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## Overview

### Useful For

Determining whether a T-cell population is polyclonal or monoclonal using body fluid or tissue specimens

### Special Instructions

- [Hematopathology Patient Information](#)

### Method Name

Polymerase Chain Reaction (PCR)

### NY State Available

Yes

## Specimen

### Specimen Type

Varies

### Shipping Instructions

Body fluid or spinal fluid specimens must arrive within 4 days 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 4 days/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

**Container/Tube:** Unstained tissue slides

**Specimen Volume:** 10 slides

**Specimen Stability:** Ambient

**Specimen Type:** Spinal fluid

**Container/Tube:** Sterile vial

**Specimen Volume:** 5 to 10 mL

**Specimen Stability Information:** Ambient 4 days/Refrigerated

**Specimen Type:** Extracted DNA

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

**Specimen Volume:** Entire specimen

**Collection Instructions:**

1. Label specimen as extracted DNA and source of specimen
2. Indicate volume and concentration of DNA on label

**Specimen Stability Information:** Refrigerated/Ambient

## Forms

1. [Hematopathology Patient Information](#) (T676)
2. If not ordering electronically, complete, print, and send a [Hematopathology/Cytogenetics Test Request](#) (T726) with the specimen.

## Specimen Minimum Volume

Body fluid or Spinal fluid: 1 mL

Tissue: 50 mg

Extracted DNA: 50 microliters at 20 ng/mL

## Reject Due To

Bone marrow core biopsies Paraffin shavings	Reject
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**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Varies	Varies		

**Clinical & 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 TCR, 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, polymerase chain reaction) 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 polymerase chain reaction (PCR) technique and the problem of nonuniform (skewed) amplification of target T-cell gene rearrangements. The latter problem can

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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 Jul;138(1):31-43
2. van Krieken JHJM, 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 Feb;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 Feb;21(2):215-221
4. Langerak AW, Groenen PJTA, Bruggemann M, et al: EuroClonality/BIOMED-2 guidelines for interpretation and reporting of Ig/TCR clonality testing in suspected lymphoproliferations. *Leukemia.* 2012 Oct;26(10):2159-2171. doi: 10.1038/leu.2012.246
5. Davies K, Staniforth J, Haowei Xie, W, et al: Advances in the assessment of T-cell clonality. *Diagn Histopathol.* 2020 Sept;26(9):388-397

**Performance****Method Description**

Genomic DNA is extracted from the tissue source. T-cell receptor beta (*TCRB*) and T-cell receptor gamma (*TCRG*) loci (official designations *TRB* and *TRG*, respectfully) are amplified by polymerase chain reaction (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 using a 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.(Unpublished Mayo method)

**PDF Report**

No

**Day(s) Performed**

Monday through Friday

**Report Available**

7 to 14 days

**Specimen Retention Time**

Extracted DNA: 3 months

**Performing Laboratory Location**

Rochester

**Fees & 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 account representative. 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 US 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
TCGRV	T Cell Receptor Gene Rearrange, V	In Process

Result ID	Test Result Name	Result LOINC® Value
MP016	Specimen:	31208-2
19936	Final Diagnosis:	22637-3
608953	Signing Pathologist	19139-5