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**
  - 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.

- **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.

- **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.

- **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™

Suspected Cytopenia/MDS

**BM Morphology, Flow Cytometry, & Karyotype**

- **Abnormal**
  - Possible MDS
  - MDS FISH Panel
    - Focus::Myeloid™ NGS Panel
- **Normal**

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**Specimen Requirements**

<table>
<thead>
<tr>
<th>Test</th>
<th>TAT (Mon.-Fri.)</th>
<th>Tissue</th>
<th>Shipping Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Morph. &amp; IHC</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Morphology</td>
<td>2-4</td>
<td>FFPE block*/H&amp;E slide</td>
<td>Room temperature</td>
</tr>
<tr>
<td>IHC Evaluation</td>
<td>2-4</td>
<td>FFPE tissue block*</td>
<td>Room temperature</td>
</tr>
<tr>
<td><strong>Flow</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myeloid/Lymphoid Panel</td>
<td>1-2</td>
<td>1 Green/NaHeparin or 1 Lavender/EDTA tube PB or BM (2 ml)</td>
<td>Room temperature or 2-8°C</td>
</tr>
<tr>
<td>Focus::Myeloid™ NGS Panel</td>
<td>10-14</td>
<td>1 Lavender/EDTA tube PB or BM (2-3 ml)</td>
<td>Room temperature or 2-8°C</td>
</tr>
<tr>
<td><strong>MDS</strong></td>
<td></td>
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</tr>
<tr>
<td>MDS FISH Panel</td>
<td>3-5</td>
<td>1 Green/NaHeparin or 1 Lavender/EDTA tube PB or BM (3-5 ml)</td>
<td>Room temperature</td>
</tr>
<tr>
<td>Karyotype</td>
<td>5-7</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>MDS Complete™ Panel</strong></td>
<td>10-14</td>
<td>1 Green/NaHeparin or 1 Lavender/EDTA tube PB or BM (5-7 ml); FFPE tissue block*</td>
<td>PB/BM: room temperature or 2-8°C FFPE: room temperature</td>
</tr>
</tbody>
</table>

* If FFPE tissue block is not available, fifteen 3-5 µm unstained slides are also acceptable.

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**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).