

Overview

Useful For

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

Identifying prognostic markers associated multiple myeloma or other plasma cell proliferative disorders

Reflex Tests

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

Testing Algorithm

This test includes a charge for the probe application, analysis, and professional interpretation of results for 1 probe set (2 individual fluorescence in situ hybridization [FISH] probes) on pre-sorted plasma cells. 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.

This test is performed using either the diagnostic or follow-up analysis algorithm.

If sufficient plasma cells are identified, the **diagnostic** plasma cell FISH panel includes testing for the following abnormalities using the FISH probes listed:

- 1p loss/1q gain, CDKN2C/1q22 probe set
- t(8q24.21;var) or MYC rearrangement, MYC break-apart 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(6;14)(p21;q32) IGH::CCND3 fusion, CCND3/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

Hyperdiploidy, as determined by flow cytometry, will be incorporated into the final interpretation. For samples with an unsuccessful flow evaluation for hyperdiploidy and sufficient plasma cells, FISH testing for the following abnormalities will be performed using the probes listed:

- +3 (trisomy 3) and/or +7 (trisomy 7), D3Z1/D7Z1 probe set

+9 (trisomy 9) and/or +15 (trisomy 15), D9Z1/D15Z4 probe set

If sufficient plasma cells are identified, the **follow-up** plasma cell FISH panel includes testing for the following abnormalities using the FISH probes listed:

- 1p deletion/1q gain, CDKN2C/1q22 probe set
- t(8q24.21;var) or MYC rearrangement, MYC break-apart probe set
- 17/17p-, TP53/D17Z1 probe set

If no abnormalities are observed in the **follow-up** myeloma FISH panel, reflex testing may be performed to identify the following high-risk abnormalities, if originally identified in the diagnostic specimen, using the probes listed:

- t(4;14)(p16.3;q32) IGH::FGFR3 fusion, FGFR3/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

Follow-up testing is determined by the results of previous MPCDS / mSMART, Plasma Cell Proliferative Disorder, FISH, Bone Marrow testing, reported at this laboratory.

Appropriate ancillary probes may be performed at consultant discretion to render comprehensive assessment. Any additional probes will have the results included within the final report and will be performed at an additional charge.

Method Name

Only orderable as part of a profile. For more information see MSMRT / Mayo Algorithmic Approach for Stratification of Myeloma and Risk-Adapted Therapy Report, Bone Marrow.

Fluorescence In Situ Hybridization (FISH)

NY State Available

Yes

Specimen

Specimen Type

Bone Marrow

Specimen Required

Only orderable as part of a profile. For more information see MSMRT / Mayo Algorithmic Approach for Stratification of Myeloma and Risk-Adapted Therapy Report, Bone Marrow.

Specimen Type: Redirected bone marrow

Preferred: Yellow top (ACD)

Acceptable: Lavender top (EDTA) or green top (heparin)

Specimen Volume: 4 mL

Specimen Minimum Volume

2 mL

Reject Due To

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

Specimen Stability Information

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

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 over age 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. Patients with more aggressive multiple myeloma experience suboptimal responses to some therapeutic approaches; therefore, identifying these patients is critically important for selecting appropriate treatment options.

Reference Values

Only orderable as part of a profile. For more information see MSMRT / Mayo Algorithmic Approach for Stratification of Myeloma and Risk-Adapted Therapy Report, Bone Marrow.

An interpretive report will be provided.

Interpretation

A neoplastic clone is detected when the percent 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 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.

Clinical Reference

1. Swerdlow SH, Campo E, Harris NL, et al, eds. WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues. 4th ed. IARC Press; 2017. WHO Classification of Tumours, Vol 2
2. 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
3. Rajkumar SV, Landgren O, Mateos MV. Smoldering multiple myeloma. *Blood*. 2015;125(20):3069-3075. doi:10.1182/blood-2014-09-568899
4. Muchtar E, Dispenzieri A, Kumar SK, et al. Interphase fluorescence in situ hybridization in untreated AL amyloidosis has an independent prognostic impact by abnormality type and treatment category. *Leukemia*. 2017;31(7):1562-1569. doi:10.1038/leu.2016.369
5. Lakshman A, Paul S, Rajkumar SV, et al. Prognostic significance of interphase FISH in monoclonal gammopathy of undetermined significance. *Leukemia*. 2018;32(8):1811-1815. doi:10.1038/s41375-018-0030-3
6. Bochtler T, Hegenbart U, Kunz C, et al. Prognostic impact of cytogenetic aberrations in AL amyloidosis patients after high-dose melphalan: a long-term follow-up study. *Blood*. 2016;128(4):594-602. doi:10.1182/blood-2015-10-676361
7. Treatment guidelines: multiple myeloma. mSMART 3.0. Accessed March 11, 2025. Available at www.msmart.org/mm-treatment-guidelines

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. If necessary, hyperdiploidy will be assessed using enumeration strategy probe sets for chromosomes 3, 7, 9, and 15. Rearrangements involving *IGH* and *MYC* 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
14 days

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

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
MPCDS	mSMART Eval, PCPDs, FISH	93357-2

Result ID	Test Result Name	Result LOINC® Value
606091	mSMART Result Summary	62357-9
606092	mSMART Evaluation	57802-1
606093	Interpretation	69965-2
606094	Result Table	93356-4
606095	Result	62356-1
606096	Reason for Referral	42349-1
606097	Specimen	31208-2
606098	Source	85298-8

606099	Method	85069-3
606100	Additional Information	48767-8
606101	Disclaimer	62364-5
606102	Released By	18771-6