**Overview**

**Useful For**
Determining whether a B-cell or plasma cell population is polyclonal or monoclonal in specimens other than blood or bone marrow

Identifying neoplastic cells as having B-cell or plasma cell differentiation

Monitoring for a persistent neoplasm by detecting an immunoglobulin gene rearrangement profile similar to that from a previous neoplastic specimen

**Testing Algorithm**
The following algorithms are available in Special Instructions:

- Gastric MALT Lymphoma Diagnostic Algorithm
- Gastric MALT Posttherapy Follow-up Algorithm

**Special Instructions**
- Hematopathology Patient Information
- Gastric MALT Posttherapy Follow-up Algorithm
- Gastric MALT Lymphoma Diagnostic Algorithm

**Method Name**
Genomic DNA Extracted Followed by Polymerase Chain Reaction (PCR)

**NY State Available**
Yes

**Specimen**

**Specimen Type**
Varies

**Shipping Instructions**
Body fluid or spinal fluid must arrive within 4 days (96 hours) of collection.

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

**Specimen Type:** Body fluid

**Container/Tube:** Sterile container

**Specimen Volume:** At least 5 mL

**Collection Instructions:**
1. If the volume is large, pellet cells prior to sending.
2. Send less volume at ambient temperature or as a frozen cell pellet.

**Specimen Stability Information:**

Body Fluid: Ambient/Refrigerated/Frozen

Cell Pellet: Frozen

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

**Container/Tube:** Paraffin block

**Specimen Stability Information:** Ambient

**Specimen Type:** Frozen tissue

**Container/Tube:** Plastic container

**Specimen Volume:** 100 mg

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

**Specimen Stability Information:** Frozen

**Specimen Type:** Paraffin-embedded tissue

**Container/Tube:** Paraffin block

**Specimen Stability Information:** Ambient

**Specimen Type:** Tissue

**Slides:** Unstained slides

**Specimen Volume:** 10 Slides

**Specimen Stability Information:** Ambient

**Specimen Type:** Spinal fluid

**Container/Tube:** Sterile vial

**Specimen Volume:** 5-10 mL

**Specimen Stability Information:** Ambient/Refrigerated

**Specimen Type:** Extracted DNA from blood or bone marrow

**Container/Tube:** 1.5- to 2-mL tube
**Specimen Volume:** Entire specimen

**Collection Instructions:** Label specimen as extracted DNA from blood or bone marrow and provide indication of volume and concentration of DNA

**Specimen Stability Information:** Refrigerated/Ambient

**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**

Body and spinal fluid: 1 mL

Tissue: 50 mg

Extracted DNA from blood or bone marrow: 50 microliters (mcL) at 20 ng/mcL

**Reject Due To**

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<tbody>
<tr>
<td>Other</td>
<td>Bone marrow core biopsies, paraffin shavings</td>
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**Specimen Stability Information**

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<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
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**Clinical and Interpretive**

**Clinical Information**

The immunoglobulin (Ig) genes (heavy, kappa, and lambda) are comprised of numerous, discontinuous coding segments. As B cells develop, the segments are rearranged such that each mature B cell and plasma cell has a unique rearrangement profile. Other cell types usually retain the nonrearranged gene structures. Clonal expansion of any B cell or plasma cell will result in a population of cells that all contain an identical Ig gene rearrangement profile.

Reactive B-cell or plasma cell expansions are polyclonal, with each clone containing relatively few cells and no single clone predominating. Conversely, neoplastic clones are generally large such that the clonal cells are the predominant B cells or plasma cells present.

In the appropriate clinical and pathologic setting, detection of a prominent Ig gene rearrangement profile may be equated to the presence of a neoplastic B-cell or plasma cell clone.

**Reference Values**

An interpretive report will be provided.

**Interpretation**

An interpretive report will be provided.
The interpretation of the presence or absence of a predominant immunoglobulin (Ig) gene rearrangement profile is sometimes subjective. These results must always be interpreted in the context of other clinicopathologic information to determine the significance of the result.

The detection of a clonal Ig gene rearrangement by this test is not synonymous with the presence of a B-cell or plasma cell neoplasm.

**Cautions**

This test is neither 100% sensitive nor 100% specific.

False-negative results may occur if the immunoglobulin (Ig) gene has numerous point mutations introduced during expansion in a follicle center (somatic hypermutation) such that none of the PCR primers will bind. False-negatives will also occur if the clonal cells have not rearranged the Ig genes being evaluated or are present below the sensitivity level of the assay (sensitivity is quite variable but the assay requires that at least 1%-5% of the nucleated cells present be clonal). False-positive results are rare but may occur if a predominant clone (or small number of clones) is produced or sampled from a polyclonal expansion.

The test does not provide information regarding:

- The differentiation of the clonal cell population (neoplastic cells other than B cells or plasma cells may occasionally have Ig gene rearrangements)

- Whether a prominent clone is physiologic or neoplastic

**Clinical Reference**


**Performance**

**Method Description**

Genomic DNA is extracted from all specimens.

In the PCR assay, a total of 34 upstream and 5 downstream primers are used (InVivoScribe IGH and IGK Gene Clonality Analyte Specific Reagents). The primers are designed to amplify fragments from all theoretical rearrangements of the immunoglobulin (Ig) heavy and Ig kappa light chain genes. Each unique rearrangement should produce PCR fragments of unique sizes. The primers cannot amplify anything if the Ig genes are not rearranged because the distance is too great. The primers are labeled with a fluorescent tag so that the PCR product can be detected. The PCR fragments are analyzed by capillary gel electrophoresis using the Applied Biosystems (ABI) 3130XL machine for fragment size and amount. (van Dongen JJ, Langerak AW, Bruggemann M, et al: Design and standardization of PCR primers and protocols for detection of clonal immunoglobulin and T-cell receptor gene recombinations in suspect lymphoproliferations: report of the BIOMED-2 Concerted Action BMH4-CT98-3936. Leukemia 2003 December;17[12]:2257-2317; van Dongen JJ, Wolvers-Tettero IL: Analysis of immunoglobulin and T-cell receptor genes. Part 1: basic and technical aspects. Clin Chim Acta 1991 April;198[1-2]:1-92; package inserts: IGH Gene Clonality Assay-ABI Fluorescence Detection and IGK Gene Clonality Assay-ABI Fluorescence Detection. InVivoScribe Technologies, San Diego, CA 2004; Gene Images AlkPhos Direct Labeling and Detection system. Amersham Biosciences, UK Limited)
PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday

Analytic Time
7 days

Maximum Laboratory Time
14 days

Specimen Retention Time
Remaining DNA retained 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 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
81261-IGH (Immunoglobulin heavy chain locus) (eg, leukemias and lymphomas B-cell), gene rearrangement analysis to detect abnormal clonal populations; amplified methodology (eg. polymerase chain reaction)

81264-IGK (Immunoglobulin kappa light chain locus) (eg, leukemia and lymphoma, B-cell) gene rearrangement analysis, evaluation to detect abnormal clonal populations

LOINC® Information

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