Overview

Useful For
Determining whether a T-cell population is polyclonal or monoclonal

Special Instructions
- Hematopathology Patient Information

Method Name
DNA Extracted for Analysis/Polymerase Chain Reaction (PCR)

NY State Available
Yes

Specimen

Specimen Type
Whole blood

Shipping Instructions
Specimen must arrive within 7 days (168 hours) of draw.

Necessary Information
Include relevant clinical information and cytogenetics results, if available.

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
1 mL
### Reject Due To

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>Reject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderately to severely clotted</td>
<td>Reject</td>
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</table>

### Specimen Stability Information

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

### Clinical and Interpretive

#### Clinical Information

The T-cell receptor (TCR) genes (alpha, beta, delta, and gamma) are comprised of numerous, discontinuous coding segments that somatically rearrange to produce heterodimeric cell surface T-cell receptors, either alpha/beta (90%-95% of T cells) or gamma/delta (5%-10% of T cells). With rare exceptions (e.g., some neoplastic B-lymphoid proliferations), other cell types retain the "germline" configuration of the TCR genes without rearrangement.

The marked diversity of somatic TCR-gene rearrangements is important for normal immune functions, but also serves as a valuable marker to distinguish abnormal T-cell proliferations from reactive processes. A monoclonal expansion of a T-cell population will result in the predominance of a single TCR-gene rearrangement pattern. In contrast, reactive T-cell expansions are polyclonal (or multiclonal), with no single clonotypic population predominating in the population of T cells. These distributive differences in both TCR sequence and genomic rearrangement fragment sizes can be detected by molecular techniques (e.g., PCR) and used to determine if a population of T cells shows monoclonal or polyclonal features.

#### Reference Values

An interpretive report will be provided.

Positive, negative, or indeterminate for a clonal T-cell population

#### Interpretation

An interpretive report will be provided.

Results will be characterized as positive, negative, or indeterminate for a clonal T-cell population.

In the appropriate clinicopathologic setting, a monoclonal result is associated with a neoplastic proliferation of T cells (see Cautions).

#### Cautions

To determine the significance of the result, it must always be interpreted in the context of other clinicopathologic information.

The interpretation of the presence or absence of a predominant T cell receptor (TCR)-gene rearrangement profile is sometimes subjective.
The detection of a clonal TCR-gene rearrangement by this test is not necessarily synonymous with the presence of a T-cell neoplasm. False-positive results can occur because of the sensitivity of PCR technique and the problem of nonuniform (skewed) amplification of target T-cell gene rearrangements. The latter problem can occur when the total T-cell number in a sample is limited, or because of physiologic skewing of the T-cell repertoire as seen with aging, postransplantation, or T-cell reactions in autoimmune or (nonlymphoid) malignancies. False-negative results can occur for many reasons, including tissue sampling, poor amplification, or failure to detect a small minority of T-cell gene segment rearrangements with the use of consensus PCR primers. In some cases, an indeterminate or equivocal result will occur because the pattern of gene rearrangements is abnormal (compared to typical polyclonal T-cell processes), but not definitive, for a monoclonal T-cell population. In these situations, distinction of a small monoclonal subpopulation from an over-represented, but reactive, population may not be possible.

Clinical Reference


Performance

Method Description

Genomic DNA is extracted from the blood. T-cell receptor beta (TCRB) and T-cell receptor gamma (TCRG) loci (official designations TRB and TRG, respectfully) are amplified by PCR using a multiplex primer method based on the BIOMED-2 strategy. Specific primers are labeled with fluorochrome dyes, permitting precise fragment sizing of PCR products by capillary gel electrophoresis (Applied Biosystems 3130xl Genetic Analyzer). Each amplified locus is assessed for gene rearrangement patterns and an overall interpretation of the assay is made with regards to the presence or absence of a monoclonal population.(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;17[12]:2257-2317)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Friday

Analytic Time

5 days

Maximum Laboratory Time

10 days

Specimen Retention Time

Remaining DNA retained 3 months

Performing Laboratory Location
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
81340-TCB (T cell antigen receptor, beta) (eg, leukemia and lymphoma), gene rearrangement analysis to detect abnormal clonal population(s); using amplification methodology (eg, PCR)

81342-TCG@ (T cell receptor, gamma) (eg, leukemia and lymphoma), gene rearrangement analysis, evaluation to detect abnormal clonal population(s)

LOINC® Information

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<th>Result LOINC Value</th>
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<td>18210</td>
<td>Final Diagnosis:</td>
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