

IGH Gene Clonality Detection by PCR and Capillary Electrophoresis

Clinical Indication and Relevance

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

Methodology

DNA is isolated and amplified by PCR using BIOMED-2 primers targeting the VH framework 1, 2, 3, DH and JH sequences of the IGH gene. The gene rearrangements are detected by analyzing the PCR products by capillary gel electrophoresis.

Sensitivity

The assay sensitivity for detection of clonal B-cell populations is 5% 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)

81261: *IGH@* (Immunoglobulin heavy chain locus), gene rearrangement analysis to detect abnormal clonal population(s); amplified methodology

G0452-26: Molecular pathology procedure; physician interpretation and report

References

1. Evans PA et al. *Leukemia*. 21:207, 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