

MPN Complete™

Myeloproliferative neoplasms (MPN) correspond to a group of blood cancers that include chronic myelogenous leukemia (CML), primary myelofibrosis (PMF), polycythemia vera (PV), essential thrombocythemia (ET), hyper eosinophilic syndrome, and mast cell disorders. Over 200,000 people in the US are living with MPN and most cases develop slowly. Some MPNs can progress to acute leukemia. In addition to the patient's general clinical features, treatment depends on the MPN subtype, therefore determining the right MPN subtype is critical. By offering the most comprehensive testing panel available, CGI's MPN 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 MPN 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 for diagnosing and subtyping MPN.

IHC Evaluation

If necessary, a panel of Ig may be utilized to further immunophenotype MPN. Panel includes CD34, CD117 (cKIT), MPO, Muramidase Glycophorin A, mast cell tryptase, and CD25.

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.

BCR-ABL1 Translocation [International Scale]

This assay utilizes quantitative PCR to diagnose and monitor CML cases for therapeutic response, minimal residual disease (MRD), and early relapse.

ABL Kinase Domain Mutation Analysis

ABL kinase domain mutation is associated with a poor prognosis, high risk of progression and confers levels of resistance to CML treatments including imatinib, dasatinib and nilotinib.

JAK2 V617F Mutation Analysis

The JAK2 V617F mutation is used to diagnose or confirm the diagnosis of PV, ET or PMF. It is found in 90% of patients with PV and in nearly 50% of patients with ET or PMF.

JAK2 Exon 12 Mutation Analysis

The JAK2 Exon 12 mutation is used to diagnose or confirm the diagnosis of PV in JAK2 V617F mutation negative patients.

CALR Mutation Analysis

Patients who are clinically suspected with ET or PMF, and are negative for the JAK2 V617F mutation, are recommended to be tested for CALR mutations. CALR mutations represent a novel clonal marker found in 50-71% of ET and 56-88% of PMF, and are associated with longer overall survival in PMF patients.

MPL 515/505 Mutation Analysis

Somatic mutations of codons 515 and 505 in the MPL virus oncogene are clonal markers of ET and PMF. These markers are used to diagnose these two diseases and is often ordered as a reflexed test when JAK2 V617F and CALR mutations are negative.

cKIT D816 Mutation Analysis

The c-KIT D816 mutation can assist with initial diagnosis of systemic mastocytosis (SM) and treatment response to imatinib therapy.

Focus::Myeloid™ NGS Panel

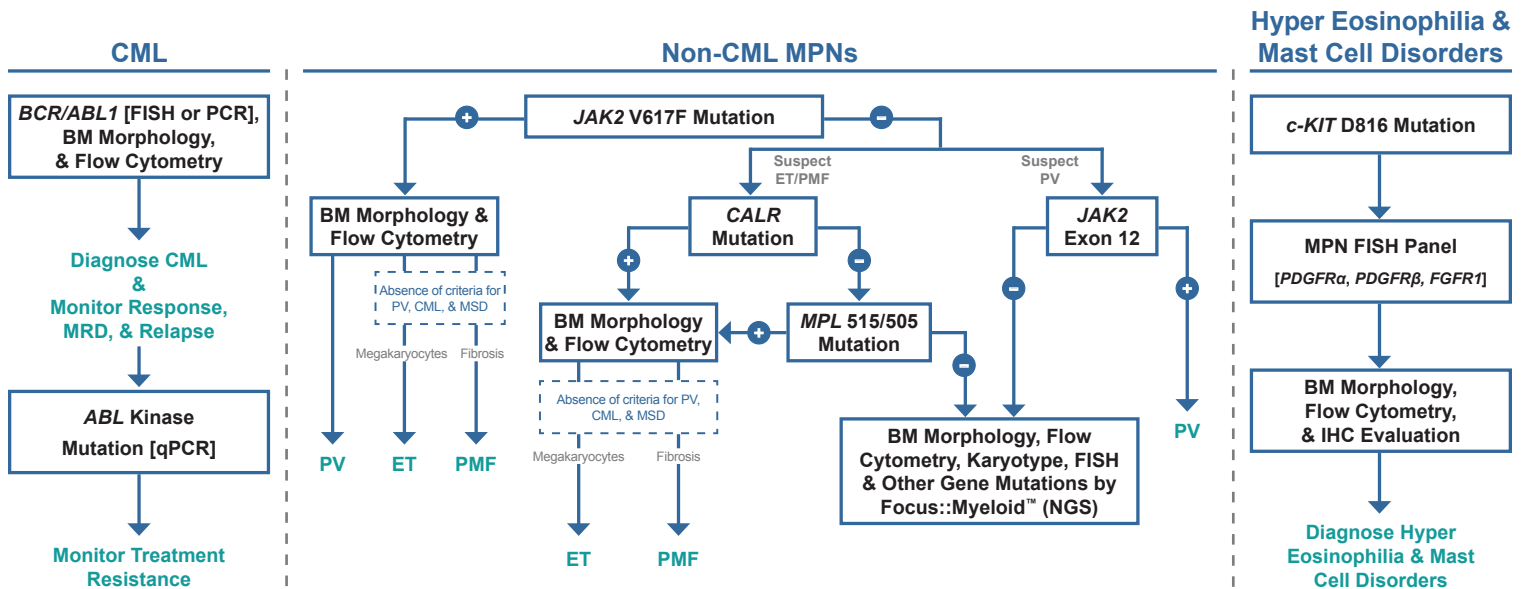
Focus::Myeloid™ is a next-generation sequencing (NGS) panel, supplemented by individual gene sequencing, that provides actionable information for improved diagnosis, prognosis, and risk stratification in acute myeloid leukemia (AML), myelodysplastic Syndrome (MDS), and MPN. Focus::Myeloid™ contains 54 biomarkers including JAK2, MPL, cKIT, and CALR.

FISH

Myeloproliferative Neoplasm (MPN) FISH Panel

The MPD FISH panel, including PDGFRα, PDGFRβ, and FGFR1 Probes, provides diagnostic and predictive information in MPN cases with eosinophilia. FISH for BCR-ABL1 detects both cryptic and noncryptic BCR-ABL1 translocations in suspected CML cases.

Diagnostic Work Up for MPN Complete™



This work up is intended as a guide for the comprehensive suite of diagnostic tests included in MPN Complete™ to diagnose and monitor MPN. 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	24-48 hours	FFPE block*/H&E slide	Room temperature
	IHC Evaluation	24-48 hours	FFPE tissue block*	Room temperature
Flow	Myeloid/Lymphoid Panel	<24 hours	1 Green/NaHeparin or 1 Lavender/EDTA tube PB or BM (2 ml)	Room temperature or 2-8°C
Molecular Diagnostics	BCR-ABL1 Translocation	3-5 days	1 Lavender/EDTA tube PB or BM (3-5 ml)	Room temperature or 2-8°C
	ABL Kinase Domain Mutation	10-14 days		
	JAK2 V617F Mutation	3-5 days		
	JAK2 Exon 12 Mutation	7-10 days		
	CALR Mutation	5-7 days		
	MPL 515/505 Mutation	7-10 days		
	c-KIT D816 Mutation	10-14 days		
Focus::Myeloid™ NGS Panel	10-14 days	1 Lavender/EDTA tube PB or BM (2-3 ml)	Room temperature or 2-8°C	
FISH	MPD FISH Panel	3-5 days	1 Green/NaHeparin or 1 Lavender/EDTA tube PB or BM (3-5 ml)	Room temperature
	MPN Complete™ Panel	10-14 days	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).