Sensitive CML Monitoring

Xpert® BCR-ABL Ultra

Sensitivity, precision, and ease of use

US-IVD. For In Vitro Diagnostic Use.
Cepheid’s Xpert® BCR-ABL Ultra test solves many of the present challenges in monitoring patients with Chronic Myeloid Leukaemia, including accuracy (remarkably precise International Scale calibration) and speed (in hours) of reporting molecular response. These performance characteristics are important from initiation of therapy to the deep remissions possible with the array of available therapeutic options.”

Michael J. Mauro, M.D.
Leader, Myeloproliferative Neoplasms Program
Memorial Sloan Kettering Cancer Center

The Need

Each year, 1.9 newly diagnosed Chronic Myelogenous Leukaemia (CML) patients are identified per 100,000 individuals. CML prevalence is estimated to increase at an annual rate of 4%, and the number of individuals living with this disease will double by 2030.

Managing CML in most diagnosed patients is achieved by oral administration of a Tyrosine Kinase Inhibitor (TKI) that specifically targets the activity of the BCR-ABL fusion protein. Currently, assessing treatment efficacy for CML requires a molecular diagnostic assay to measure the level of BCR-ABL transcript (RNA). Patients are tested for BCR-ABL every 3 months according to established international guidelines.

Quantitative results are first normalized against a reference gene such as ABL. Subsequently, results are converted to an International Scale (IS) that harmonizes reporting of the molecular response.

Despite efforts to optimise disease management, only one-third of newly diagnosed CML patients are adequately monitored during the first year of treatment. Therefore, more accessible molecular testing is needed for CML patient outcomes to improve.

The Solution

Xpert BCR-ABL Ultra is a quantitative test for BCR-ABL major breakpoint (p210) transcripts that provides highly sensitive and on-demand molecular results.

Based on the innovative GeneXpert® technology, Xpert BCR-ABL Ultra automates the entire test process including RNA isolation, reverse transcription, and fully-nested real-time PCR of BCR-ABL target gene and ABL reference gene, in one fully automated cartridge.

Unprecedented performance

Ease of use
- < 2.5 hours total process
- Simply add treated blood sample and an off-board reagent to the Xpert cartridge
- Results aligned to the IS lot-to-lot through secondary standards calibrated to the BCR-ABL WHO panel

Sensitive
- Includes two internal controls
- 4 mL input volume of whole blood ensures reproducible detection of low-level transcripts
- High sensitivity and low inter-laboratory variation
- Clinically demonstrated limit of detection of <4.5-log reduction (0.0030%)
The Impact

• Clinician: Same day information supports informed clinical decisions
• Patient: Faster results reduce patient anxiety
• Laboratory: Flexibility and simplicity for more streamlined workflow

Move your lab forward

• Decrease costs: Eliminates need for standard curve and replicate testing
• Optimised lab organisation: Free up technician time for other lab services
• Flexible: Any number of samples, any day of the week, with a fixed cost per reportable result
• Simple Reporting: One page report with results aligned to the IS

Process Mapping of Different Laboratory Scenarios

Performance

The Clinical performance of Xpert® BCR-ABL Ultra was evaluated by comparison to an FDA cleared molecular assay, which detects and quantifies the mRNA transcripts for the p210 translocation types and uses the ABL gene as an endogenous control mRNA transcript.

Fresh, prospectively collected EDTA whole blood specimens, and frozen lysates, from patients with CML at any stage of disease, following initial diagnosis, with or without prior exposure to Tyrosine Kinase Inhibitor therapy or other CML treatment were used.

LINEAR REGRESSION

BLAND-ALTMAN PLOT

Workflow

3 Easy Steps

1. Transfer the Wash Reagent into Chamber

2. Pipette entire contents of prepared sample (~4.5mL) into the sample chamber (S)

3. Insert cartridge and start test

Xpert® BCR-ABL Ultra provides individual on-demand measurement of BCR-ABL transcript levels down to 4.5 log reduction for individuals with CML.

CATALOG NUMBER
Xpert BCR-ABL (10 tests) ................................................. GXBCRABL-US-10

References:
3. NCCN guidelines
9. Cepheid Product Insert