Test Definition: BALLM

B-ALL Monitoring, MRD Detection, BM

Overview

Useful For

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

Testing Algorithm

See Acute Leukemias of Ambiguous Lineage Testing Algorithm Â in Special Instructions

Special Instructions

- Acute Leukemias of Ambiguous Lineage Testing Algorithm

Method Name

Immunophenotyping

NY State Available

Yes

Specimen

Specimen Type

Bone Marrow

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.

Specimen Required

Container/Tube:

Preferred: Yellow top (ACD solution A or B)
Acceptable: Lavender top (EDTA), green top (sodium heparin)
Specimen Volume: 3 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).

Specimen Minimum Volume

1 mL

Reject Due To

Gross hemolysis	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Bone Marrow	Ambient	72 hours	

Clinical and Interpretive

Clinical Information

B-cell lymphoblastic leukemia/lymphoma (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 also occurs in adults. Patients with B-ALL typically present with a high blast count in the peripheral blood and bone marrow replacement with the disease. 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 minimal residual disease (MRD) in the 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 lymphoblastic leukemia (B-ALL) minimal 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 who have a previous confirmed diagnosis of B-cell lymphoblastic leukemia. Treatment with antibodies to CD19 may interfere with the ability to detect minimal residual disease (MRD).

Supportive Data

Sixty seven patient samples were analyzed with 38 of these showing no measurable minimal residual disease (MRD). Three of these had levels greater than 20% ALL 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: ALL-REZ BFM Study Group. 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;27:377-384

2. Borowitz MJ, Devidas M, Hunger SP, et al: Children's Oncology Group. 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;111:5477-5485

3. Borowitz MJ, Pullen DJ, Winick N, et al: 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;68:18-24

4. Campana D: Role of minimal residual disease monitoring in adult and pediatric acute lymphoblastic leukemia. Hematol Oncol Clin North Am 2009;23:1083-1098

5. Chen W, Karadikar NJ, McKenna RW, Kroft SH: Stability of leukemia-associated immunophenoypes in precursor B-lymphoblastic leukemia/lymphoma. a single institution experience. Am J Clin Pathol 2007;127:39-46

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;108:97-102

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;100:52-58

8. Guillaume N, Penther D, Vaida I, et al: CD66c expression in B-cell lymphoblastic leukemia: strength and weakness. Int J Lab Hematol 2011;33:92-96

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;115:4657-4663

10. Wood BL: Principals of minimal residual disease detection for hematopoietic neoplasms by flow cytometry. Cytometry B Clin Cytom 2016;90:47-53

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, et al: 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;94B:112-120)

PDF Report

No

Day(s) and Time(s) Test Performed

Specimens are processed Monday through Sunday and reported Monday through Friday

Analytic Time

1 day

Maximum Laboratory Time

4 days

Specimen Retention Time

14 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 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, BM	In Process

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