

MDS Complete™

Myelodysplastic Syndromes (MDS) represent a group of diseases of the blood and bone marrow characterized by ineffective hematopoiesis and peripheral blood cell cytopenias. Over 60,000 people in the US are living with a history of MDS. The major clinical concerns associated with MDS include the high prevalence of comorbidities caused by cytopenias and the risk of progression to acute myeloid leukemia (AML). Today, morphology and cytogenetics play an important role in diagnosis, risk stratification, and prognostication. Recent discoveries of recurrent gene regions containing molecular mutations associated with MDS, have shown to help greatly improve upon traditional risk stratification methods, of which, molecular testing is absent. By offering the most comprehensive testing panel available, CGI's MDS 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 MDS 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 MDS.

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

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 MDS, acute myeloid leukemia (AML), and myeloproliferative neoplasms (MPN). Focus::Myeloid™ includes all biomarkers listed in current NCCN diagnostic and treatment guidelines for MDS.

FISH

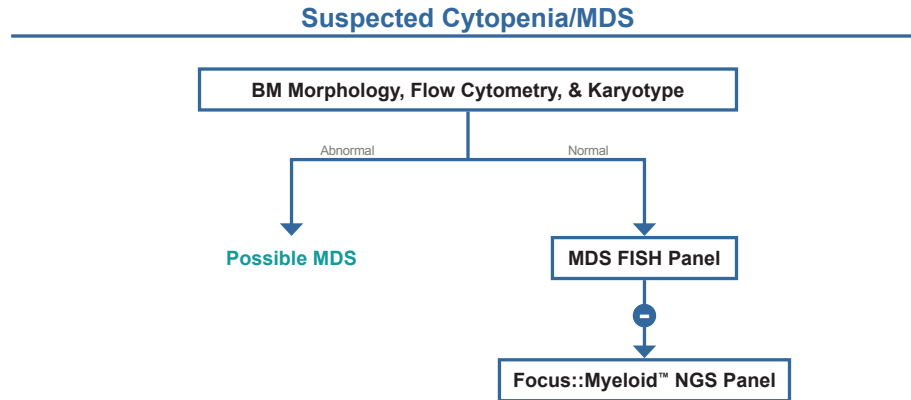
Myelodysplastic Syndrome (MDS) FISH Panel

The MDS FISH panel, including 5p15.2/5q31, CEP7/7q31, CEP8, 20q12, and 11q23/MLL, provides critical diagnostic and predictive information for risk stratification in MDS.

Karyotype

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

Diagnostic Work Up for MDS Complete™



This work up is intended as a guide for the comprehensive suite of diagnostic tests included in MDS Complete™ to diagnose and monitor MDS. 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
FISH	MDS FISH Panel	3-5	1 Green/NaHeparin or 1 Lavender/EDTA tube PB or BM (3-5 ml)	Room temperature
	Karyotype	5-7		
MDS 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).