MolecularMD
1341 SW Custer Dr.,
Portland, OR 97219

T: 1-877-459-4979
F: 1-503-459-4976
www.molecularmd.com

MolecularMD
Better Performance. Better Decisions.

BCR-ABL KINASE DOMAIN SEQUENCING SERVICES

TEST DESCRIPTION

MolecularMD has developed a sensitive and specific direct sequencing assay for screening of mutations in BCR-ABL. Our assay detects mutations between amino acids 30 and 510 including the kinase domain SH3, SH2 and regions 3' to the ABL kinase domain.

Over 40 amino acid substitutions in the tyrosine kinase domain of BCR-ABL can be detected by MolecularMD's sequencing assay. These substitutions have been identified in CML patients who develop resistance to tyrosine kinase inhibitors and related treatments.

Direct sequencing is a non-biased approach that has a sensitivity of 20-30% in the identification of BCR-ABL mutant clones.

DISEASE RELEVANCE:
Chronic Myelogenous Leukemia (CML)

DRUG RELEVANCE:
ABL tyrosine kinase inhibitors such as imatinib (Gleevec®) and dasatinib (Sprycel®)

TEST SPECIFICATIONS

METHODOLOGY:	Direct Sequencing
CPT CODES:	Please call Customer Service or refer to the MolecularMD website.
LIMIT OF DETECTION:	20-30% of the mutant allele among non-mutated alleles
CONTROLS:	BCR-ABL WT and various mutants covering the entire kinase domain
REPORTING:	Amino acid change in ABL kinase domain
TURN AROUND TIME:	8 business days, 4 business days if RNA is available (MolecularMD accepts Saturday deliveries)

SPECIMEN REQUIREMENTS

SPECIMEN	PERIPHERAL BLOOD		BONE MARROW
SPECIMEN TUBE	EDTA	PAXgene	EDTA
VOLUME	10 mL	5 mL	2 mL
STORAGE	R.T.*	R.T.**	R.T.
STABILITY	48 hrs	72 hrs	48 hrs
SHIPPING	Ambient	Ambient	Ambient
OTHER	DO NOT FREEZE	2 tubes	DO NOT FREEZE

* R.T. = Room Temperature
** If PAXgene tubes are expected to arrive at MolecularMD after 72 hours of blood draw, FREEZE at -20ºC, then -70ºC/-80ºC and ship on dry ice.

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SAMPLE REPORT

PHYSICIAN / FACILITY / CLIENT INFORMATION

PHYSICIAN: physician test
CONTACT PERSON: physician test
LOCATION: Test location
CONTACT PHONE #:

PATIENT INFORMATION

NAME/INITIALS: test, seq
ID #: 002NOV
DOB: 03/01/1947
AGE: 60 SEX: M

SPECIMEN INFORMATION

SPECIMEN ID #: NOV2007-000002
SPECIMEN DATE: 03/01/2007 TIME 10:00am
RECEIVED DATE: 03/02/2007 TIME 9:00am
REPORT DATE: 03/14/2007

RESULTS & INTERPRETATION

BCR-ABL Kinase Domain Sequencing Results

Tube	Mutation 1	Mutation 2	Mutation 3
EDTA	E255V	N/A	N/A

INTERPRETATION

The E255V mutation was detected.

Test Description:

As per your request, we have completed mutation analysis of BCR-ABL, a marker for the presence of transcriptionally active Philadelphia chromosome positive leukemia cells. For this assay, the total RNA from whole blood leukocytes is reverse transcribed with random primers and the cDNA product is amplified with BCR-ABL-specific primer sets. The PCR product is then sequenced with ABL-specific primers. The assay detects mutations in the ABL kinase domain and additional ABL domains of the BCR-ABL fusion protein, between amino-acids amino-acids 30 and 510. The limit of detection of the assay is 20-30% depending on the the mutation.

Electronically Signed By:

Courtney Fuller
Scientist
(Case signed 03/14/2007)

Chad Galderisi DO FCAP
Pathologist
(Case Reviewed 03/14/2007)

This test was developed and it's performance characteristics determined by this laboratory. It has not been been cleared or approved by the FDA.
The laboratory is regulated under CLIA of 1988.