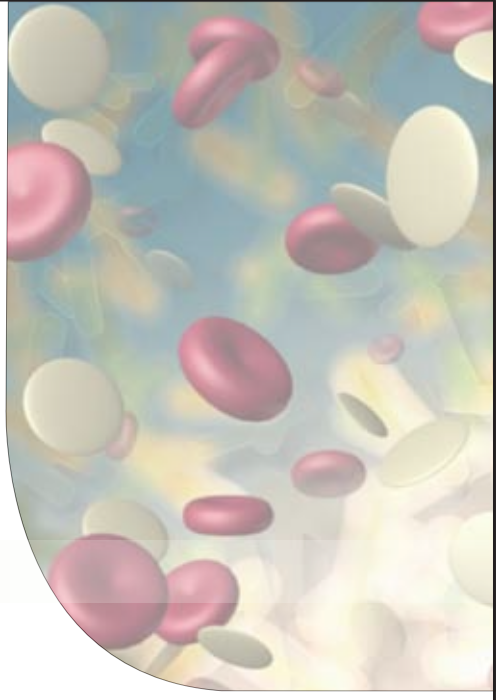
Unipath
SPECIALTY LABORATORY Ltd.



IS (International Scale) BCR-ABL1 Quantification

TEST DESCRIPTION

Unipath BCR-ABL1 quantification assay allows for accurate and reliable measurement of the p210 BCR-ABL1 transcript at International scale. The assay primers span BCR exons b2 and b3 and ABL1 exon 2 such that both b2a2 and b3a2 p210 BCR-ABL1 transcripts are detected. The assay enables detection down to three copies of BCR-ABL1 and has a linear dynamic range of 5 logs. Unique RNA Controls used in the assay allow for determination of Major Molecular Response (MMR) levels based on the International Scale (IS), as established by the International Randomized Interferon versus STI571 (IRIS) study.1

Major Molecular Response (MMR) reflects a patient's response to CML treatment. MMR is defined as greater or equal to a 3-log reduction in the ratio of BCR-ABL1: control gene from a standardized median baseline value.

1. NEJM 2006; 355:2408-2417 2. NEJM 2003; 349:1423-1432 3. NEJM 2010; 362:2251-2259 4. NEJM 2010; 362:2260-2270

CANCER RELEVANCE
- **Chronic myelogenous leukemia**

DRUG RELEVANCE
- **Imatinib/ Gleevac**

SENSITIVITY
- **One leukemic cell in 1 million normal cells**

TURN AROUND TIME
- **10-12 Days**

CONTACT

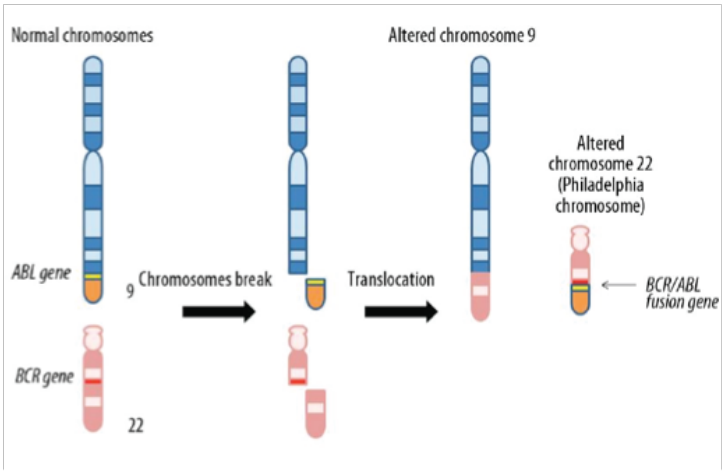
- unipathmdx@gmail.com

OR call on 079-49006800/31

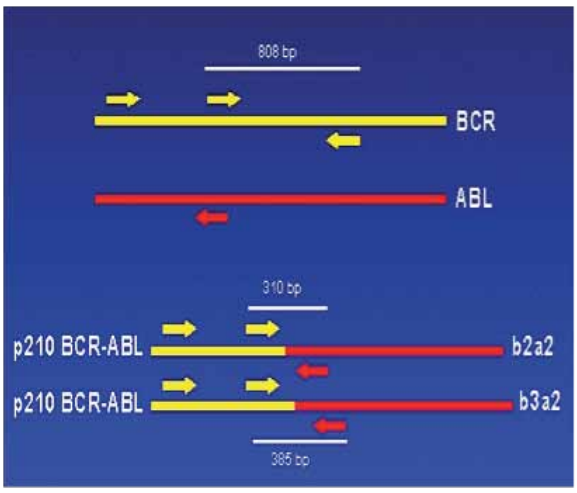
CLINICAL UTILITY

Targeted BCR-ABL1 kinase inhibitors are an effective first-line treatment for the majority of Ph+ CML and Ph+ ALL patients. Serial analysis of BCR-ABL1 levels is an effective method for monitoring treatment efficacy for the majority of Ph+ CML patients.

