CANCER GENETICS
Empowering Personalized Cancer Treatment

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

CLL/SLL

# MatBA®-CLL/SLL Array-CGH Assay

## Overview

Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL) arise through clonal expansion of CD5+ B lymphocytes. Accurate prognostication for treatment options is highly desirable in CLL/SLL considering that it occurs almost exclusively in elderly adults (median age at diagnosis is 65 years) and that patients display great clinical heterogeneity in the course of their disease. Mature B-cell neoplasms, such as CLL/SLL, exhibit frequent genomic alterations that have diagnostic and prognostic significance. One such type of alteration is gain or loss of genomic loci, which in the current test, is assayed by array comparative genomic hybridization (array-CGH) permitting the simultaneous detection of gain and loss at multiple loci.

## Clinical Indications

Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma.

## Clinical Utility

Aids in determining prognosis and treatment selection at diagnosis and during patient monitoring.

**INFORM**

MatBA®-CLL/SLL assesses **multiple prognostic genomic biomarkers** including some not assessed by FISH.

**PREDICT**

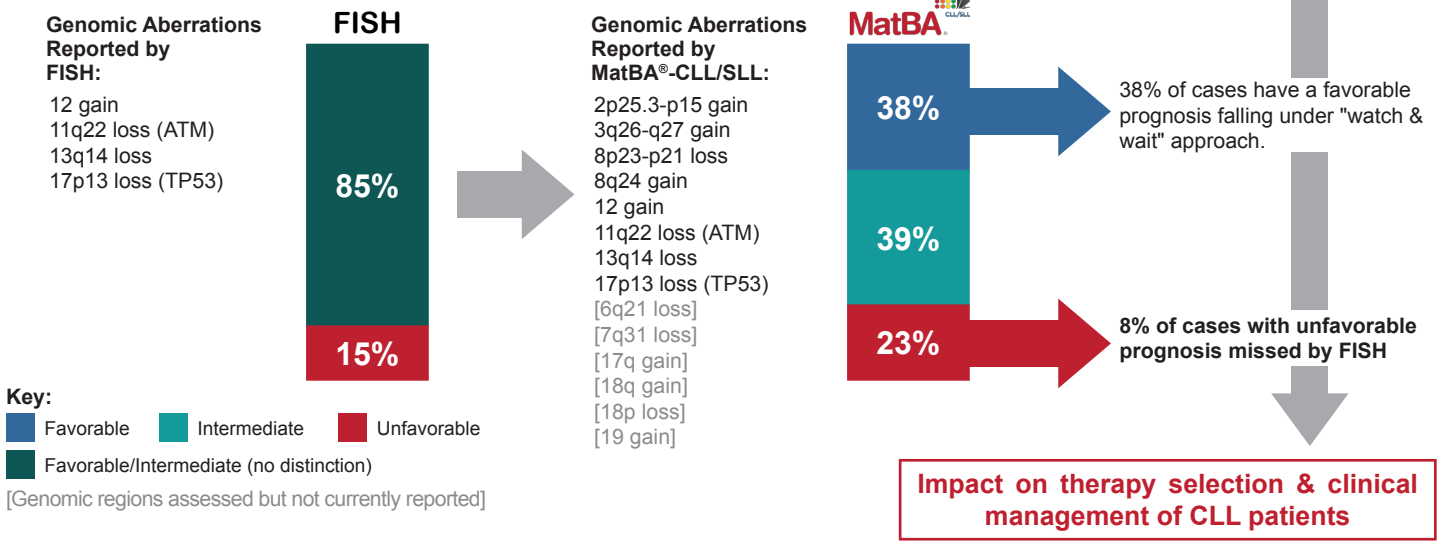
By assessing specific genomic regions, MatBA®-CLL/SLL can provide the patient's **prognostic outcome**.

**DECIDE**

Together with other clinical and laboratory findings, MatBA®-CLL/SLL can assist in devising the **best treatment plan for an individual patient**.

### CLL Risk Stratification Per Prognostic Category

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




**Patients stratified into FISH "Favorable/Intermediate" 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 for CLL and >70 cells in 100 mononuclear cells for SLL (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 2-3ml or 3-5 FFPE sections at 10µm thickness on regular slides or in a tube.
- Stored and transported at room temperature.

**CGI Laboratory 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

## MatBA®-CLL/SLL Array-CGH Sample Report

**Results:**

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

**Interpretation:** ***Positive for the loss of 13q (MIR-15A/16.1) and borderline loss of 11q (ATM). Loss of 11q (ATM) in CLL/SLL 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/small lymphocytic lymphoma (CLL/SLL) are considered to have diagnostic and prognostic value. Loss of 13q at one locus (*MIR15A/16-1*) or both loci (*MIR15A/16-1* and *RB1*) is observed in approximately 50% of CLL/SLL 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/SLL 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

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