





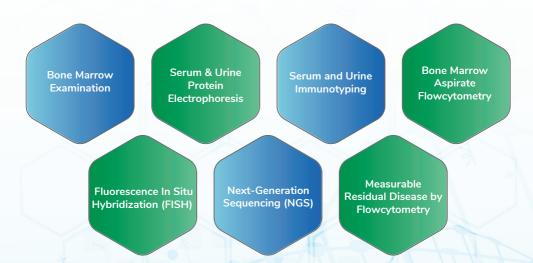
# PLASMA CELL DYSCRASIAS

**Plasma cells** are terminally differentiated and non-dividing immune cells arising from B Lymphocytes. Their primary function is to secrete antibodies to fight infection.

**Plasma Cell Dyscrasias** result from expansion of a clone of immunoglobulin secreting heavy chain class-switched, terminally differentiated cells that typically secrete a single homogeneous monoclonal immunoglobulin (M protein).

#### **Categorization of Plasma Cell Dyscrasias** Plasma Cell Myeloma (Multiple Myeloma) Plasmacytoma Smoldering (asymptomatic) plasma Solitary plasmacytoma of bone cell myeloma • Extraosseous (extramedullary) Non-secretory myeloma plasmacytoma Plasma cell leukemia Plasma cell neoplasms with Monoclonal immunoglobulin associated Paraneoplastic deposition disease syndrome • Primary amyloidosis • POEMS syndrome • Systemic light and heavy chain • TEMPI syndrome (provisional) deposition diseases

# Comprehensive Portfolio of Plasma Cell Dyscrasias at MedGenome



### **Diagnostic Criteria of Multiple Myeloma\***

History and Physical Examination

All diagnostic tests under one roof at MedGenome Labs

CBC, differential, and platelet count

Peripheral blood smear

Serum BUN/creatinine electrolytes, liver function tests, albumin, calcium, serum uric acid, serum LDH, and beta-2 microglobulin

Creatinine clearance (calculated or measured directly)

Serum quantitative immunoglobulins, serum protein electrophoresis (SPEP), and serum immunofixation electrophoresis (SIFE)

24 hour urine for total protein, urine protein electrophoresis (UPEP), and urine Immunofixation Electrophoresis (UIFE)

Serum free light chain (FLC) assay

Whole body low dose CT scan or FDG PET/CT

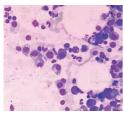
Bone marrow aspirate and biopsy, including immunohistochemistry (IHC) and/or multi parameter flow cytometry

Plasma cell fluorescence in situ hybridization (FISH) panel on bone marrow [del(13), del 17p13), t(4;14), t(11;14), t(14;16), t(14;20), 1q21 gain/1q21 amplification, 1p deletion]

Natriuretic Peptide Tests (BNP, NT-proBNP)

\*As per NCCN 2023

# **Tests offered at MedGenome**



Bone marrow aspirate showing plasma cell predominance

#### **Bone Marrow Examination**

Proliferation of abnormal plasma cells in bone marrow aspirate and biopsy can be determined.

Test Name	Test Code	Sample Type And Container	Sample Volume	Methodology	Turn Around Time (TAT)
Bone Marrow Aspiration Morphology	MGM2629	Bone Marrow aspirate in EDTA	2 ml	Light Microscopy	2 Days

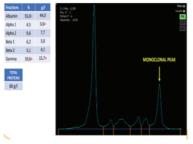
#### Serum and Urine Protein Electrophoresis

- Quantitative Screening Test
- Demonstrates a single narrow peak in the Gamma/ Beta/Alpha regions (M Spike/ Protein)
- Both serum and 24 hour urine should be assessed for M protein.
- Helps in plasma cell disorder classification (MGUS, Smoldering Myeloma or Symptomatic myeloma)
- Establishes staging of symptomatic myeloma (stage I, II and III);
- Monitoring the increase of malignant disease or the evolution from a nonmalignant state to a malignant state
- Monitoring the treatment response.

