MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: November 10, 2021
Effective Date: December 13, 2021

B-Cell Lymphoblastic Leukemia/Lymphoma, FISH, Tissue

Test ID: BLBLF

Useful for:
Detecting a neoplastic clone in paraffin embedded specimens associated with the common chromosome abnormalities seen in patients with B-cell lymphoblastic leukemia/lymphoma.

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, including the standard (diagnostic) B-cell lymphoblastic lymphoma (B-LBL) FISH panel and the individual B-LBL FISH probes (per client request).

The FISH panel for patients **30 years and younger** 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 and iAMP21
14q32 rearrangement, IGH break-apart
8q24.1 rearrangement, MYC break-apart

If the initial 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:
1q25 rearrangement, ABL2 break-apart
5q33 rearrangement, PDGFRB break-apart
9p24.1 rearrangement, JAK2 break-apart

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9q34 rearrangement, ABL1 break-apart

The initial FISH panel for patients **older than 30 years of age** includes testing for the following abnormalities using the FISH probes listed:
t(9;22) BCR/ABL1

If BCR/ABL1 fusion is not observed, the 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:
1q25 rearrangement, ABL2 break-apart
5q33 rearrangement, PDGFRB break-apart
9p24.1 rearrangement, JAK2 break-apart
9q34 rearrangement, ABL1 break-apart

If the previous FISH probe sets demonstrate normal or nonclassical abnormalities, the following probe sets will be performed:
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
14q32 rearrangement, IGH break-apart
11q23 rearrangement, MLL (KMT2A) break-apart

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.

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.

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Reflex Tests:

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

Methods:

Fluorescence In Situ Hybridization (FISH)

Reference Values:

An interpretive report will be provided.

Specimen Requirements:

Preferred Specimen	Tissue
Preferred:	Tissue 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. Paraffin embedded specimens can be from any anatomic location (skin, soft tissue, lymph node, etc). 2. Bone specimens that have been decalcified will be attempted for testing, but the success rate is approximately 50%.
Acceptable Specimen	Slides
Collection Instructions:	20 Consecutive, unstained, 5 micron-thick sections placed on positively charged slides and 1 hematoxylin and eosin-stained slide.
Minimum Volume:	Fifteen 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.

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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 x 2, 88291-DNA probe, each (first probe set), interpretation and report

88271 x 2-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.

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