T-Cell Receptor (TCR) Gene Rearrangement, PCR

**Test Code:** 5592  
**Department:** Molecular Oncology

**Test Synonyms:**  
- T-Cell Rearrangement  
- Gene Rearrangement for T-cell lymphoma  
- T-Cell Clonality  
- T-Cell Receptor Gamma Clonality  
- T-Cell Receptor Beta Clonality

**CPT Code(s):**  
- 83891  
- 83892  
- 83898 x 2  
- 83909 x 2

**Background:**  
T-cell lymphomas account for approximately 15% of non-Hodgkin lymphomas and may pose a diagnostic challenge on the basis of histopathology alone, and particularly in early stages of disease. The heterodimeric T-cell surface receptors, either alpha/beta or gamma/delta, are produced following somatic rearrangement of the T-cell receptor (TCR) genes (alpha, beta, delta, and gamma). This process is vital to the function of T-cells in normal immune function, but can be exploited to aid in the distinction between reactive (benign) versus neoplastic processes of T-cell proliferation. A reactive, benign T-cell proliferation is characterized by a polyclonal expansion of T-cells, whereas a malignant process is characterized by a clonal expansion of one specific T-cell population with a unique T cell receptor gene rearrangement. In conjunction with morphology, flow cytometry, and immunohistochemistry, the detection of a clonal T-cell gene rearrangements by polymerase chain reaction (PCR) can be used to aid in the diagnosis of malignant T-cell lymphoma.

**Clinical Utility:**  
PCR-based detection of rearranged T-cell receptor genes can be used to help establish a diagnosis of T-cell lymphoma, monitor for treatment response, and/or measure minimal residual disease (MRD).

**Methodology:**  
By extracting genomic DNA from blood, lymph node, bone marrow, or other tissue types T-cell receptor gamma and/or T-cell receptor beta are amplified by PCR using a multiplex primer method based on the BIOMED-2 strategy. Precise fragment sizing of the amplicons is accomplished using capillary gel electrophoresis. The presence or absence of a monoclonal T cell population is determined based on the overall assessment of the electrophoretic pattern.

**Sensitivity:**  
> 95% for the detection of clonality in most tissue types.  
False negative results could be due to:  
- Rare clone-specific gene rearrangements that do not bind to any of the primers in BIOMED-2 multiplex mixture.  
- Clonal T cells present at low abundance in polyclonal background, below the analytical sensitivity of the assay (~1-10%, depending on the loci).

The presence of a clonal T cell receptor gene rearrangement does not always equate to the presence of T cell malignancy.
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Specificity:
As cross-lineage TCR gene rearrangements have been reported in immature B-cell malignancies, interpretation of this test requires clinical, morphologic, and immunophenotypic correlation. False positive gene rearrangement results are rare but could result from the inadvertent sampling of a predominant T cell clone from within a polyclonal population.

Specimen Requirements:
- 5-10 mL of blood or bone marrow — yellow (ACD) or purple (EDTA) tube; or
- formalin-fixed paraffin-embedded (FFPE) tissue block or 10 slides (5 micron)
- Refrigerate or keep at room temperature.

A REQUISITION FORM MUST ACCOMPANY ALL SAMPLES. Please include detailed clinical information.

Test Performed (Days):
Monday, Wednesday, Friday

Turn Around Time:
5-7 days

Shipment Sensitivity Requirements:
Package and ship specimen to remain cold, but not frozen. Ship via overnight express, using the FedEx priority overnight label provided. Contact Client Services for shipping kits and instructions at (855) 535-1522.

References: