CANCER GENETICS®

Empowering Personalized Cancer Treatment

AML COMPLETE

AML Complete™

Acute myeloid leukemia (AML) is a bone marrow cancer that progresses rapidly creating a therapeutically challenging disease to accurately diagnose and prognosticate. Approximately 38,000 people in the US are living with a history of AML. Bone marrow analysis with cytogenetics is used to predict remission rates, relapse risks, and overall survival outcomes. Molecular markers such as mutations and small insertions/deletions exhibit clinical relevance by helping to refine prognostic groups. Common molecular markers include CEBPA, FLT3-ITD, cKIT, and NPM1. Interpretation of the clinical relevance of mutations in AML must be considered in the context of cytogenetic-risk categories but also with respect to other mutations. By offering the most comprehensive testing panel available, CGI's AML Complete™ Program can help in determining the best personalized course of action for the patient.

The Benefits of Personalized Medicine

Clinicians have long known that patients respond differently to treatment. Genomics is now helping them in apprehending each patient's unique genetic make-up and the probable outcome of their disease. Testing patients for specific biomarkers can provide insight into diagnosis, prognosis, and the patient's likelihood of responding to certain treatments.

Tests being offered in the Complete™ Programs include biomarkers that rely on various methodologies and that have diagnostic and prognostic significance for each patient.

List of AML Complete™ Tests

Physicians can order tests individually or allow CGI pathologists and directors to determine a panel evaluation as determined necessary.

Morphology & IHC

Morphology
The morphological assessment provides critical information used to detect aberrant cell lineage maturation/dysplasia in AML.

IHC Evaluation
A panel of IHC may be utilized to further evaluate individual MDS cases to differentiate cell lineage and to enumerate blast count. Panel includes CD34, CD117 (cKIT), MPO, Muramidase, and Glycophorin A.

Flow Cytometry

Myeloid/Lymphoid Panel
The myeloid lymphoid panel determines expression levels of cell surface antigens by flow cytometry that provide information for the diagnosis and for monitoring therapy. This panel includes CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11b, CD11c, CD13, CD14, CD15, CD16, CD19, CD20, CD22, CD23, CD33, CD34, CD38, CD45, CD56, CD57, CD64, CD71, CD117, HLA-DR, sKappa, sLambda.

Molecular Diagnostics

Focus::Myeloid™ NGS Panel [CLIA]
Focus::Myeloid™ is a unique next-generation sequencing (NGS) panel, supplemented by individual gene sequencing, with 54 biomarkers that provides actionable information for improved diagnosis, prognosis, and risk stratification in AML, myelodysplastic syndrome (MDS), and myeloproliferative neoplasms (MPN). Focus::Myeloid™ includes the four commonly evaluated biomarkers (CEBPA, FLT3, cKIT, and NPM1) as well as other clinically relevant biomarkers associated with AML.

CEBPA Mutation Analysis [Sanger Sequencing]
CEBPA mutations are present in approximately 13-18% of patients with cytogenetically normal AML and appear to be associated with a favorable prognosis when other adverse prognostic factors, such as FLT3-ITD mutations, are absent.

FLT3-ITD Mutation Analysis [PCR fragment analysis]
FLT3-ITD mutations occur in approximately 30% of cytogenetically normal AML. Studies have shown a negative prognostic influence of FLT3-ITD mutations, resulting in shorter remission durations and shorter overall survival.

cKIT Mutation Analysis [Sanger Sequencing]
cKIT mutations are found in approximately 30% of AML with t(8;21) or inv(16) and are categorized as having an intermediate risk status.

NPM1 Mutation Analysis [Sanger Sequencing]
NPM1 mutations occur in approximately 28-35% of patients with AML. Patients with normal cytogenetics and NPM1 mutations in the absence of FLT3-ITD mutations, are categorized as having a favorable risk status.

FISH

Acute Myeloid Leukemia (AML) FISH Panel
The AML FISH panel, including t(8;21), t(15;17), inv(16), and 11q23, provides critical diagnostic information about the AML sub-classification and predictive information for risk stratification.

