MAYO CLINIC LABORATORIES

Test Definition: BALLM

B-Cell Lymphoblastic Leukemia Monitoring, Measurable/Minimal Residual Disease Detection, Flow Cytometry, Varies

Overview

Useful For
Aids in monitoring a previously confirmed diagnosis of B-cell acute lymphoblastic leukemia

Testing Algorithm
For information see Acute Leukemias of Ambiguous Lineage Testing Algorithm.

Special Instructions
- Acute Leukemias of Ambiguous Lineage Testing Algorithm

Method Name
Immunophenotyping

NY State Available
Yes

Specimen

Specimen Type
Varies

Additional Testing Requirements
If cytogenetic tests are also desired 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.

Shipping Instructions
Specimens must be received within 72 hours of collection.

Necessary Information
A copy of the diagnostic flow cytometry report is required.

Specimen Required
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
Collection Instructions:
1. Send whole blood specimen in original tube. **Do not aliquot**.
2. Label specimen as whole blood.

Specimen Type: Bone marrow
Container/Tube:
Preferred: Yellow top (ACD solution A or B)
Acceptable: Lavender top (EDTA), green top (sodium heparin)
Specimen Volume: 6 mL
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.

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

Specimen Minimum Volume
Whole blood: 2 mL
Bone marrow: 1 mL

Reject Due To

Gross hemolysis	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Ambient	72 hours	

Clinical & Interpretive

Clinical Information
B-cell acute lymphoblastic leukemia (B-ALL) is a neoplasm of precursor cells (lymphoblasts) committed to B-cell lineage. B-ALL is the most common acute leukemia in children and adolescents and can also occur in adults. Patients with B-ALL typically present with a high blast count in the peripheral blood and bone marrow. The diagnosis of B-ALL is based on a combination of morphologic features showing primarily small blasts with open chromatin and high N:C ratio, and an immunophenotype showing immaturity (CD34 and/or TdT expression) associated with B-cell lineage markers (CD19, CD22, and CD79a).

New therapeutic approaches in B-ALL have been increasingly successful. One of the most important predictors of the disease relapse is the ability to detect measurable residual disease (MRD) in bone marrow specimens following induction phase of the therapy (day 28). Immunophenotyping studies are necessary as morphologic features are not sufficient to detect MRD. The absence of MRD (at 0.002% sensitivity) is an important prognostic indicator in these patients.

This test may also be used to establish an immunophenotypic fingerprint of tumor cells at diagnosis to monitor MRD in these patients after treatments or allogeneic stem cell transplant.

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 the presence or absence of B-cell acute lymphoblastic leukemia (B-ALL) measurable residual disease (MRD) is provided. Patients who have detectable MRD by this assay are considered to have residual/recurrent B-ALL.

Cautions

This test is only appropriate for patients with a previous confirmed diagnosis of B-cell acute lymphoblastic leukemia. Treatment with antibodies to CD19 may interfere with the ability to detect measurable residual disease.

Supportive Data

Sixty-seven patient samples were analyzed with 38 of these showing no measurable residual disease (MRD). Three of these had levels greater than 20% acute lymphoblastic leukemia involvement. Eleven of these had 0.13% to 10.0% MRD involvement. The 15 with the lowest percent MRD involvement ranged from 0.003% to 0.08%. In addition, 25 normal bone marrows showed no MRD.

Clinical Reference

1. Bader P, Kreyenberg H, Henze GH, et al. Prognostic value of minimal residual disease quantification before allogeneic stem-cell transplantation in relapsed childhood acute lymphoblastic leukemia: the ALL-REZ BFM Study Group. J Clin Oncol. 2009;27(3):377-384
2. Borowitz MJ, Devidas M, Hunger SP, et al. Clinical significance of minimal residual disease in childhood acute lymphoblastic leukemia and its relationship to other prognostic factors: a Children's Oncology Group study. Blood. 2008;111(12):5477-5485
3. Borowitz MJ, Pullen DJ, Winick N, Martin PL, Bowman WP, Camitta B. Comparison of diagnostic and relapse flow cytometry phenotypes in childhood acute lymphoblastic leukemia: implications for residual disease detection: a report from the children's oncology group. Cytometry B Clin Cytom. 2005;68(1):18-24
4. Campana D. Role of minimal residual disease monitoring in adult and pediatric acute lymphoblastic leukemia. Hematol Oncol Clin North Am. 2009;23(5):1083-vii
5. Chen W, Karandikar NJ, McKenna RW, Kroft SH. Stability of leukemia-associated immunophenotypes in precursor B-lymphoblastic leukemia/lymphoma: a single institution experience. Am J Clin Pathol. 2007;127(1):39-46
6. Coustan-Smith E, Ribeiro RC, Stow P, et al. A simplified flow cytometric assay identifies children with acute

lymphoblastic leukemia who have a superior clinical outcome. Blood. 2006;108(1):97-102
7. Coustan-Smith E, Sancho J, Behm FG, et al. Prognostic importance of measuring early clearance of leukemic cells by flow cytometry in childhood acute lymphoblastic leukemia. Blood. 2002;100(1):52-58
8. Guillaume N, Penther D, Vaida I, et al. CD66c expression in B-cell acute lymphoblastic leukemia: strength and weakness. Int J Lab Hematol. 2011;33(1):92-96
9. Stow P, Key L, Chen X, et al. Clinical significance of low levels of minimal residual disease at the end of remission induction therapy in childhood acute lymphoblastic leukemia. Blood. 2010;115(23):4657-4663
10. Wood BL. Principles of minimal residual disease detection for hematopoietic neoplasms by flow cytometry. Cytometry B Clin Cytom. 2016;90(1):47-53

Performance

Method Description

Flow cytometric immunophenotyping (high sensitivity) of bone marrow is performed to evaluate the presence or absence of B lymphoblastic leukemia minimal residual disease using the following antibodies: BALLM Panel: CD10, CD19, CD20, CD22, CD24, CD34, CD38, CD45, CD58, and CD66c.(Cherian S, Miller V, McCullouch V, Dougherty K, Fromm JR, Wood BL. A novel flow cytometric assay for detection of residual disease in patients with B-lymphoblastic leukemia/lymphoma post anti-CD19 therapy. Cytometry B Clin Cytom. 2018;94(1):112-120)

PDF Report

No

Day(s) Performed

Preanalytical processing: Monday through Saturday
Results reported: Monday through Friday

Report Available

1 to 4 days

Specimen Retention Time

14 days

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Main Campus

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 and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It 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 9-Flow cytometry; additional cell surface, cytoplasmic or nuclear marker (each)
88188-Flow Cytometry Interpretation, 9 to 15 Markers

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
BALLM	B-ALL Monitoring, MRD Detection, V	102084-1

Result ID	Test Result Name	Result LOINC® Value
CK173	BALLM Result	No LOINC Needed
CK174	Final Diagnosis	22637-3
CK175	Special Studies	30954-2
CK176	Microscopic Description	22635-7