MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: November 7, 2022
Effective Date: December 13, 2022

MayoComplete Plasma Cell Myeloma, Next-Generation Sequencing, Varies

Test ID: NGPCM

Useful for:

Evaluating multiple myeloma at the time of diagnosis and at disease relapse or when changing clinical management to provide prognostic information and determine potential therapeutic implications

Genetics Information:

This test includes next-generation sequencing to evaluate the following 26 genes and select intronic regions: BIRC3, BRAF, CCND1, CDKN2A, CRBN, CUL4A, CUL4B, CXCR4, DIS3, EGFR, IDH1, IDH2, IKZF1, IKZF3, KRAS, MYC, MYD88, NRAS, NSD2, PIK3CA, PIM1, STAT3, TENT5C, TP53, TRAF3, and XBP1.

Reflex Tests:

Test ID	Reporting Name	Available Separately	Always Performed
CSPMM	NGPCM Pre-Analysis Cell Sorting, BM	No	No

Methods:

Next-Generation Sequencing (NGS)

Interpretation:

Genomic variants detected by this test will be documented in a detailed laboratory-issued report. This report will contain information regarding the detected alterations and their associations with prognosis or possible therapeutic implications in plasma cell myeloma. The information in the clinical report may be used by the patient's clinician to help guide decisions concerning management. Final interpretation of next-generation sequencing results requires correlation with all relevant clinical, pathologic, and laboratory findings and is the responsibility of the managing clinician.

Specimen Requirements:

Submit only 1 of the following specimens:

Specimen Type: Bone marrow aspirate
Container/Tube: Lavender or pink top (EDTA) or yellow top (ACD)
Specimen Volume: 2 mL
Collection Instructions:
1. Minimum plasma cell percentage is 5%.
2. Invert several times to mix bone marrow.
3. Send bone marrow specimen in original tube. Do not aliquot.
4. Label specimen as bone marrow.
5. Fresh specimen is required for this test, as testing is performed on sorted cells.
Specimen Stability Information: Ambient (preferred) 4 days/Refrigerate
Minimum volume: 1ml

Specimen Type: Paraffin-embedded bone marrow clot
Container/Tube: Paraffin block
Collection Instructions:
1. Send 1 slide stained with hematoxylin and eosin.
2. Minimum plasma cell percentage is 20%.
3. Required amount of tissue area is at least 25mm(2).
4. Tissue should be fixed in 10% neutral-buffered formalin. Other fixatives are not acceptable.
5. Decalcified specimens (eg, bone marrow core biopsies) are not acceptable.
Specimen Stability Information: Ambient

Specimen Type: Tissue slide; bone marrow clot
Slides: 10 unstained slides
Container/ Tube: Transport in plastic slide holders.
Collection Instructions:
1. Send 10 unstained, nonbaked slides with 5-micron thick sections of tissue and 1 slide stained with hematoxylin and eosin
2. Minimum amount of plasma cells is 20%
3. Required amount of tissue area is at least 25mm(2).
4. Tissue should be fixed in 10% neutral-buffered formalin. Other fixatives are not acceptable.
5. Decalcified specimens (eg, bone marrow core biopsies) are not acceptable.
Specimen Stability Information: Ambient

Specimen Stability Information:

Specimen Type	Temperature	Time
Varies	Varies	

Cautions:

This test is a targeted next-generation sequencing (NGS) panel assay that encompasses 26 genes with variable full exon, partial region (including select intronic or noncoding regions), or hot spot coverage (depending on specific genetic locus). Therefore, this test will not detect other genetic abnormalities in genes or regions outside the specified target areas. The test detects single base substitutions (ie, point mutations), as well as small insertion or deletion type events. This test is not configured to detect structural genomic rearrangements (ie, translocations), gene fusions, copy number alterations, or large-scale (segmental chromosome region) deletions and other complex genomic changes.

This assay does not distinguish between somatic and germline alterations in analyzed gene regions, particularly with variant allele frequencies near approximately 50% or 100%. If nucleotide alterations in genes associated with germline mutation syndromes are present and there is a strong clinical suspicion or family history of malignant disease predisposition, additional genetic testing and appropriate counseling may be indicated. Some apparent mutations classified as variants of undetermined significance may represent rare or low population frequency polymorphisms.

Prior treatment for hematologic malignancy could affect the results obtained in this assay. In particular, prior allogeneic hematopoietic stem cell transplant may cause difficulties in either resolving somatic or polymorphic alterations or assigning variant calls correctly to donor and recipient fractions, if pertinent clinical or laboratory information (eg, chimerism engraftment status) is not provided.

NGS testing should not be pursued if the initial plasma cell percentage is below approximately 5% by cytologic differential count in the bone marrow aspirate, as the ability to obtain a sufficiently enriched target plasma cell population for evaluation is significantly less likely. Inadequate samples (eg, insufficient DNA quantity or quality) will preclude further testing and will be noted in the interpretive report.

CPT Code:
81450

Day(s) Performed: Monday through Friday

Report Available: 16 to 21 days

Questions

Contact Connie Penz, Laboratory Technologist Resource Coordinator at 800-533-1710.