B-Cell Acute Lymphocytic Leukemia Minimal Residual Disease Detection by Flow Cytometry (COG Protocol)

**Indications for Ordering**

Detection of minimal residual disease (MRD) in patients with B-ALL
- The assay is performed according to the Children’s Oncology Group (COG) protocol and is appropriate for patients enrolled in COG clinical trials
  - Although developed to meet COG requirements, this assay is applicable to any patient (at any age) with B-ALL
- Specimens include Day 29 post-induction bone marrow or induction Day 8 peripheral blood

**Test Description**

**Test methodology**
- Multiparameter flow cytometry analysis (6 color) of bone marrow and peripheral blood specimens
  - COG approved protocol
- Antigens included:
  - CD3, CD9, CD10, CD13, CD19, CD20, CD33, CD34, CD38, CD45, CD58, CD71, Syto 16

**Tests to Consider**

Primary test
- B-Cell Acute Lymphocytic Leukemia (B-ALL) Minimum Residual Disease Detection by Flow Cytometry (COG Protocol) 3000724

Related test(s)
- 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
- Chromosome FISH, Interphase 2002298
  - Use to individually order one or more oncology FISH probes when FISH panels are not desired

**Disease Overview**

**Diagnosis/treatment/follow-up issues**
- Aid in monitoring therapy in individuals with established diagnosis
- This test is not appropriate for initial diagnosis of ALL

**Test Interpretation**

**Sensitivity/specificity**
- Clinical sensitivity: limit of detection – 0.01%

**Results**

Antigens will be reported as positive or negative
- Positive results will be reported as percentage

**Limitations**
- Poor cell viability may adversely affect antigens and impede the ability to properly identify neoplastic cells
- Number of events collected may affect sensitivity
- Flow results should not be used alone to diagnose malignancy
  - Should be interpreted in conjunction with morphology, clinical information, and other necessary ancillary tests for a definitive diagnosis