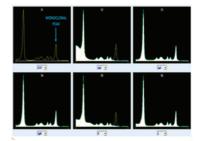
Test Name	Test Code	Sample Type And Container	Sample Volume	Methodology	Turn Around Time (TAT)
Serum Protein Electrophoresis	MGM1974	Serum In Red/ Yellow Top Vacutainer	2-3 ml	Capillary Electrophoresis	7 Days
Urine Protein Electrophoresis	MGM2321	24 Hour Urine Sample In Sterile Container	24 hour Urine Sample	Capillary Electrophoresis	7 Days

#### Serum and Urine Immunotyping

- Confirmatory gold standard method to confirm the presence of a monoclonal protein
- Distinguishes heavy chain and light chain type of M Protein.



Serum protein electrophoresis showing monoclonal peak in gamma region.



Serum protein Immunotyping showing IgG-Kappa monoclonal protein.

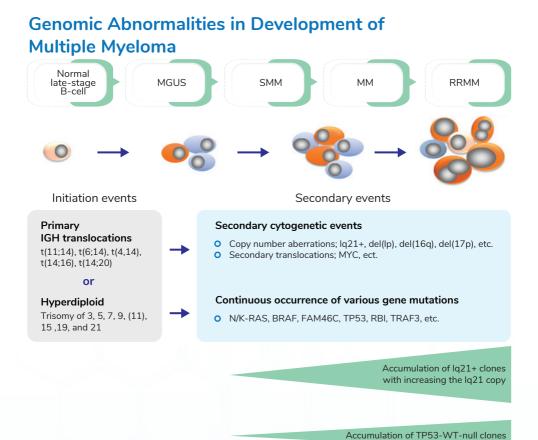
Test Name	Test Code	Sample Type And Container	Sample Volume	Methodology	Turn Around Time (TAT)
Serum Immunotyping	MGM1956	Serum In Red/ Yellow Top Vacutainer	2-3 ml	Capillary Electrophoresis	7 Days

### Bone Marrow Aspirate Immunophenotyping

- Fully automated IVD approved immunophenotyping flowcytometer (3 laser 10 color)
- Plasma cells are identified using gating antibodies CD38 and CD138
- The surface CD marker and cytoplasmic kappa/ lambda expression are then noted in these cells to identify the abnormal clone.
- Enables Measurable Residual Disease (MRD) assessment to monitor treatment.
- Panel of antibodies used to isolate the residual abnormal clonal plasma cells from the normal
- The test is internally developed at MedGenome and validated with a Limit of Detection (LOD) of 0.005%.

Test Name	Test Code	Sample Type And Container	Sample Volume	Methodology (Markers)	Turn Around Time (TAT)
Multiple Myeloma Flowcytometry	MGM418	Bone Marrow aspirate in EDTA	2-3 ml	Flowcytometry - (CD45, CD38, CD138, CD319, CD19, CD20, cKappa, cLambda, CD27, CD117, CD56)	2 Days
Multiple myeloma MRD By Flow cytometry	MGM1667	Bone Marrow aspirate in EDTA	2 ml (FIRST PULL)	Flowcytometry - (CD45, CD38, CD138, CD319, CD19, CD20, cKappa, cLambda, CD27, CD28, CD81, CD117, CD56)	2 Days





#### \*Cancers 2021, 13(2), 256

Fluorescence in situ hybridization (FISH) & Next Generation Sequencing (NGS) helps in stratifying individuals with a newly diagnosed multiple myeloma into risk groups for prognosis and selection of therapy based on genomic biomarkers.

