Department of Medical and Molecular Genetics
Division of Diagnostic Genomics

Laboratory Test Directory

FISH Analysis – Acute Lymphoblastic Leukemia (ALL)

CPT Code(s): 88237, 88275, 88271 (x per probe)

Service Code (IU Health): 53101259, 53100707, 53100640

Ordering Recommendation: For pediatric and adult acute lymphoblastic leukemia (ALL) and is useful for detection of known or suspected genetic abnormalities to confirm or establish diagnosis and prognostic grouping important for subsequent therapy. Companion testing with chromosome analysis is recommended.

Synonyms: FISH, Hematopoietic malignancy, acute lymphocytic leukemia, ALL, acute lymphoblastic leukemia.

Methodology: Fluorescence in situ hybridization (FISH) analysis.

Performed: Monday through Friday

Reported: 2-3 days

Panels: ALL Panel - 4/10/17 centromeres, 9p21(CDKN2A)/9cen, t(9;22)(BCR/ABL/ASS), 11q23(MLL), t(12;21)(ETV6-RUNX1). Each probe may be run individually.

Specimen Requirements

Patient Preparation: None

Collect: Non-diluted bone marrow aspirate in sodium heparin vacutainer, heparinized syringe or flask with sterile media (provided upon request).

Specimen Volume: Preferred: 2 mL for normal WBC (decreased WBC requires more, elevated WBC requires less); 0.5 mL (minimum).

Storage/Transport: Room temperature. Do not freeze or expose to extreme temperatures.

Unacceptable Conditions: Frozen specimens. Formalin-fixed specimens.

Stability: Ambient: 48 hours; Frozen: Unacceptable
Interpretive Data

**Characteristics:** Negative (Normal) – no evidence of BCR/ABL1 t(9;22), MLL rearrangement, TEL/AML rearrangement, or copy number gain with CEP4, CEP10 and/or CEP17
Positive (Abnormal) – one or more of the above rearrangements or anomalies detected

**Reference Interval:** When the percent of cells with an abnormality exceeds the normal reference range for any given probe, it is considered an abnormal clone. Absence of an abnormal clone does not rule out the possibility of a neoplastic disorder. The normal range varies with each observed signal pattern and is listed in the table below. A report detailing interpretation of results will be provided.

<table>
<thead>
<tr>
<th>Probe Name</th>
<th>Normal Range (%)</th>
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<tbody>
<tr>
<td>4cen, 10cen, 17cen</td>
<td>0 – 6.0</td>
</tr>
<tr>
<td>9p21/9cen</td>
<td>0 – 4.0</td>
</tr>
<tr>
<td>9q34/22q11.2 (ABL1, ASS, BCR)</td>
<td>0 – 7.0</td>
</tr>
<tr>
<td>11q23 (MLL)</td>
<td>0 – 5.5</td>
</tr>
<tr>
<td>12p13/21q22 (ETV6/RUNX1)</td>
<td>0 – 5.5</td>
</tr>
</tbody>
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**Incidence:** 1.5/100,000
Most common leukemia in childhood with a peak incidence at 2-5 years.

**Limitations:** The probes in this FISH panel detect only specific aberrations. Chromosomal alterations present outside the regions targeted by the probes will not be detected.

**References:**


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