

## Overview

### Useful For

Detecting a neoplastic clone associated with the common chromosome abnormalities seen in patients with various B-cell lymphomas

Tracking known chromosome abnormalities and response to therapy in patients with B-cell lymphomas

### Reflex Tests

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

### Testing Algorithm

This test does not include a pathology consultation. If a pathology consultation is desired, PATHC / Pathology Consultation should be ordered and the appropriate FISH test will be ordered and performed at an additional charge. Mayo Hematopathology Consultants are involved in both the preanalytic (tissue adequacy and probe selection, when applicable) and postanalytic (interpretation of FISH results in context of specific case, when applicable) phases.

Depending on the lymphoma subtype suspected, the most appropriate probes to order are listed in the table: Common Chromosome Abnormalities in B-cell Lymphomas in Clinical Information.

If the patient is being tracked for known abnormalities, indicate which probes should be used.

A charge and CPT code is applied for each probe set hybridized, analyzed, and reported.

Initial probe sets are run and completed within 4 days. If, based on testing algorithms, results of the initial probe sets require reflex testing, complete results will be available within 10 days.

The following algorithms are available in Special Instructions:

[-Aggressive B-cell Lymphoma Diagnostic Algorithm](#)

[-Gastric MALT Lymphoma Diagnostic Algorithm](#)

[-Gastric MALT Posttherapy Follow-up Algorithm](#)

### Special Instructions

- [Aggressive B-cell Lymphoma Diagnostic Algorithm](#)
- [Gastric MALT Posttherapy Follow-up Algorithm](#)
- [Gastric MALT Lymphoma Diagnostic Algorithm](#)

### Method Name

Fluorescence In Situ Hybridization (FISH)

### NY State Available

Yes

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## Specimen

### Specimen Type

Tissue

### Advisory Information

This assay detects chromosome abnormalities observed in paraffin-embedded tissue samples of patients with B-cell lymphoma. If a blood or bone marrow specimen is submitted, the test will be cancelled and BLPF / B-Cell Lymphoma, FISH, Varies, will be added and performed as the appropriate test.

### Shipping Instructions

Advise Express Mail or equivalent if not on courier service.

### Necessary Information

**A reason for referral and pathology report are required in order for testing to be performed.** Send information with specimen. Acceptable pathology reports include working drafts, preliminary pathology or surgical pathology reports.

### Specimen Required

**Submit only 1 of the following specimens:**

**Specimen Type:** Lymph node

**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.

**Acceptable:** Slides

**Collection Instructions:** For each probe set ordered, 2 consecutive, unstained, 5 micron-thick sections placed on positively charged slides, and 1 hematoxylin and eosin-stained slide.

**Specimen Type:** Solid tumor

**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.

**Acceptable:** Slides

**Collection Instructions:** For each probe set ordered, 2 consecutive, unstained, 5 micron-thick sections placed on positively charged slides, and 1 hematoxylin and eosin-stained slide.

### Forms

If not ordering electronically, complete, print, and send a [Hematopathology/Cytogenetics Test Request](#) (T726) with the specimen.

### Specimen Minimum Volume

See Specimen Required

**Reject Due To**

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

**Specimen Stability Information**

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

**Clinical and Interpretive**
**Clinical Information**

Mature B-cell lymphoma can be low grade, intermediate grade, or high grade, and the prognosis and clinical course are highly variable. Genetic abnormalities have emerged as one of the most important prognostic markers in B-cell lymphomas and can aid in diagnosis. Several chromosome abnormalities and variants of these abnormalities have been associated with various lymphoma subtypes (see table). Conventional chromosome studies cannot be employed on paraffin-embedded tissue, and molecular genetic analyses are often problematic in the study of lymphomas. FISH permits the detection of abnormal gene associated with various chromosome translocations and inversions in B-cell lymphoma (see table).

Common Chromosome Abnormalities in B-cell Lymphomas		
Lymphoma Type	Chromosome Abnormality	FISH Probe
Burkitt (pediatric, < or =18 years old)	8q24.1 rearrangement	5'/3' MYC
	t(2;8)(p12;q24.1)	IGK/MYC
	t(8;14)(q24.1;q32)	MYC/IGH
	t(8;22)(q24.1;q11.2)	MYC/IGL
	3q27 rearrangement	3'/5' BCL6
Diffuse large B-cell, Burkitt-like "double-hit"	18q21 rearrangement	3'/5' BCL2
	8q24.1 rearrangement	5'/3' MYC
	t(8;14)(q24.1;q32)	MYC/IGH
	---- <b>Reflex:</b> t(2;8)(p12;q24.1)	IGK/MYC
	---- <b>Reflex:</b> t(8;22)(q24.1;q11.2)	MYC/IGL
	---- <b>Reflex:</b> 3q27 rearrangement	3'/5' BCL6
Large BCL with IRF4 Rearranged	---- <b>Reflex:</b> 18q21 rearrangement	3'/5' BCL2
	6p24.3 rearrangement	3'/5' IRF4
	18q21 rearrangement	3'/5' BCL2
	3q27 rearrangement	3'/5' BCL6
Follicular	18q21 rearrangement	3'/5' BCL2