Test Name	Test Code	Sample Type And Container	Sample Volume	Methodology	Turn Around Time
FISH for Multiple Myeloma (5 markers)[t(11:14) - IGH/CCND1; t(4:14)/ FGFR3/IGH; t(14:16)/IGH/MAF; 13q deletion; 17p deletion	MGM 1162	Bone marrow aspirate in Sodium Heparin	2-3 ml	FISH	6 Days
FISH for Multiple myeloma with Plasma Enrichment- [t(11;14) - IGH/CCND1; t(4;14)/ FGFR3/IGH; t(14;16)/IGH/MAF; 13q deletion; 17p deletion with 1q gain/1pdel]	MGM 2680	Bone marrow aspirate in Sodium Heparin	2-3 ml	FISH	6 Days
FISH for Multiple Myeloma-Comprehensive Panel with Plasma Enrichment [DelL17p Del 13p, MYC-Breakapart Probe, Hyper dip- loidy(5p15/9q22/15q22), IGH-Breakapart Probe & 1q gain/1p del]	MGM 2590	Bone marrow aspirate in Sodium Heparin	2-3 ml	FISH	6 Days

Test Name	Test Code	Sample Type And Container	Sample Volume	Methodology	Turn Around Time
IGHV gene mutation analysis by NGS	MGM 1342	Bone Marrow Aspirate in EDTA	2-3 ml	Next Generation Sequencing	14 days
Leukemia Panel (SNVs, small INDELs and CNVs) by NGS	MGM 499	Bone Marrow Aspirate in EDTA	2-3 ml	Next Generation Sequencing	12 days
Leukemia Fusion Panel by NGS (Gene arrangements/ translocation)	MGM1824	Bone Marrow Aspirate in EDTA	2-3 ml	Next Generation Sequencing	10 days

## Disease Staging and Risk Stratification Systems for Multiple Myeloma\*

Stage	International Staging System (ISS)	Revised -ISS (R-ISS)
I	Serum beta-2 microglobulin <3.5 mg/L Serum albumin ≥3.5 g/dL	ISS stage I and standard-risk chromosomal abnormalities by FISH and serum LDH ≤ the upper limit of normal
II	Not ISS stage I or III	Not ISS stage I or III
111	Serum beta-2 microglobulin ≥5.5mg/L	ISS stage III and either high risk chromosomal ab- nomalities by FISH or serum LDH > the upper limit of normal

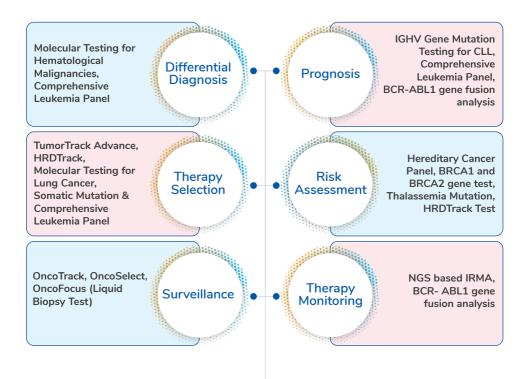
### Factors considered High Risk for Multiple Myeloma\*

Cytogenetic abnormalities	<ul> <li>t(4;14)</li> <li>t(14;16)</li> <li>Del(17p)/monosomy 17</li> <li>1q21 gain/1q21 amplification</li> </ul>	<ul> <li>MYC translocation</li> <li>TP53 mutation [with del(17p)]</li> <li>Tetrasomies</li> <li>Complex karyotype (when done) or karyotypic del(13)</li> </ul>
Other risk factors	<ul> <li>High risk gene expression signature</li> <li>Extramedullary disease</li> <li>Circulating plasma cells</li> <li>High plasma cell proliferation</li> <li>Frailty</li> </ul>	<ul> <li>Renal failure</li> <li>Thrombocytopenia</li> <li>High serum FLC</li> <li>Lymphopenia</li> <li>Immunoparesis</li> <li>Elevated LDH</li> </ul>

\*As per NCCN 2023

## **MedGenome Prima**

offers precision genetic testing for a wide range of Oncology and Haematology tests :





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