MAYO CLINIC LABORATORIES

Test Definition: TCGRV

T-Cell Receptor Gene Rearrangement, PCR, Varies

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:

Preferred:
Specimen Type: Paraffin-embedded tissue
Container/Tube: Paraffin block
Collection Instructions:
1. Decalcified specimens (eg, bone marrow core biopsies) are **not acceptable**.
2. Indicate specimen source.
3. Include pathology report.
Specimen Stability Information: Ambient
Additional Information: If the quality of the biopsy specimen is poor, testing should not be ordered. Testing may be canceled if DNA requirements are inadequate.

Acceptable:
Specimen Type: Tissue slide
Slides: 20 Unstained slides
Container/Tube: Transport in plastic slide holders

Collection Instructions:
1. Send 20 unstained, nonbaked slides with 5-micron thick sections of tissue.
2. Decalcified specimens (eg, bone marrow core biopsies) are **not acceptable**.
3. Indicate specimen source.
4. Include pathology report.
Specimen Stability Information: Ambient
Additional Information: Testing may be canceled if resultant extracted DNA does not meet concentration requirements.

Specimen Type: Body fluid
Sources: Pleural, peritoneal, vitreous and spinal fluid
Container/Tube: Sterile container
Specimen Volume: At least 5 mL
Collection Instructions:
1. If the volume is greater than 5 mL, pellet cells and then store and send refrigerated.
2. Specify the type of fluid being submitted.
Specimen Stability Information: Refrigerate (preferred)/Ambient 4 days

Specimen Type: Frozen tissue
Container/Tube: Plastic container
Specimen Volume: 100 mg
Collection Instructions:
1. Freeze tissue within 1 hour of collection.
2. Indicate specimen source.
Specimen Stability Information: Frozen

Specimen Type: Extracted DNA
Container/Tube: 1.5- to 2-mL tube
Specimen Volume: Entire specimen
Collection Instructions:
1. DNA must be extracted within 7 days of collection.
2. Label specimen as extracted DNA and source of specimen.
3. Provide volume and concentration of DNA on label.
Specimen Stability Information: Frozen (preferred)/Refrigerated/Ambient
Additional Information: DNA must be extracted in a CLIA-certified laboratory or equivalent and must be extracted from a specimen type listed as acceptable for this test (including applicable anticoagulants). We cannot guarantee that all extraction methods are compatible with this test. If testing fails, one repeat will be attempted, and if unsuccessful, the test will be reported as failed and a charge will be applied.

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: 1 mL; Frozen tissue: 50 mg; Extracted DNA: 50 microliters (mcL) at 20 ng/mcL; Tissue slides: 10 unstained slides

Reject Due To

Bone marrow core biopsies	Reject
Paraffin shavings	Reject
Broken or cracked unstained slides	Reject
Frozen body fluid	Reject

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.

Interpretation

Results will be characterized as positive, negative, or indeterminate for a clonal T-cell population and include an interpretive report.

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 occur when the total T-cell number in a sample is limited or due to physiologic skewing of the T-cell repertoire as seen with aging, post-transplantation, 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.

Broken or cracked unstained slides are not compatible with the instrumentation used in our performing laboratories and will be rejected. Additional material may be requested.

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
4. Langerak AW, Groenen PJ, Bruggemann M, et al. EuroClonality/BIOMED-2 guidelines for interpretation and reporting of Ig/TCR clonality testing in suspected lymphoproliferations. Leukemia. 2012;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. Diag Histopathol. 2020;26(9):388-397

Performance

Method Description

Genomic DNA is extracted from the specimen. 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
Fresh/frozen tissue: 2 weeks; Extracted DNA: 3 months; FFPE tissue: Unused portions of blocks will be returned to the client. Unstained slides/body fluid: Not retained

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

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