Overview

Useful For
Determining whether a B-cell or plasma cell population is polyclonal or monoclonal in peripheral blood specimens

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 one from a previous neoplastic specimen

Special Instructions

- Hematopathology Patient Information

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

NY State Available
Yes

Specimen

Specimen Type
Whole blood

Shipping Instructions
Specimen must arrive within 168 hours of draw.

Specimen Required

Container/Tube:

- Preferred: EDTA (lavender top)
- Acceptable: ACD (yellow top)

Specimen Volume: 4 mL

Collection Instructions:

1. Invert several times to mix blood.

2. Send specimen in original tube.

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
Test Definition: BCGR
Immunoglobulin Gene Rearrange, B

1 mL

Reject Due To

<p>| | |</p>
<table>
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<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject</td>
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<tr>
<td>Other</td>
<td>Moderately to severely clotted</td>
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Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Whole blood</td>
<td>Ambient (preferred)</td>
<td>7 days</td>
<td></td>
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<tr>
<td></td>
<td>Refrigerated</td>
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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 1 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 insert: 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**

5 days

**Maximum Laboratory Time**

7 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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<th>Order LOINC Value</th>
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<tr>
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<td>Immunoglobulin Gene Rearrange, B</td>
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