Molecular Diagnostic Laboratory
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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

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Barnes-Jewish Hospital, Institute of Health
Mail Stop 90-28-344
425 South Euclid Avenue, Room 5970
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Clinical information must be provided with specimen referral in order to correctly interpret test results.

Current Pricing

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

Branford S, Fletcher L, Cross N, et al. Desirable performance characteristics for BCR-ABL measurement on an international reporting scale to allow consistent interpretation of individual patient response and comparison of response rate between clinical trials. Blood 2008;113:3330-3338.

White HE, Matejschuk P, Rigsby P, et al. Establishment of the first World Health Organization International Genetic Reference Panel for quantification of BCR-ABL mRNA. Blood 2010;116:e111-117.

Xpert® BCR-ABL Monitor Technical Manual. Cepheid, 5/2011 revision