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MAYO CLINIC LABORATORIES

Test Definition: COGTF

T-Cell Acute Lymphoblastic Leukemia/Lymphoma (ALL), Children's Oncology Group Enrollment Testing, FISH, Varies

Overview

Useful For

Detecting, at diagnosis, recurrent common chromosome abnormalities associated with T-cell acute lymphoblastic leukemia/lymphoma (T-ALL) in patients being considered for enrollment in Children's Oncology Group (COG) clinical trials and research protocols

As an adjunct to conventional chromosome studies in pediatric patients with T-ALL being considered for enrollment in COG protocols

Evaluating specimens in which chromosome studies are unsuccessful

This test **should not be used** to screen for residual T-ALL/lymphoblastic lymphoma

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
COGTB	Probe, Each Additional (COGTF)	No, (Bill Only)	No

Testing Algorithm

This test is only performed on specimens from pediatric patients being considered for enrollment in a Children's Oncology Group (COG) protocol. Additional charges will be incurred for all reflex or additional probe sets 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 test is performed as panel testing only using the following analysis algorithm.

The **diagnostic** pediatric/young adult T-cell acute lymphoblastic leukemia L fluorescence in situ hybridization (FISH) panel includes testing for the following abnormalities using the FISH probes listed:
ABL1 amplification or t(9;22)(q34;q11.2), ABL1/BCR probe set
t(11q23;var) or *KMT2A* rearrangement, KMT2A break-apart probe set
1p33 rearrangement or *STIL* deletion, TAL1/STIL probe set
t(5;14)(q35;q32) or *TLX3::BCL11B* fusion, TLX3/BCL11B probe set
t(7q34;var) or *TRB* rearrangement, TRB break-apart probe set
t(14q11.2;var) or *TRA* rearrangement, TRA break-apart probe set
t(10;11)(p12;q14) or *MLLT10::PICALM* fusion, MLLT10/PICALM fusion probe set

Appropriate ancillary probes may be performed at consultant discretion to render comprehensive assessment. Any

additional probes used will have the results included within the final report and will be performed at an additional charge. In the following situations, additional (reflex) testing may be performed at the laboratory's discretion and may be influenced by available karyotype results or other FISH testing.

When a *KMT2A* rearrangement is identified, testing may be performed with 1 or more dual-fusion (D-FISH) probe sets in an attempt to identify the translocation partner. Reflex testing is performed for the following abnormalities, using the FISH probes listed:
t(4;11)(q21;q23) or *KMT2A::AFF1* fusion, AFF1/KMT2A probe set
t(6;11)(q27;q23) or *KMT2A::AFDN* ;fusion, AFDN/KMT2A probe set
t(9;11)(p22;q23) or *KMT2A::MLLT3* fusion, MLLT3/KMT2A probe set
t(10;11)(p12;q23) or *KMT2A::MLLT10* fusion, MLLT10/KMT2A probe set
t(11;19)(q23;p13.1) or *KMT2A::MLLT1* fusion, KMT2A/ELL probe set
t(11;19)(q23;p13.3) or *KMT2A::ELL* fusion, KMT2A/MLLT1 probe set

When a *TRA* rearrangement is identified, testing may be performed in an attempt to identify the translocation partner. Probes include identification of t(10;14)(q24;q11.2) *TRA::TLX1* fusion or t(11;14)(p13;q11.2) *TRA::LMO2* fusion.

When a *TRB* rearrangement is identified, testing may be performed in an attempt to identify the translocation partner. Probes include identification of t(7;10)(q34;q24) *TRB::TLX1* fusion or t(7;11)(q34;p13) *TRB::LMO2* fusion.

In the absence of *BCR::ABL1* fusion or apparent episomal amplification of *ABL1*, when an extra or atypical ABL1 signal is identified, testing using the ABL1 break-apart probe set may be performed to identify a potential variant translocation involving *ABL1,* t(9;var)(q34;?).

For more information See Acute Leukemias of Ambiguous Lineage Testing Algorithm.

Method Name
Fluorescence In Situ Hybridization (FISH)

NY State Available
Yes

Specimen

Specimen Type
Varies

Ordering Guidance
This test is only performed on specimens from pediatric patients being considered for enrollment in a Children's Oncology Group (COG) protocol. If this test is ordered and the laboratory is informed that the patient is not on a COG

protocol, this test will be canceled and automatically reordered by the laboratory as TALFP / Pediatric T-Lymphoblastic Leukemia/Lymphoma Panel, FISH, Varies.