Karyotype
Karyotyping enables genome-wide detection of aberrations at low resolution that have a diagnostic and prognostic significance.

201 Route 17 North • Rutherford • NJ 07070 • Office 201.528.9200 • Fax 201.528.9201
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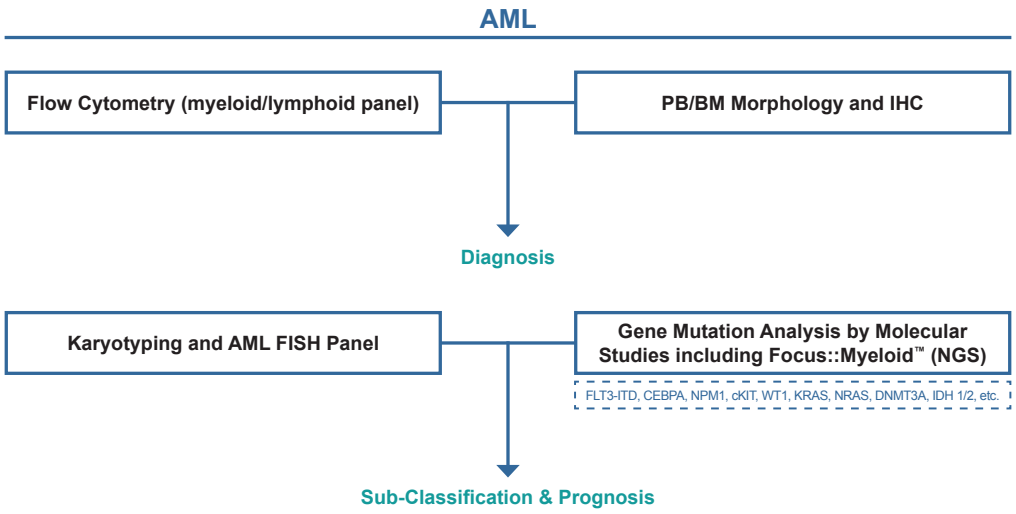
AML COMPLETE

Diagnostic Work Up for AML Complete™



This work up is intended as a guide for the comprehensive suite of diagnostic tests included in AML Complete™ to diagnose and monitor AML. Physicians can order tests individually or allow CGI pathologists and directors to determine a panel evaluation as determined necessary.

Specimen Requirements

	Test	TAT (Mon.-Fri.)	Tissue	Shipping Requirements
Morph. & IHC	**Morphology**	2-4	FFPE block*/H&E slide	Room temperature
	IHC Evaluation	2-4	FFPE tissue block*	Room temperature
Flow	**Myeloid/Lymphoid Panel**	1-2	1 **Green**/NaHeparin **or** 1 **Lavender**/EDTA tube PB or BM (2 ml)	Room temperature or 2-8°C
MDx	**Focus::Myeloid™ NGS Panel**	10-14	1 **Lavender**/EDTA tube PB or BM (2-3 ml)	Room temperature or 2-8°C
	CEBPA Mutation	7-10		
	FLT3-ITD Mutation	7-10		
	cKIT Mutation	7-10		
	NPM1 Mutation	7-10		
FISH	**AML FISH Panel**	3-5	1 **Green**/NaHeparin tube PB or BM (3-5 ml)	Room temperature
	Karyotype	5-7		
AML Complete™ Panel		10-14	1 **Green**/NaHeparin **or** 1 **Lavender**/EDTA tube PB or BM (5-7 ml); FFPE tissue block*	PB/BM: room temperature or 2-8°C FFPE: room temperature

* If FFPE tissue block is not available, fifteen 3-5 µm unstained slides are also acceptable. PB: peripheral blood BM: bone marrow FFPE: formalin-fixed paraffin-embedded

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), California (COS 00800558).

201 Route 17 North • Rutherford • NJ 07070 • Office 201.528.9200 • Fax 201.528.9201
www.cancergenetics.com