MAYO CLINIC LABORATORIES

Test Definition: PCPDS

Plasma Cell Proliferative Disorder, High Risk with Reflex Probes, Diagnostic FISH Evaluation, Bone Marrow

Overview

Useful For

Detecting, at diagnosis, recurrent common high-risk chromosome abnormalities associated with multiple myeloma or other plasma cell proliferative disorders, using a laboratory-designated probe set algorithm

Identifying high-risk prognostic markers associated with multiple myeloma or other plasma cell proliferative disorders

This test **should not be used** to track the progression of disease.

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
PCPDB	Probe, Each Additional (PCPDS)	No, (Bill Only)	No

Additional Tests

Test Id	Reporting Name	Available Separately	Always Performed
CSPCF	PCPDS Pre-Analysis Cell Sorting, BM	No	Yes

Testing Algorithm

Pre-analysis plasma cell sorting will be performed to determine if sufficient plasma cells are present within the provided specimen at an additional charge.

This test includes a charge for probe application, analysis, and professional interpretation of results for 1 probe set (2 individual fluorescence in situ hybridization [FISH] probes). Additional charges will be incurred for all reflex or additional probe sets performed. Analysis charges will be incurred based on the number of cells analyzed per probe set. If an insufficient number of plasma cells are available for analysis, no analysis charges will be incurred.

If sufficient plasma cells are identified, the plasma cell high-risk FISH panel includes testing for the following abnormalities using the FISH probes listed:
1p deletion/1q gain, CDKN2C/1q22 probe set
t(14q32;var) or *IGH* rearrangement, IGH break-apart probe set
-17/17p-, TP53/D17Z1 probe set

If an *IGH* rearrangement is identified, appropriate reflex testing will be performed in an attempt to identify the translocation partner using the FISH probes listed:

t(4;14)(p16.3;q32) *IGH::FGFR3* fusion, FGFR3/IGH probe set
t(11;14)(q13;q32) or *IGH::CCND1* fusion, CCND1/IGH probe set
t(14;16)(q32;q23) *IGH::MAF* fusion, IGH/MAF probe set
t(14;20)(q32;q12) *IGH::MAFB* fusion, IGH/MAFB probe set

Appropriate ancillary probes may be performed at consultant discretion to render comprehensive assessment. FISH probes for enumeration of chromosomes 3, 7, 9, and 15 will only be performed at the laboratory's discretion to resolve or confirm concerns of hyperdiploidy. Any additional probes will have the results included within the final report and will be performed at an additional charge.

Method Name
PCPDS, PCPDB: Fluorescence In Situ Hybridization (FISH)
CSPCF: Flow Cytometric Cell Selection

NY State Available
Yes

Specimen

Specimen Type
Bone Marrow

Ordering Guidance
Fresh bone marrow received within 96 hours post-collection is required for this test.

For the **most complete** genetic evaluation on fresh bone marrow specimens, order MSMRT/ Mayo Algorithmic Approach for Stratification of Myeloma and Risk-Adapted Therapy Report, Bone Marrow.

For evaluation of high-risk abnormalities, with reflex probes, on fixed cell pellet specimens or bone marrow specimens that will be received greater than 96 hours post-collection, order MFCDF / Myeloma, High Risk, with Reflex Probes, Diagnostic FISH Evaluation, Fixed Cell Pellet. If the specimen received for this test is a fixed cell pellet or is greater than 96 hours from collection, this test will be canceled and automatically reordered by the laboratory as MFCDF.

For testing paraffin-embedded tissue samples from patients with a plasma cell disorder, order PLASF / Plasma Cell Proliferative Disorder, FISH, Tissue. If the specimen received for this test is paraffin-embedded, this test will be canceled and automatically reordered by the laboratory as PLASF.

Shipping Instructions
1. Specimen should arrive within 96 hours of collection.
2. Advise Express Mail or equivalent if not on courier service.

Necessary Information

1. A reason for testing must be provided. If this information is not provided, an appropriate indication for testing may be entered by Mayo Clinic Laboratories.

2. A flow cytometry and/or a bone marrow pathology report should be submitted with each specimen. The laboratory will not reject testing if this information is not provided, but appropriate testing and interpretation may be compromised or delayed.

Specimen Required

Container/Tube:

Preferred: Yellow top (ACD)

Acceptable: Green top (sodium heparin) or lavender top (EDTA)

Specimen Volume: 4 mL

Collection Instructions:

1. It is preferable to send the first aspirate from the bone marrow collection.
2. Invert several times to mix bone marrow.
3. Send bone marrow in original tube. **Do not aliquot.**

Forms

If not ordering electronically, complete, print, and send a Hematopathology/Cytogenetics Test Request (T726) with the specimen.

