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
    - VH FR1-JH; VH FR2-JH; VH FR3-JH
  - IgK
    - VK-JK; VK-Kde; JcK intron-Kde
- 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