Overview

Useful For
Establishing the diagnosis of lymphoplasmacytic lymphoma/Waldenstrom macroglobulinemia
Helping to distinguish lymphoplasmacytic lymphoma/Waldenstrom macroglobulinemia (low-grade B-cell lymphoma) from other subtypes

Special Instructions
- Hematopathology Patient Information

Method Name
Allele-Specific Polymerase Chain Reaction (PCR)

NY State Available
Yes

Specimen

Specimen Type
Varies

Shipping Instructions
Peripheral blood or bone marrow specimens must arrive within 10 days (240 hours) of collection.

Necessary Information
The following information is required:

1. Pertinent clinical history
2. Clinical or morphologic suspicion
3. Date of collection
4. Specimen source

Specimen Required
Submit only 1 of the following specimens:

Specimen Type: Bone marrow

Container/Tube: EDTA (lavender top), ACD solution B (yellow top), or heparin (green top)

Specimen Volume: 2 mL

Collection Instructions:

1. Invert several times to mix bone marrow.
2. Send specimen in original tube.

3. Label specimen as bone marrow.

**Specimen Stability:** Ambient (preferred)/Refrigerated

**Specimen Type:** Paraffin-embedded tissue

**Container/Tube:** Paraffin block

**Specimen Stability:** Ambient

**Specimen Type:** Peripheral blood

**Container/Tube:** EDTA (lavender top), ACD solution B (yellow top), or heparin (green top)

**Specimen Volume:** 3 mL

**Collection Instructions:**

1. Invert several times to mix blood.

2. Send specimen in original tube.

3. Label specimen as blood.

**Specimen Stability:** Ambient (preferred)/Refrigerated

**Specimen Type:** Frozen tissue

**Container/Tube:** Plastic container

**Specimen Volume:** 100 mg

**Collection Instructions:** Freeze tissue within 1 hour of collection.

**Specimen Stability:** Frozen

**Specimen Type:** Paraffin-embedded bone marrow aspirate clot

**Container/Tube:** Paraffin block

**Specimen Stability:** Ambient

**Specimen Type:** Unstained slides

**Container/Tube:** Unstained tissue slides

**Specimen Volume:** 10 slides
Test Definition: MYD88
MYD88 L265P Gene Mutation Analysis

Specimen Stability: Ambient

Specimen Type: Extracted DNA

Container/Tube: 1.5- to 2-mL tube with indication of volume and concentration of the DNA

Specimen Volume: Entire specimen

Collection Instructions: Label specimen as extracted DNA and source of specimen and include indication of volume and concentration of the DNA.

Specimen Stability: Frozen (preferred)/Refrigerated

Specimen Type: Methanol-acetic acid (MAA) fixed pellets

Container/Tube: Plastic container

Specimen Stability: Ambient (preferred)/Refrigerated

Forms
1. Hematopathology Patient Information (T676) in Special Instructions

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

Specimen Minimum Volume
Blood, Bone marrow: 1 mL
Extracted DNA: 50 mcL at 20 ng/mcL

Reject Due To

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>Reject</th>
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<tbody>
<tr>
<td>Bone marrow core biopsies Paraffin shavings Moderately to severely clotted</td>
<td>Reject</td>
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Specimen Stability Information

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<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
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<tbody>
<tr>
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<td>Varies</td>
<td>10 days</td>
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Clinical and Interpretive

Clinical Information
Single point mutation in MYD88 L265P is present in 67% to 100% of patients with lymphoplasmacytic lymphoma and these patients typically have clinical manifestations of Waldenstrom macroglobulinemia (often designated LPL/WM).

Reference Values
Mutation present or absent based on expected mutant PCR product size. Concurrent amplification of wild type
MYD88 fragment determined for sample amplification integrity. MYD88 gene (NCBI accession NM_002468.4).

**Interpretation**
Mutation present or not detected; an interpretive report will be issued.

**Cautions**
This test is a targeted assay and will not detect any alteration at the MYD88 codon 265 that does not result in the L>P amino acid change. It will also not detect additional MYD88 mutations, including insertion or deletion events. The analytical sensitivity of the assay (1% MYD88 L265P in a wild-type background) can be affected by a variety of factors, including biologic availability (ie, tumor burden), fixation of paraffin-embedded specimens, or nonspecific PCR interferences. Rare cases of lymphoplasmacytic lymphoma/Waldenstrom macroglobulinemia (LPL/WM) have been reported lacking the MYD88 L265P abnormality, so a negative result would not completely exclude this diagnosis, but would make the possibility of LPL/WM more unlikely.

**Clinical Reference**

**Performance**

**Method Description**
This is a laboratory-developed test using research use only (RUO) reagents. Extracted DNA from the clinical specimen is subjected to a single-tube allele-specific PCR using MYD88 exon 5 primers that simultaneously amplify both a wild-type sequence fragment and a fragment containing the specific nucleotide change resulting in L265P, if present. PCR products are visualized by capillary electrophoresis and the presence of mutated and wild-type amplicons is determined according to the expected specific PCR product sizes.(Unpublished Mayo method)

**PDF Report**
No

**Day(s) and Time(s) Test Performed**
Monday through Friday; 1 p.m.

**Analytic Time**
Test Definition: MYD88
MYD88 L265P Gene Mutation Analysis

3 days

Maximum Laboratory Time
5 days

Specimen Retention Time
DNA 3 months

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 and its performance characteristics 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
81305

LOINC® Information

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<td>MYD88 L265P Gene Mutation Analysis</td>
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