear marker 88185 x 9-Flow cytometry; additional cell surface, cytoplasmic or nuclear marker (each) 88188-Flow Cytometry Interpretation, 9 to 15 markers

Day(s) Performed: Monday through Saturday **Report Available:** 1 to 4 days

Questions

Contact Connie Penz, Laboratory Technologist Resource Coordinator at 800-533-1710.