B and T Cell Gene Rearrangement by PCR

Effective Date: November 1, 2010 **Performing Department:** Molecular Pathology

Clinical Significance: Most malignant lymphomas are readily identifiable by laboratory methods such as histology and immunohistochemistry and/or flow cytometry. There are some lymphoproliferative lesions, however, where the abnormal lymphocytes are difficult to identify by routine histology. The clonal lymphocytes may be few in number within the tissue, or possibly dispersed within a background of polyclonal "reactive" lymphocytes or other inflammatory cells. Existing immunochemical markers may not readily identify the lymphocytes as malignant cells, a phenomenon that can occur in some T cell neoplasms. In such cases, identification of a genetically abnormal, clonal T or B lymphocyte population can be key to establishing the correct histopathologic diagnosis.

Method: Genomic DNA is extracted from patient's specimen and amplified by PCR using the standardized BIOMED-2 PCR primers from *InVivo*Scribe Technologies.

These primer sets detect up to approximately 98% of B cell neoplasms and 94% of T cell neoplasms. The assay sensitivity is approximately 5%. Some non-neoplastic conditions may result in false positive results due to transient, reactive "clonal" lymphocyte populations. Therefore, all results should be interpreted in the context of other histopathologic and clinical data.

This test was developed and its performance was established and confirmed by South Bend Medical Foundation (SBMF). This test is not cleared or approved by the U.S. FDA. This test is used for clinical purposes and should not be regarded as investigational or for research. SBMF is authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing.
This test is performed pursuant to an agreement with *InVivo*Scribe Technologies and Roche Molecular Systems, Inc.

Use: Identification of clonal T or B cell population(s) in tissue suspected of harboring a neoplastic lymphoproliferative lesion.

SPECIMEN REQUIREMENTS AND COLLECTION:

- 5 ml of peripheral blood, or bone marrow aspirate anti-coagulated with ethylene–diaminetetra–acetic acid (EDTA);
  Minimal volume: 1 mL; OR
- Formalin-fixed paraffin embedded tissue block; OR
- Tissue fixed in 10% buffered formalin.
  Minimal volume: 50 mg

Transport: Ambient temperature

Testing Schedule: As received, results in 14 days

Order:	36168 B-cell and T-cell gene rearrangement, PCR	CPT: 83891; 83900; 83901x14; 83909x10; 83912-26
	36169 B-cell rearrangement by PCR	CPT: 83891; 83900; 83901x5; 83909x5; 83912-26
	36170 T-cell rearrangement by PCR	CPT: 83891; 83900; 83901x7; 83909x5; 83912-26

Please direct any questions, or comments regarding this notice to Deborah H. Sun, Ph.D. (dsun@sbmf.org), Dr. Bobbie C. Sutton (bsutton@sbmf.org) or Sally Cornwall (scornwall@sbmf.org) or call South Bend Medical Foundation, (574) 234-4176 or (800) 544-0925.