

Congenital Infantile Leukemia, FISH, Tissue

Test ID: CILPF

Useful for:

Detecting a neoplastic clone associated with the common chromosome abnormalities and classic rearrangements seen in infant patients with leukemia using tissue specimens.

Testing Algorithm:

This test includes a charge for application of the first probe set (2 fluorescence in situ hybridization [FISH] probes) and professional interpretation of results. Additional charges will be incurred for all reflex probes performed. Analysis charges will be incurred based on the number of cells analyzed per probe set. If no cells are available for analysis, no analysis charges will be incurred.

This FISH test allows different combinations of probes to be utilized based on the patient's age and clinical question, per client request.

All probes marked with an asterisk* will be performed as reflex testing, without notification, if the corresponding region was disrupted or potentially disrupted. Patients found to have a MYC rearrangement will be reflexed to the break-apart BCL6 and BCL2 probe sets. Patients found to have 3 copies of KAT6A will be reflexed with D8Z2/MYC.

The FISH panel for patients **younger than 3 months** includes testing for the following abnormalities using the FISH probes listed:

11q23 rearrangement, MLL (KMT2A)

*t(4;11)(q21;q23) AFF1/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-

t(8;16), [M4,M5], KAT6A/CREBBP

*D8Z2/MYC for trisomy 8

t(1;22), [M7], RBM15/MKL1

+13/+21, 13q14 and 21q22

If no classic abnormalities are observed, other FISH probes may be offered by the laboratory.

The FISH panel is dependent on the reason for testing and the patient's diagnosis (acute myeloid leukemia [AML], B-cell acute lymphoblastic leukemia [ALL], or T-cell ALL).

The initial FISH panel for patients **3 months to 18 months of age** with AML includes testing for the following abnormalities:

11q23 rearrangement, MLL (KMT2A)

*t(4;11)(q21;q23) AFF1/MLL

*t(9;11)(p22;q23) MLLT3/MLL

*t(10;11)(p12;q23) MLLT10/MLL

*t(11;19)(q23;p13.1) MLL/ELL

If an MLL disruption is not identified, the following secondary AML FISH probes will be evaluated:

inv(16), [M4, Eos], MYH11/CBFB

t(8;21), [M2], RUNX1T1/RUNX1

t(15;17), [M3], PML/RARA

12p13 rearrangement, ETV6 break-apart

*t(7;12)(q36;p13), MNX1/ETV6

t(8;16), [M4,M5], KAT6A/CREBBP

inv(16), GLIS2/CBFA2T3

11p15.4 rearrangement, NUP98 break-apart

t(1;22), [M7], RBM15/MKL1

The initial FISH panel for patients **3 to 18 months of age** with B-cell ALL includes testing for the following abnormalities:

11q23 rearrangement, MLL (KMT2A)

*t(4;11)(q21;q23) AFF1/MLL

*t(9;11)(p22;q23) MLLT3/MLL

*t(10;11)(p12;q23) MLLT10/MLL

*t(11;19)(q23;p13.3) MLL/MLLT1

If an MLL disruption is not identified, the following secondary panel of B-cell ALL FISH probes will be evaluated:

+9/9p-, CDKN2A/D9Z1

t(9;22) BCR/ABL1 fusion

-17/17p-, TP53/D17Z1

t(1;19)(q23;p13), PBX1/TCF3 fusion

Hyperdiploidy, +4,+10,+17: D4Z1/D10Z1/D17Z1

t(12;21)(p13;q22), ETV6/RUNX1 fusion and iAMP21

*12p13 rearrangement, ETV6 break-apart

14q32 rearrangement, IGH break-apart

8q24.1 rearrangement, MYC

*3q27 rearrangement, BCL6 break-apart

*18q21 rearrangement, BCL2 break-apart

If a classic B-cell ALL abnormality was not been identified in the first 11 probes analyzed, the following tertiary panel of B-cell ALL FISH probes will be evaluated, 9p24.1 rearrangement, JAK2