BCR ABL FUSION



TRANSCRIPTS TESTED IN TEST



Comparison of diffetent Methods to Detect Minimal Residual Disease in Patients

Method	Target	Sensitivity	Advantages	Disadvantages
Morphology	Cellular morphology	5%	Standard	Poor sensitivity
Cytogenetic	Chromosome structure	1%-5%	Widely available	Low sensitivity Bone marrow only
FISH*	Specific genetic markers	0.1%-5%	Fast (1-2 days)	Does not detect other clonal events
Quantitative RT - PCR	RNA sequence	0.001%-0.01%	Very sensitive	Poor standardization Laboratory intensive

Figure 1:

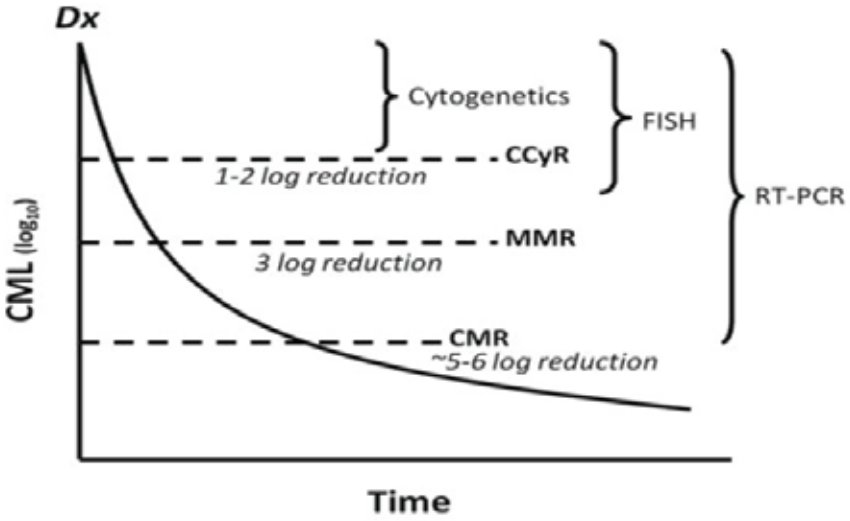
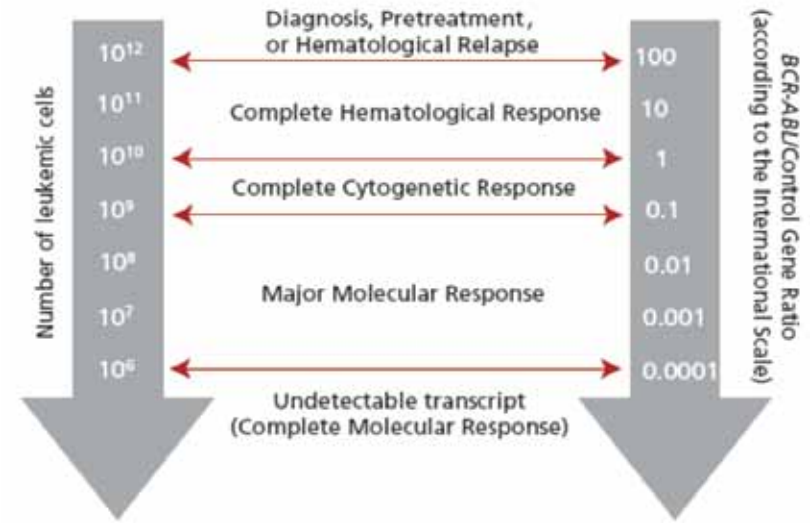


Figure 1. Disease burden and tests: The figure shows the reduction of CML burden and the sensitivity of assays (plot not to scale). Routine cytogenetic analysis will fail to detect the Philadelphia chromosome (CCyR) after a 1-2 log reduction in CML burden. The detection limit of reverse-transcriptase PCR is approximately a 5- to 6-log reduction in disease burden. From Radich JP. Blood. 2009; 114:3376-3381

The BCR-ABL Transcript Percent Parallels the Number of Leukemic Cells.



Assay Summary

Methodology	Quantitative Real-time PCR
Specimen	EDTA Blood/ Bone Marrow
Sensitivity	One tumor cell in 1x108 normal cells
Reporting	BCR-ABL1:ABL1 ratio, MMR value,
Turn Around Time	10-12 business days
Limit of Quantification	3 BCR-ABL1 copies

ISO 9001 International Standard Certification LIC No QAC/R91/3585 NABL M-0520

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