CANCER GENETICS
Empowering Personalized Cancer Treatment

MatBA® CLL/SLL
INFORM PREDICT DECIDE
Mature B-Cell Neoplasm Array

Case Study #174

MatBA®-CLL/SLL Improves Patient Prognosis Accuracy

Resolves prognostic discrepancy between FISH and molecular analyses

Patient Case 174: 64 year old female.
Clinical History: Untreated.
Specimen: Peripheral blood.

Clinical Dilemma

Conflicting Prognoses

FISH Analysis: Reported a **favorable/intermediate outcome** (loss of 13q).

Molecular Analysis: Reported a **poor outcome** (IGHV status: unmutated).

Contradictory prognoses left a key clinical question:
What is this patient's prognosis?

Clinical Solution

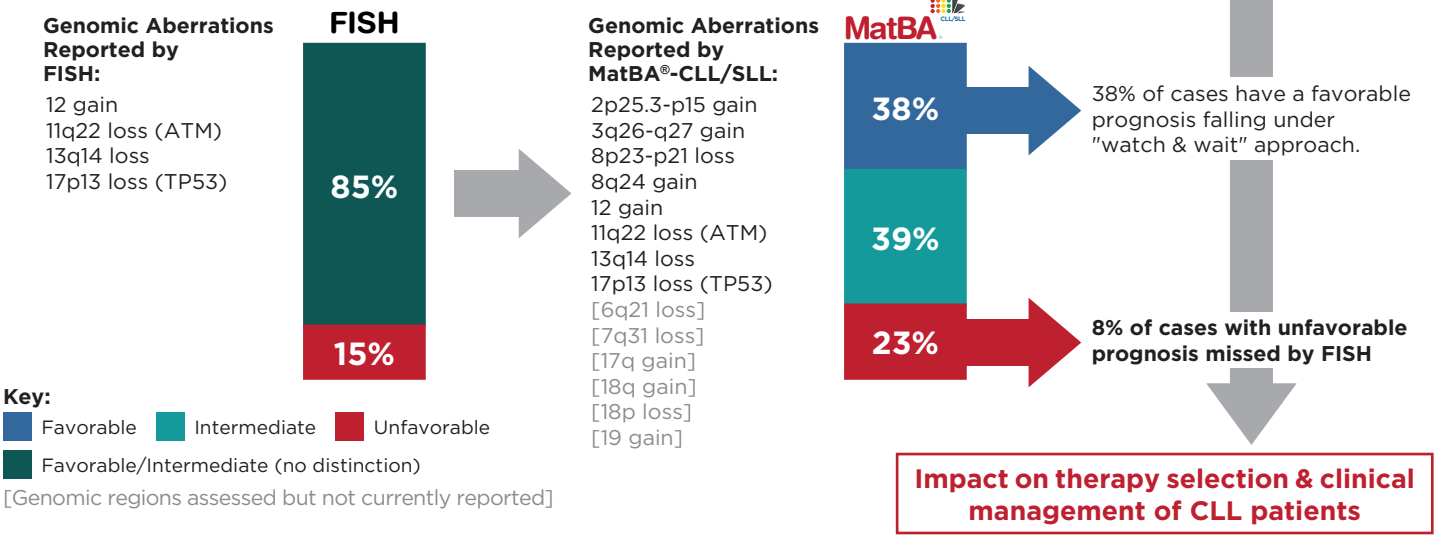
INFORM
- Detected **gain of 2p**, **loss of 13q at 2 loci**, **loss of 18p**.
- Includes biomarkers not assessed by FISH.

PREDICT
- The comprehensive genomic assessment gives data that resolves the initial discrepancy
- The genomic aberrations detected confirmed the **patient's high risk for a poor outcome**.

DECIDE
- Test results were used for proper **clinical management selection**.
- The genomic aberrations detected are evidence for this patient's unfavorable prognosis. The clinician may choose to **select an aggressive course of treatment**.

