MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: November 12, 2021
Effective Date: December 13, 2021

B-Cell Acute Lymphoblastic Leukemia/Lymphoma (ALL), Pediatric, FISH, Varies

Test ID: BALPF

Useful for:

Evaluation of pediatric bone marrow and peripheral blood specimens by fluorescence in situ hybridization probe analysis for classic rearrangements and chromosomal copy number changes associated with B-cell acute lymphoblastic leukemia/lymphoma (B-ALL) and Philadelphia chromosome-like acute lymphoblastic leukemia (Ph-like ALL)

As an adjunct to conventional chromosome studies in performed in pediatric patients with B-ALL and Ph-like ALL

Evaluating specimens in which standard cytogenetic analysis is unsuccessful

Testing Algorithm:

This test includes a charge for the probe application, analysis, and professional interpretation of results for 11 probe sets (23 individual fluorescence in situ hybridization [FISH] probes). Additional charges will be incurred for all reflex or additional probe sets performed.

If the patient clinically relapses, a conventional chromosome study is useful to identify cytogenetic changes in the neoplastic clone or the possible emergence of a new therapy-related myeloid clone.

The standard (diagnostic) pediatric/young adult B-cell acute lymphoblastic leukemia (B-ALL) FISH panel includes testing for the following abnormalities using the FISH probes listed:
+9/9p-, CDKN2A/D9Z1
t(9;22) BCR/ABL1
11q23 rearrangement, MLL (KMT2A) break-apart
-17/17p-, TP53/D17Z1
t(1;19)(q23;p13), PBX1/TCF3
Hyperdiploidy, +4,+10,+17: D4Z1/D10Z1/D17Z1
t(12;21)(p13;q22), ETV6/RUNX1 fusion, iAMP21
14q32 rearrangement, IGH break-apart
t(Xp22.33;var) or t(Yp11.32;var), P2RY8 rearrangement
t(Xp22.33;var) or t(Yp11.32;var), CRLF2 rearrangement
8q24.1 rearrangement, MYC break-apart

If the standard (diagnostic) pediatric/young adult B-ALL FISH panel demonstrates normal or nonclassical abnormalities, the Philadelphia chromosome-like acute lymphoblastic leukemia (Ph-like ALL) panel will be performed.

The Ph-like ALL panel includes testing for the following kinase activating chromosome abnormalities, using the FISH probes listed below as well as *IKZF1* deletion which often accompanies Ph-like ALL:
1q25 rearrangement, ABL2 break-apart
5q33 rearrangement, PDGFRB break-apart
9p24.1 rearrangement, JAK2 break-apart
9q34 rearrangement, ABL1 break-apart
7p-, IKZF1/CEP7

When an MLL (KMT2A) rearrangement is identified, reflex testing will be performed to identify the translocation partner. Probes include identification of:
t(4;11)(q21;q23) AFF1/MLL
t(6;11)(q27;q23) MLLT4(AFDN)/MLL
t(9;11)(p22;q23) MLLT3/MLL
t(10;11)(p12;q23) MLLT10/MLL
t(11;19)(q23;p13.1) MLL/ELL
t(11;19)(q23;p13.3) MLL/MLLT1

When an IGH and/or CRLF2 rearrangement is identified, reflex testing will be performed using the CRLF2/IGH fusion probe set to identify a potential t(X;14)(p22.33;q32) or t(Y;14)(p11.32;q32) cryptic translocation.

In the absence of BCR/ABL1 fusion, when an extra ABL1 signal is identified, reflex testing will be performed using the ABL1 break-apart probe set to evaluate for the presence or absence of an *ABL1* rearrangement.

In the absence of ETV6/RUNX1 fusion, when an extra ETV6 signal is identified, reflex testing will be performed using the ETV6 break-apart probe set to evaluate for the presence or absence of an *ETV6* rearrangement.

If a MYC rearrangement is identified, both the BCL2 and BCL6 probe sets will be performed.

Reflex Tests:

Test ID	Reporting Name	Available Separately	Always Performed
BALPB	Probe, Each Additional (BALPF)	No (Bill Only)	No

Methods:
Fluorescence In Situ Hybridization (FISH)

Reference Values:
An interpretive report will be provided.

Specimen Requirements:

Preferred Specimen Type: Bone marrow

Preferred Container/Tube: Yellow top (ACD)

Acceptable Container/Tube: Green top (heparin) or lavender top (EDTA)

Specimen Volume: 2-3 mL

Minimum Volume: 1 mL

Collection Instructions:

1. It is preferable to send the first aspirate from the bone marrow collection.
2. Invert several times to mix bone marrow.

Acceptable Specimen Type: Blood

Preferred Container/Tube: Yellow top (ACD)

Acceptable Container/Tube: Green top (heparin) or lavender top (EDTA)

Specimen Volume: 6 mL

Minimum Volume: 2 mL

Collection Instructions:

1. Invert several times to mix blood.

Note:
1. A reason for testing and a flow cytometry and/or a bone marrow pathology report should be submitted with each specimen. The laboratory will not reject testing if this information is not provided, however appropriate testing and/or interpretation may be compromised or delayed in some instances. If this information is not provided, an appropriate indication for testing may be entered by Mayo Clinic Laboratories.

2. If the patient has received an opposite sex bone marrow transplant, note this information on the request.

Specimen Stability Information:

Specimen Type	Temperature	Time
Varies	Ambient (preferred)	
	Refrigerated	

Cautions:

This test is not approved by the US Food and Drug Administration, and it is best used as an adjunct to existing clinical and pathologic information.

Fluorescence in situ hybridization (FISH) is not a substitute for conventional chromosome studies because the latter detects many chromosome abnormalities associated with other hematological disorders that would be missed by this FISH panel test.

Bone marrow is the preferred specimen type for this FISH test. If bone marrow is not available, a blood specimen may be used if there are malignant cells in the blood specimen (as verified by a hematopathologist).

CPT Code:

88271 x 23, 88275 x 11, 88291 x 1-FISH Probe, Analysis, Interpretation; 11 probe sets

88271 x 2, 88275 x 1-FISH Probe, Analysis; each additional probe set (if appropriate)

Day(s) Performed: Monday through Friday **Report Available:** 7 to 10 days

Questions

Contact Joshua Couchene Laboratory Technologist Resource Coordinator at 800-533-1710.