

## 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**

Gross hemolysis	Reject
Moderately to severely clotted	Reject

**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Whole blood	Ambient (preferred)	7 days	
	Refrigerated	7 days	

**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 (eg, 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 (ie, 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, posttransplantation, 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

1. Liu H, Bench AJ, Bacon CM, et al: A practical strategy for the routine use of BIOMED-2 PCR assays for detection of B- and T-cell clonality in diagnostic haematopathology. *Br J Haematol* 2007;138(1):31-43
2. Van Krieken JH, Langerak AW, Macintyre EA, et al: Improved reliability of lymphoma diagnostics via PCR-based clonality testing: report of the BIOMED-2 Concerted Action BHM4-CT98-3936. *Leukemia* 2007;21(2):201-206
3. Bruggemann M, White H, Gaulard P, et al: Powerful strategy for polymerase chain reaction-based clonality assessment in T-cell malignancies Report of the BIOMED-2 Concerted Action BHM4 CT98-3936. *Leukemia* 2007;21(2):215-221

### 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

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**

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**

Test ID	Test Order Name	Order LOINC Value
TCGR	T Cell Receptor Gene Rearrange, B	In Process

Result ID	Test Result Name	Result LOINC Value
18210	Final Diagnosis:	22637-3