Ultra-Sensitive CML Monitoring

Xpert® BCR-ABL Ultra

Sensitivity, precision and ease of use
The need

Each year 1.0-1.5 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
- 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 (0.0032%)
THE IMPACT

- **Clinician:** Same day information supports informed clinical decisions, including inclusion in treatment discontinuation research.
- **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 was evaluated by comparison with an in-house assay based on the Europe Against Cancer (EAC) standardized ‘real-time’ quantitative reverse transcriptase polymerase chain reaction (RQ-PCR) of fusion gene transcripts for residual CML disease. This routine assay was calibrated for the ABL reference gene and BCR-ABL target gene using the Institute for Reference Materials and Measurements (IRMM) plasmid dilutions. In the study, peripheral blood was acquired prospectively from subjects with CML into EDTA tubes. Each specimen was split for comparison testing with the routine assay and the Xpert BCR-ABL Ultra assay. Total recruitment included 54 subjects whose paired results were within the detectable range of both assays.

**LINEAR REGRESSION**

\[ y = 0.8582x - 0.3476 \]

\[ R^2 = 0.9242 \]

**BLAND-ALTMAN PLOT**

Data provided by D. Colomer, Hematopathology Unit, Hospital Clinic, IDIBAPS, Barcelona, Spain.
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 INFORMATION

Xpert BCR-ABL Ultra (10 tests) ............................................................... GXBCRABL-CE-10

References:
8. Cepheid Product Insert

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