At follow-up, conventional cytogenetic studies (CHRBM / Chromosome Analysis, Hematologic Disorders, Bone Marrow) and targeted T-cell ALL fluorescence in situ hybridization (FISH) probes can be evaluated based on the abnormalities identified in the diagnostic study. Order TALMF / T-Cell Acute Lymphoblastic Leukemia/Lymphoma (ALL), Specified FISH, Varies and request specific probes or abnormalities.

Additional Testing Requirements

At diagnosis, conventional cytogenetic studies (COGBM / Chromosome Analysis, Hematologic Disorders, Children's Oncology Group Enrollment Testing, Bone Marrow) and this panel should be performed. If there is limited specimen available, only this test will be performed.

Shipping Instructions

Advise Express Mail or equivalent if not on courier service.

Necessary Information

1. Children's Oncology Group (COG) registration number and protocol number should be submitted with each specimen. The laboratory will not reject testing if this information is not provided; however, appropriate testing may be compromised or delayed.
2. A reason for testing must be provided. If this information is not provided, an appropriate indication for testing may be entered by Mayo Clinic Laboratories.
3. 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, but appropriate testing and interpretation may be compromised or delayed.
4. If the patient has received an opposite sex bone marrow transplant, note this information on the request.
5. If the patient has Down syndrome, note this information on the request.

Specimen Required

Submit only 1 of the following specimens:

Preferred
Specimen Type: Bone marrow
Container/Tube:
Preferred: Yellow top (ACD)
Acceptable: Green top (sodium heparin) or lavender top (EDTA)
Specimen Volume: 2 to 3 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.
3. Send bone marrow specimen in original tube. **Do not aliquot.**

Acceptable
Specimen Type: Whole blood
Container/Tube:
Preferred: Yellow top (ACD)
Acceptable: Green top (sodium heparin) or lavender top (EDTA)
Specimen Volume: 6 mL
Collection Instructions:
1. Invert several times to mix blood.
2. Send whole blood specimen in original tube. **Do not aliquot.**

Forms
If not ordering electronically, complete, print, and send a Children's Oncology Group Test Request (T829) with the specimen.

Specimen Minimum Volume
Bone marrow: 1 mL; Whole blood: 2 mL

Reject Due To

Fresh tissue	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Ambient (preferred)		
	Refrigerated		

Clinical & Interpretive

Clinical Information
In the United States, the incidence of acute lymphoblastic leukemia (ALL) is roughly 6000 new cases per year (as of 2019). ALL accounts for approximately 70% of all childhood leukemia cases (ages 0 to 19 years), making it the most common type of childhood cancer.

Approximately 85% of pediatric cases of ALL are B-cell lineage (B-ALL) and 15% are T-cell lineage (T-ALL). T-ALL is more common in adolescents than younger children and accounts for 25% of adult ALL. When occurring as a primary lymphoblastic lymphoma (LBL), approximately 90% are T-cell lineage versus only 10% B-cell lineage. T-LBL often present as a mediastinal mass in younger patients with or without concurrent bone marrow involvement.

An abnormal karyotype is found in 50% to 70% of T-ALL cases, although many of the classic abnormalities are "cryptic" by conventional chromosome studies and must be identified by fluorescence in situ hybridization studies (FISH) and are

associated with various prognoses. One predictive marker, amplification of the *ABL1* gene region, has been identified in 5% of T-ALL, and these patients may be responsive to targeted tyrosine kinase inhibitors.

A summary of the characteristic chromosome abnormalities identified in T-ALL are listed in the following table.

Table. Common Chromosome Abnormalities in T-cell Acute Lymphoblastic Leukemia/Lymphoma

