

TCR Beta Gene Clonality Detection by PCR and Capillary Electrophoresis

Clinical Indication and Relevance

- Aids in the diagnosis of T-cell malignancies
- Detection of disease or minimal residual disease monitoring

Methodology

DNA is isolated and amplified by PCR using BIOMED-2 primers targeting V β , D β and J β sequences. The gene rearrangements are detected by analyzing the PCR products by capillary gel electrophoresis.

Sensitivity

The assay sensitivity for detection of clonal T-cell populations is 10% of lymphocytes.

Turn-around Time

Five to seven working days

Sample Requirements

Collect

- Peripheral blood (PB): 3-5 mL, in purple top (sodium EDTA) tube; yellow top (ACD) tube acceptable.
- Bone marrow aspirate (BM): 1-3 mL, drawn into a syringe containing anticoagulant and then delivered in purple top tube (EDTA).
- Fresh or frozen tissue: fresh tissue should be obtained in a sterile manner, and a minimum 3 mm³ of tissue is required. Put fresh tissues in culture medium or snap freeze (see transport section below).
- Formalin-fixed paraffin-embedded (FFPE) tissue blocks: send FFPE tissue blocks to the lab, or contact lab for instructions about cutting sections for molecular studies.

Transport

- PB or BM samples should be delivered immediately to the lab at 2-8°C (wet ice or cold packs). PB and BM specimens should not be frozen.
- Fresh tissue samples should be delivered at room temperature in RPMI culture medium to the lab within 3 hours of collection, or snap frozen in liquid nitrogen at -70°C and packed in dry ice for delivery. Please do not allow frozen tissues to thaw.
- Formalin-fixed paraffin embedded (FFPE) tissue blocks can be delivered at room temperature.

Stability

PB or BM samples: ambient - 1 hour; refrigerated - 48 hours.

Unacceptable Samples

- Serum or plasma; frozen PB or BM; clotted blood; severely hemolyzed samples
- Tissue samples fixed in Zenker's, B5, or Bouin's fixatives
- Bone marrow biopsies decalcified in formic acid

CPT Code(s)

81340: *TRB@* (T cell antigen receptor, beta) gene rearrangement analysis to detect abnormal clonal population(s); using amplification methodology

References

1. Brüggemann M et al. *Leukemia*. 21:215, 2007
2. Langerak AW et al. *Leukemia*. 26:2159, 2012
3. Van Dongen JJ et al. *Leukemia*. 17:2257, 2003
4. Van Krieken JH et al. *Leukemia*. 21:201, 2007