	3q27 rearrangement	3'/5' BCL6
	Predominantly diffuse subtype only: deletion of 1p36	TNFRSF14/1q22
Mantle Cell	t(11;14)(q13;q32)	CCND1/IGH
	Blastoid subtype only: deletion of 17p	TP53/D17Z1
	Blastoid subtype only: 8q24.1 rearrangement	5'/3' MYC
MALT	18q21 rearrangement	5'/3' MALT1
Splenic Marginal Zone	Deletion of 7q	D7Z1/7q32
	Deletion of 17p	TP53/D17Z1

### 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.

Detection of an abnormal clone is supportive of a diagnosis of a B-cell lymphoma. The specific abnormality detected may help subtype the neoplasm.

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

### Cautions

This test is not approved by the FDA and it is best used as an adjunct to existing clinical and pathologic information.

Fixatives other than formalin (eg, Prefer, Bouin) may not be successful for FISH assays.

Paraffin-embedded tissues that have been decalcified are generally unsuccessful for FISH analysis. The pathologist reviewing the hematoxylin and eosin-stained slide may find it necessary to cancel testing.

### Supportive Data

Each probe was independently tested on a set of formalin-fixed, paraffin-embedded tissue specimens from patients diagnosed with a B-cell lymphoma and noncancerous lymph node specimens. Normal cutoffs were calculated based on the results from 25 normal specimens. For each probe set, a series of chromosomally abnormal specimens were evaluated to confirm each probe set detected the anomaly it was designed to detect.

### Clinical Reference

WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues. Edited by SH Swerdlow, E Campo, NL Harris. IARC, Lyon 2017

### Performance

### Method Description

This test is performed using either commercially available or laboratory-developed probes. Rearrangements involving *MYC*, *BCL2*, *BCL6*, *CCND2*, *IRF4*, or *MALT1* are detected using dual-color break-apart (BAP) strategy probes,

translocations involving *MYC*, *MALT1*, or *CCND1/IGH* are identified using dual-color, dual-fusion (D-FISH) strategy probes, and deletions (*7q32*, *TNFRSF14* (*1p36*), and *TP53*) using enumeration strategy probes. Formalin-fixed, paraffin-embedded tissues are cut at 5 microns and mounted on positively charged glass slides. The selection of tissue and the target areas on the hematoxylin and eosin (H and E)-stained slide is performed by a pathologist. Using the H and E-stained slide as a reference, target areas are etched with a diamond-tipped etcher on the back of the unstained slide to be assayed. The probe set is hybridized to the appropriate target areas and 2 technologists each analyze 100 interphase nuclei (200 total) with the results expressed as the percent abnormal nuclei. (Unpublished Mayo method)

**PDF Report**

No

**Day(s) and Time(s) Test Performed**

Specimens are processed Monday through Sunday.

Results reported Monday through Friday, 8 a.m.-5 p.m.

**Analytic Time**

4 days

**Maximum Laboratory Time**

10 days

**Specimen Retention Time**

Slides and H&E used for analysis are retained by the laboratory in accordance to CAP and NYS requirements. Client provided paraffin blocks and extra unstained slides (if provided) will be returned after testing is complete.

**Performing Laboratory Location**

Rochester

**Fees and 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 Regional Manager. For assistance, contact [Customer Service](#).

**Test Classification**

This test was developed using an analyte specific reagent. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

**CPT Code Information**

88377 (if 1 probe set)

88377 x 2 (if 2 probe sets)

88377 x 3 (if 3 probe sets)

88377 x 4 (if 4 probe sets)

88377 x 5 (if 5 probe sets)

88377 x 6 (if 6 probe sets)

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
BLYM	B-cell Lymphoma, FISH, Tissue	In Process

Result ID	Test Result Name	Result LOINC Value
603063	Result Summary	50397-9
603064	Interpretation	69965-2
603065	Result Table	93356-4
603066	Result	62356-1
GC026	Reason for Referral	42349-1
603067	Specimen	31208-2
603068	Source	85298-8
603069	Tissue ID	80398-1
603070	Method	85069-3
603071	Additional Information	48767-8
603072	Disclaimer	62364-5
603073	Released By	18771-6