Specimen Minimum Volume

Bone marrow: 2 mL

Reject Due To

Fresh tissue	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Bone Marrow	Ambient (preferred)	4 days	
	Refrigerated	4 days	

Clinical & Interpretive

Clinical Information

Multiple myeloma is a hematologic neoplasm that generally originates in the bone marrow and develops from malignant plasma cells. There are 4 main categories of plasma cell proliferative disorders: monoclonal gammopathy of undetermined significance (MGUS), monoclonal immunoglobulin deposition diseases (amyloidosis), plasmacytoma, and multiple myeloma. MGUS, which occurs in 3% to 4% of individuals older than 50 years, represents the identification of

an asymptomatic monoclonal protein, yet approximately 1% per year will progress to multiple myeloma. Amyloidosis represents a rare group of deposition disorders including primary amyloidosis vs. light chain and heavy chain disease. Plasmacytomas represent isolated collections of bone or extramedullary plasma cells with a risk for development of multiple myeloma. Generalized bone pain, anemia, limb numbness or weakness, symptoms of hypercalcemia, and recurrent infections are all symptoms that may indicate multiple myeloma.

As myeloma progresses, the malignant plasma cells interfere with normal blood product formation in the bone marrow resulting in anemia and leukopenia. Myeloma also causes an overstimulation of osteoclasts, causing excessive breakdown of bone tissue without the normal corresponding bone formation. These bone lesions are seen in approximately 66% of myeloma patients. In advanced disease, bone loss may reach a degree where the patient suffers fractures easily.

Multiple myeloma is increasingly recognized as a disease characterized by marked cytogenetic, molecular, and proliferative heterogeneity. This heterogeneity is manifested clinically by varying degrees of disease aggressiveness. Multiple myeloma patients with more aggressive disease experience suboptimal responses to some therapeutic approaches; therefore, identifying these patients is critically important for selecting appropriate treatment options.

Reference Values

An interpretive report will be provided.

Interpretation

A neoplastic clone is detected when the percentage of cells with an abnormality exceeds the normal reference range for any given probe set.

The absence of an abnormal clone does not rule out the presence of a plasma cell clone or another neoplastic disorder.

Cautions

This test is not approved by the US Food and Drug Administration, and it is best used as an adjunct to existing clinical and pathologic information.

If no fluorescence in situ hybridization (FISH) signals are observed post-hybridization, the case will be released indicating a lack of FISH results.

If an insufficient number or plasma cells are identified in the sample, the case will be cancelled.

If the sample is not received within 96 hours of collection, the case will be cancelled and reordered as MFCDF / Myeloma, High Risk, with Reflex Probes, Diagnostic FISH Evaluation, Fixed Cell Pellet.

Clinical Reference

1. WHO Classification of Tumours Editorial Board, eds. Haematolymphoid tumours. 5th ed. IARC Press; 2024:603-630. WHO Classification of Tumours. Vol 11
2. Arber D., Borowitz, Cook J, et al. The International Consensus Classification of Myeloid and Lymphoid Neoplasms. Wolter Kluwer; 2025:384-396
3. Kumar SK, Rajkumar SV. The multiple myelomas-current concepts in cytogenetic classification and therapy. Nat Rev

Clin Oncol. 2018;15(7):409-421. doi:10.1038/s41571-018-0018-y
4. Lu X, Andersen EF, Banerjee R, et al. Guidelines for the testing and reporting of cytogenetic results for risk stratification of multiple myeloma: a report of the Cancer Genomics Consortium Plasma Cell Neoplasm Working Group. Blood Cancer J. 2025;15(1):86
5. Gagnon MF, Midthun SM, Fangel JA, et al. Superior detection rate of plasma cell FISH using FACS-FISH. Am J Clin Pathol. 2024;161(1):60-70. doi:10.1093/ajcp/aqad108

Performance

Method Description
This test is performed using commercially available and laboratory-developed probes on sorted plasma cells. Deletion of the *TP53* locus from chromosome 17 or monosomy 17 and deletion of the *CDKN2C* locus or gain of the 1q22 locus are detected using enumeration strategy probe sets. Rearrangements involving *IGH* are detected using dual-color break-apart strategy probe sets. Dual-color, dual-fusion fluorescence in situ hybridization strategy probe sets are used when a rearrangement of the *IGH* gene is detected. For each probe set, 50 plasma cells (if possible) are scored and the result for each probe is reported.(Unpublished Mayo method)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
7 to 10 days

Specimen Retention Time
4 weeks

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

Test Definition: PCPDS

Plasma Cell Proliferative Disorder, High Risk with Reflex Probes, Diagnostic FISH Evaluation, Bone Marrow

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

88271 x 2, 88274, 88291-FISH Probe, Analysis, Interpretation; 1 probe set
88271 x 2, 88274-FISH Probe, Analysis; each additional probe set (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
PCPDS	Plasma Cell Prolif, High Risk, FISH	98014-4

Result ID	Test Result Name	Result LOINC® Value
606080	Result Summary	62357-9
606081	Interpretation	69965-2
606082	Result Table	93356-4
606083	Result	62356-1
606084	Specimen	31208-2
606085	Source	39111-0
606086	Method	85069-3
606087	Additional Information	48767-8
606088	Disclaimer	62364-5
606089	Released By	18771-6
GC054	Reason for Referral	42349-1