Overview

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

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>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
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</thead>
<tbody>
<tr>
<td>FIRST</td>
<td>Flow Cytometry, Cell Surface, First</td>
<td>No, (Bill Only)</td>
<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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</tr>
</tbody>
</table>

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

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.

Specimen Required

Container/Tube:
Test Definition: ALLM  
B-ALL Monitoring, MRD Detection, BM

**Preferred:** Yellow top (ACD solution A or B)  
**Acceptable:** EDTA, 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).

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

**Specimen Minimum Volume**  
1 mL

**Reject Due To**

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>Reject</th>
</tr>
</thead>
<tbody>
<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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</thead>
<tbody>
<tr>
<td>Bone Marrow</td>
<td>Ambient</td>
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</table>

**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 0.01% sensitivity) is an important prognostic indicator in these patients.

This test is used to establish an antigen footprint of tumor cells at diagnosis to monitor minimal residual disease in these patients after treatments or transplants.

**Reference Values**  
An interpretive report will be provided.
Test Definition: ALLM
B-ALL Monitoring, MRD Detection, BM

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
Thirty-three patient samples were analyzed with 14 of these showing no measurable minimal residual disease (MRD). Nine of these had levels greater than 50% ALL involvement. Six of these had 2.19% to 24.39% MRD involvement. The 4 with the lowest percent MRD involvement were 0.2%, 0.05%, 0.02%, and 0.01% (assay sensitivity).

Clinical Reference


### 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:


#### 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

#### 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
# Test Definition: ALLM

## B-ALL Monitoring, MRD Detection, BM

### LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>ALLM</td>
<td>B-ALL Monitoring, MRD Detection, BM</td>
<td>In Process</td>
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</table>

<table>
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<tbody>
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<td>CK089</td>
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