BCR-ABL1 Quantification Services

TEST DESCRIPTION

MolecularMD BCR-ABL1 quantification services allow for accurate and reliable measurement of the p210 BCR-ABL1 transcript. 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.[2]

MolecularMD employs a MMR reference value that has been validated with participants of the IRIS study and referenced in several recent studies.[3,4]

DISEASE RELEVANCE
- Chronic myelogenous leukemia
- Ph+ acute lymphocytic leukemia

DRUG RELEVANCE
- ABL1 tyrosine kinase inhibitors

SENSITIVITY
- One tumor cell in 1 million normal cells

STANDARD TURN AROUND TIME
- 5 days

RELATED ASSAYS
- BCR-ABL1 p190 transcript quantification
- BCR-ABL1 mutation analysis (p210 and p190)
- BCR-ABL1 fragment analysis

CLINICAL UTILITY

Targeted BCR-ABL1 kinase inhibitors are now 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.

The MolecularMD BCR-ABL1 Quantitative RT-PCR assay meets or exceeds the acceptance criteria proposed during the 2005 consensus meeting for BCR-ABL1 monitoring.

ASSAY SPECIFICATIONS

Methodology:	Quantitative real-time PCR
Interassay Variability:	Above MMR: less than 2-fold Below MMR: less than 3-fold
Sensitivity:	One tumor cell in $1x10^6$ normal cells
Limit of Quantitation:	3 BCR-ABL1 copies
Reporting:	BCR-ABL1:ABL1 ratio, MMR value, BCR-ABL1 copy number, ABL1 copy number, results of prior quatification assays
Standard Turn Around Time:	5 business days (MolecularMD accepts Saturday deliveries)

EXPERIENCE

MolecularMD's centralized CLIA-certified and CAP-accredited molecular diagnostics laboratory has a proven track record in supporting pivotal international clinical research programs. We are a preferred provider of specialty molecular diagnostics services to pharmaceutical and biotech drug developers, offering assays that are rigorously validated to provide rapid and reproducible results that enable prompt clinical decision-making relevant for both solid tumors and hematological malignancies. Our experience and commitment to quality make MolecularMD a leader in reference lab services and an optimal partner for companion diagnostics development.

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

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PHYSICIAN / FACILITY / CLIENT INFORMATION

PHYSICIAN: Test MD, MD
CONTACT PERSON: Test MD, MD

LOCATION: Test location
CONTACT PHONE 503-459-4975

PATIENT INFORMATION

INITIALS: T, T
ID #: 005NOV
DOB: 06/25/1956
AGE: 51 SEX: M

SPECIMEN INFORMATION

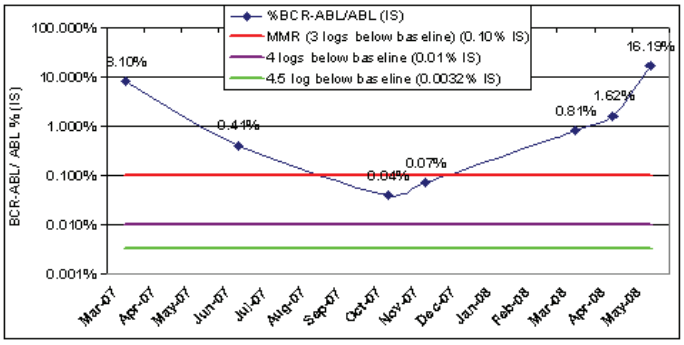
SPECIMEN ID #: NOV2008-000003
SPECIMEN DATE: 05/23/2008 TIME 2:00pm
RECEIVED DATE: 05/27/2008 TIME 10:00am
REPORT DATE: None

TEST INFORMATION

BCR-ABL FOLD CHANGE:	**From last analysis:** 10	**From lowest level:** 410		
TEST:	METHOD:	SPECIMEN:	SAMPLE QUALITY:	
1. BCR-ABL Quant.	QRT-PCR	Peripheral Blood	Good	
2. Mutation Analysis	Sequencing	Peripheral Blood	Good	
TEST 1 RESULTS	BCR/ABL (IS%) 0.1619 (16.19%)	BCR/ABL (raw%) 0.1999 (19.99%)	ABL Copies 4987	BCR-ABL Copies 997
TEST 2 RESULTS	MUTATION 1 T315I	MUTATION 2 N/A		

INTERPRETATION
MMR:** ***NO***
BCR-ABL/ABL% <= 0.01% (IS): ***NO***
BCR-ABL/ABL% <= 0.0032% (IS): ***NO***
BCR-ABL/ABL% >= 5 fold increase from lowest recorded value: ***YES***

CUMULATIVE RESULTS: QRT-PCR TREND



For more information on BCR-ABL1 Quantification, email bd@molecularmd.com or call +1 877-459-4979

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