**BCR/ABL t(9;22) major (p210) IS, Quantitative**

**Indications for testing**
CML is one of the most common hematologic malignancies and accounts for 15-20% of all cases of leukemia. The incidence of CML is approximately 1.6/100,000. More than 95% of patients with CML have the distinctive Philadelphia chromosome that result from a reciprocal translocation between the long arms of chromosomes 9 and 22. The translocation involves the transfer of the Abelson or ABL1 gene on chromosome 9 to the breakpoint cluster region, BCR, of chromosome 22, resulting in a fused BCR/ABL gene. The fusion gene produces BCR/ABL, a tyrosine kinase with deregulated activity that plays a key role in the development of CML.

**Testing Methodology**
The quantitative BCR/ABL assay is performed on the GeneXpert (Cepheid) platform. RNA is extracted, converted to cDNA, and BCR/ABL and ABL cDNA targets are quantified by real-time PCR amplification.

The analytical sensitivity of this assay is 0.01% BCR/ABL:ABL. The reproducibility of this assay is such that results within 0.5 log should be considered equivalent.

Due to assay non-linearity for BCR/ABL values greater than 10%, values in this range will be reported as ">10%".

**Specimen Requirements**
- **Peripheral blood**—1 lavender-top (EDTA) tube. Invert several times to mix blood. Forward promptly at ambient temperature.
- **Bone Marrow**—Place 1-2 mL of anticoagulated bone marrow in a lavender-top (EDTA) tube. Invert several times to mix bone marrow. Forward promptly at ambient temperature.

Specimens must be analyzed within 120 hours of draw.

**Current Pricing**
Contact Lab Customer Service for current pricing 314 362-1470.
CPT code: 81206