Cytogenetic change	Genes involved
del(1p33)	*TAL1/STIL*
t(5;14)(q35;q32)	*TLX3::BCL11B*
t(5q32;var)	*PDGFRB*
t(10;11)(p13;q14)	*PICALM::MLLT10*
Episomal amplification	*ABL1*
t(9p24.1;var)	*JAK2*
t(9q34;var)	*ABL1*
t(11q23;var)	*KMT2A*
t(4;11)(q21;q23)	*KMT2A::AFF1*
t(6;11)(q27;q23)	KMT2A::*AFDN*
t(9;11)(p21.3;q23)	*KMT2A::MLLT3*
t(10;11)(p13;q23)	*KMT2A::MLLT10*
t(11;19)(q23;p13.1)	*KMT2A::ELL*
t(11;19)(q23;p13.3)	*KMT2A::MLLT1*
t(7q34;var)	*TRB*
t(6;7)(q23;q34)	*TRB::MYB*
t(7;10)(q34;q24)	*TRB*::*TLX1*
t(7;11)(q34;p15)	*TRB*::*LMO1*
t(7;11)(q34;p13)	*TRB*::*LMO2*
t(14q11.2;var)	*TRA*
t(8;14)(q24.21;q11.2)	*TRA::MYC*
t(10;14)(q24;q11.2)	*TLX1*::*TRA*
t(11;14)(p15;q11.2)	*LMO1*::*TRA*
t(11;14)(p13;q11.2)	*LMO2*::*TRA*
del(17p)	*TP53*
Complex karyotype (> or =4 abnormalities)	

Reference Values

An interpretive report will be provided.

Interpretation

A neoplastic clone is detected when the percent of cells with an abnormality exceeds the normal reference range for any given probe set.

The absence of an abnormal clone does not rule out the presence of neoplastic disorder.

Cautions

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

Fluorescence in situ hybridization (FISH) is not a substitute for conventional chromosome studies because the latter detects chromosome abnormalities associated with other hematological disorders that would be missed in a targeted with T-cell acute lymphoblastic leukemia/lymphoma 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 circulating malignant cells in the blood specimen (as verified by a hematopathologist).

If no FISH signals are observed post-hybridization, the case will be released indicating a lack of FISH results.

Clinical Reference

1. Swerdlow SH, Campo E, Harris NL, et al, eds. WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues. IARC Press; 2017
2. Gesk S, Martin-Subero JI, Harder L, et al. Molecular cytogenetic detection of chromosomal breakpoints in T-cell receptor gene loci. Leukemia. 2003;17(4):738-745
3. Chin M, Mugishima H, Takamura M, et al. Hemophagocytic syndrome and hepatosplenic (gamma)(delta) T-cell lymphoma with isochromosome 7q and 8 trisomy. J Pediatr Hematol Oncol. 2004;26(6):375-378
4. Graux C, Cools J, Michaux L, Vandenberghe P, Hagemeijer A. Cytogenetics and molecular genetics of T-cell acute lymphoblastic leukemia: from thymocyte to lymphoblast. Leukemia. 2006;20(9):1496-1510
5. Liu Y, Easton J, Shao Y, et al. The genomic landscape of pediatric and young adult T-lineage acute lymphoblastic leukemia. Nat Genet. 2017;49(8):1211-1218

Performance

Method Description

This test is performed using commercially available and laboratory-developed probes. Rearrangements involving *TAL1/STIL, TRB, ABL1, KMT2A*, and *TRA* are detected using a dual-color break-apart (BAP) strategy probe set. Dual-color, dual-fusion fluorescence in situ hybridization (D-FISH) strategy probe sets are used to detect t(5;14), t(9;22), t(10;11), and in reflex testing when rearrangements of *KMT2A, TRB*, or *TRA* genes are detected. Amplification of the *ABL1* gene region is detected using a D-FISH probe strategy. For enumeration and BAP strategy probe sets, 100 interphase nuclei are scored; 200 interphase nuclei are scored when D-FISH probes are used. All results are expressed as the percent

abnormal nuclei.(Unpublished Mayo method)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
7 to 10 days

Specimen Retention Time
4 weeks

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

Fees & 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 account representative. For assistance, contact Customer Service.

Test Classification
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
88271 x2, 88275 x1, 88291 x1- FISH Probe, Analysis, Interpretation; 1 probe set
88271 x2, 88275x1 - FISH Probe, Analysis; each additional probe set (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
COGTF	COG, ALL (T-cell), FISH	101663-3

Result ID	Test Result Name	Result LOINC® Value
602286	Result Summary	50397-9
602287	Interpretation	69965-2
602288	Result Table	93356-4

602289	Result	62356-1
GC016	Reason for Referral	42349-1
GC017	Specimen	31208-2
602291	Source	31208-2
602292	Method	85069-3
602293	Additional Information	48767-8
602294	Disclaimer	62364-5
602295	Released By	18771-6