

# B-Cell Clonality Screening (IgH and IgK) by PCR

## Indications for Ordering

Aid in the diagnosis and monitoring of lymphoproliferative disorders and in differentiating malignant from reactive lymphoid proliferations

## Test Description

Polymerase chain reaction (PCR)/capillary electrophoresis

- DNA extracted from bone marrow, peripheral blood, or formalin-fixed, paraffin-embedded (FFPE) tissue
- BIOMED-2 primer sets target
  - IgH
    - V<sub>H</sub>FR1-J<sub>H</sub>; V<sub>H</sub>FR2-J<sub>H</sub>; V<sub>H</sub>FR3-J<sub>H</sub>
  - IgK
    - V<sub>K</sub>-J<sub>K</sub>; V<sub>K</sub>-K<sub>de</sub>; J<sub>K</sub>C<sub>K</sub> intron-K<sub>de</sub>
- *PLZF* serves as internal control to determine nucleic acid integrity and adequacy

## Tests to Consider

### Primary Test

[B-Cell Clonality Screening \(IgH and IgK\) by PCR 2006193](#)

- Diagnosis and monitoring of B-cell lymphoproliferative disorders
- Equally sensitive for both kappa- and lambda-restricted populations

### Related Test

[Leukemia/Lymphoma Phenotyping Evaluation by Flow Cytometry 3001780](#)

- Aid in evaluation of hematopoietic neoplasms (ie, leukemia, lymphoma)
- Monitor therapy in patients with established diagnosis of hematopoietic neoplasms

## Test Interpretation

### Sensitivity/Specificity

- Clinical sensitivity: >95% for mature B-cell non-Hodgkin lymphomas
- Analytical sensitivity: clonal DNA must constitute at least 10% of the population examined
- Analytical specificity: >98%

### Results

- Detected: clonal rearrangement detected
- Not detected: no clonal rearrangement detected

### Limitations

- False-negative results may be due to specimen inadequacy and mutations affecting primer sites
- Detection of clonally rearranged IgH is seen in a subset of T-cell neoplasms
  - Positive result in the test should not be used to differentiate between T- and B-cell neoplasms