CLL Risk Stratification Per Prognostic Category

Collaboration with Dr. Kanti Rai & Dr. Nicholas Chiorazzi (NSLIJ); Two Datasets, 316 specimens



Patients stratified into "Favorable/Intermediate" by FISH will benefit from distinction into proper prognostic categories by:

- Preventing the selection of "watch and wait" approach for those who would be stratified as intermediate. These patients with early-stage CLL/SLL may benefit from earlier therapy with a lower tumor burden and prior to clonal evolution.
- Delaying therapy for patients with a favorable prognosis, protecting them from toxicity and possible risk of future drug-resistant disease.
- Selecting the proper treatment for patients that initially are mis-prognosed by FISH into the favorable/intermediate category who in fact have an unfavorable prognosis.

MatBA®-CLL/SLL addresses the need to more accurately determine the prognosis of patients at diagnosis - **the greatest opportunity to impact the clinical management of CLL patients**.

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Assay Specifications

Sensitivity
Detects genomic gains and losses in up to 85% of CLL. Limit of detection is 30-40 cells in 100 mononuclear cells (assay sensitivity).

Reporting
Results are reported as positive or negative for the gain or loss of each respective alteration. Results of the assay should be interpreted in the context of available clinical, pathologic, and laboratory information. Identification of genomic gain/loss should not be used alone for the diagnosis or prognosis of CLL/SLL.

TAT
10-14 days

Specimen Requirements
- One EDTA tube (lavender) of peripheral blood or bone marrow aspirate with minimum: 2-3 ml or 3-5 µm thick formalin-fixed paraffin-embedded (FFPE) sections (10% neutral buffered) on positively coated slides.
- Specimen should be stored & transported at room temp.

Licensure
CAP (Laboratory #: 7191582, AU-ID: 1434060), CLIA (Certificate #: 31D1038733), New Jersey (CLIS ID #: 0002299), New York State (PFI: 8192), Pennsylvania (031978), Florida (800018142), Maryland (1395).

CPT Codes
81479

Patient Name:		Accession Number:	
Sex:	X Male _ Female	CGI ID No:	
Date of Birth:		Ordering Physician:	
Specimen:	Peripheral Blood	Client:	
Collected:		Client Account No:	
Received:		Client ID No:	
Reported:		Client Address:	
Clinical Hx:	CLL	Telephone:	

MatBA® - CLL/SLL Array-CGH Report

Results:

Genomic Aberration	Result for Aberration
Loss of 8p (8p23.3-p21.3)	Negative
Loss of 11q (ATM)	Negative
Loss of 13q (MIR-15A/16.1)	**Positive**
Loss of 13q (RB1)	**Positive**
Loss of 17p (TP53)	Negative
Gain of 2p	**Positive**
Gain of 3q	Negative
Gain of 8q	Negative
Gain of 12	Negative

Interpretation: ***Positive for the gain of 2p and loss of 13q at two loci. Gain of 2p in CLL patients is associated with an unfavorable prognosis.***

Description: The gain and loss of specific genomic regions in the monoclonal proliferation of B-cells in chronic lymphocytic leukemia (CLL) are considered to have diagnostic and prognostic value. Loss of 13q at one locus (MIR-15A/16.1) or both loci (MIR-15A/16.1 and RB1) is observed in approximately 50% of CLL patients and as the sole abnormality is associated with a longer overall survival. Those patients with loss of 17p (TP53) or 11q (ATM) in general, have a shorter overall survival. Other aberrations are variously observed in CLL patients with suggested prognostic value.

This assay utilizes microarray-based comparative genomic hybridization (Array CGH) to simultaneously detect the gain and loss of multiple loci in specimen DNA. Quantitative PCR is used to confirm the detected genomic gains and losses. The sensitivity of the assay is 30-40%. Samples in which the monoclonal B-cells are present at less than 30-40%, aberrations may not be detected and will be reported as no aberrations detected.

End of Report

The tests utilizing analyte-specific reagents (ASR) were developed and their performance characteristics determined by Cancer Genetics, Inc. as required by CLIA Ð88 regulations. They have not been cleared or approved for specific uses by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. These tests are used for clinical purposes. Cancer Genetics, Inc., 201 Route 17 North, Rutherford, NJ 07070. Phone number: (888) 334 - 4988 CLIA#:31D1038733; CAP LAP#: 7191582