The initial FISH panel for patients **3 to 18 months of age** with T-cell ALL includes testing for the following abnormalities:

11q23 rearrangement, MLL (KMT2A)

*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;p13.3) MLL/MLLT1
 *t(11;19)(q23;p13.1) MLL/ELL

If an MLL disruption is not identified, the following secondary panel of T-cell ALL FISH probes will be evaluated:

+9/9p-, CDKN2A/D9Z1
 t(9;22) BCR/ABL1
 -17/17p-, TP53/D17Z1
 t(5;14), TLX3/BCL11B
 7q34 rearrangement, TRB
 *t(7;10) - TRB/TLX1
 14q11.2 rearrangement, TRAD
 *t(10;14) - TLX1/TRAD
 t(10;11), MLLT10/PICALM
 1p33 rearrangement, TAL1/STIL

Reflex Tests:

Test ID	Reporting Name	Available Separately	Always Performed
_PADD	Probe, +1	No (Billy Only)	No
_PB02	Probe, +2	No (Billy Only)	No
_PB03	Probe, +3	No (Billy Only)	No
_PBCT	Probe, +2	No (Billy Only)	No
_IL25	Interphases, <25	No (Billy Only)	No
_I099	Interphases, 25-99	No (Billy Only)	No
_I300	Interphases, >=100	No (Billy Only)	No

Methods:

Fluorescence In Situ Hybridization (FISH)

Reference Values:

An interpretive report will be provided.

Specimen Requirements:

Specimen Type Tissue

Preferred: Block

Collection Instructions: Submit a formalin-fixed, paraffin-embedded (FFPE) tumor tissue block. Blocks prepared with alternative fixation methods may be acceptable; provide fixation method used.

Additional Information

1. The paraffin embedded specimen can be from any anatomic location (skin, soft tissue, lymph node, etc.).
2. Bone specimens that have been decalcified will be attempted for FISH, with a success rate of approximately 50%

Acceptable: Slides

Collection Instructions: 20 Consecutive, unstained, 5 micron-thick sections placed on positively charged slides, and 1 hematoxylin and eosin-stained slide.

Note:

A reason for testing and pathology report are required for testing to be performed. Send information with specimen. Acceptable pathology reports include working drafts, preliminary pathology or surgical pathology reports. The laboratory will not reject testing if this information is not provided, but appropriate testing and interpretation may be compromised or delayed. If this information is not provided, an appropriate indication for testing may be entered by Mayo Clinic Laboratories.

Specimen Stability Information:

Specimen Type	Temperature	Time
Tissue	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.

Fixatives other than formalin (eg, Prefer, Bouin's) may not be successful for fluorescence in situ hybridization (FISH) assays. Although FISH testing will not be rejected due to non-formalin fixation, results may be compromised.

Paraffin-embedded tissues that have been decalcified may be unsuccessful for FISH analysis. FISH studies will be attempted if sufficient tumor is present for analysis. The pathologist reviewing the hematoxylin and eosin-stained slide may find it necessary to cancel testing. If no FISH signals are observed post-hybridization, the case will be released indicating a lack of FISH results.

CPT Code:

88271 x2, 88291-DNA probe, each (first probe set), interpretation and report

88271 x2-DNA probe, each; each additional probe set (if appropriate)

88271-DNA probe, each; coverage for sets containing 3 probes (if appropriate)

88271 x 2-DNA probe, each; coverage for sets containing 4 probes (if appropriate)

88271 x 3-DNA probe, each; coverage for sets containing 5 probes (if appropriate)

88274 w/modifier 52-Interphase in situ hybridization, <25 cells, each probe set (if appropriate)

88274-Interphase in situ hybridization, 25 to 99 cells, each probe set (if appropriate)

88275-Interphase in situ hybridization, 100 to 300 cells, each 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.