

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

Varies

Shipping Instructions

Body fluid or spinal fluid specimens 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

Container/Tube: Unstained tissue slides

Specimen Volume: 10 slides

Specimen Stability: 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 with indication of volume and concentration of DNA

Specimen Volume: Entire specimen

Collection Instructions: Label specimen as extracted DNA from blood or bone marrow

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 fluid or Spinal fluid: 1 mL

Tissue: 50 mg

Extracted DNA from Blood or Bone Marrow: 50 microliters at 20 ng/mcL

Reject Due To

Other	Bone marrow core biopsies Paraffin shavings
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Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Varies		

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 rearranged 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 tissue source. 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

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

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
19936	Final Diagnosis:	22637-3
MP016	Specimen:	31208-2