Overview

Useful For

Supporting the diagnosis of plasmacytoma or myeloma when coordinated with a surgical pathology consultation

Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
_I099	Interphases, 25-99	No, (Bill Only)	No
_I300	Interphases, >=100	No, (Bill Only)	No
_IL25	Interphases,	No, (Bill Only)	No
_PADD	Probe, +1	No, (Bill Only)	No
_PB02	Probe, +2	No, (Bill Only)	No
_PB03	Probe, +3	No, (Bill Only)	No
_PBCT	Probe, +2	No, (Bill Only)	No

Testing Algorithm

This test does not include a pathology consult. If a pathology consult is requested, PATHC / Pathology Consultation should be ordered and the appropriate fluorescence in situ hybridization (FISH) test will be ordered and performed at an additional charge.

This test includes a charge for application of the first probe set (2 FISH probes) and professional interpretation of results. Additional charges will be incurred for all reflex probes performed. Analysis charges will be incurred based on the number of cells analyzed per probe set. If no cells are available for analysis, no analysis charges will be incurred.

A minimum of 25% plasma cell involvement is required for a successful paraffin plasma cell FISH evaluation. If a bone marrow clot specimen is submitted with less than 25% plasma cell involvement, the PLASF / Plasma Cell Proliferative Disorder, FISH, Tissue will be cancelled.

For decalcified (bone) specimens, one FISH probe (breakapart IGH) will be attempted. If this FISH probe is unsuccessful, the sample will be cancelled due to lack of hybridization due to the decalcification process. If the IGH FISH probe is successful, additional FISH probes will be evaluated based on the sample received (bone marrow clot vs. plasmacytoma) as listed below.

The initial panel for bone marrow clot specimens includes testing for the following abnormalities using the probes listed:

17p-, *TP53*/D17Z1

1q gain, *TP73*/1q22

14q32 rearrangement, *IGH*

Based on the results from the initial panel, reflex testing may be performed to identify the following abnormalities using the probes listed:

t(11;14)(q13;q32), *CCND1*/*IGH*

t(14;16)(q32;q23) *IGH*/*MAF*

t(4;14)(p16.3;q32) *FGFR3*/*IGH*

t(14;20)(q32;q12) *IGH*/*MAFB*

The initial panel for plasmacytoma specimens includes testing for the following abnormalities using the probes listed:

17p-, *TP53*/D17Z1

1q gain, *TP73*/1q22

8q24.1 rearrangement, *MYC*

-13/13q-, *RB1*/*LAMP1*

+9/+15, D9Z1/D15Z4

+3/+7, D3Z1/D7Z1

14q32 rearrangement, *IGH*

t(11;14)(q13;q32), *CCND1*/*IGH*

Based on the results from the initial panel, reflex testing may be performed to identify the following abnormalities using the probes listed:

t(14;16)(q32;q23) *IGH*/*MAF*

t(4;14)(p16.3;q32) *FGFR3*/*IGH*

t(14;20)(q32;q12) *IGH*/*MAFB*

t(6;14)(p21;q32), *CCND3*/*IGH*

This test is not designed for follow-up testing.

Method Name

Fluorescence In Situ Hybridization (FISH)

NY State Available

Yes

Specimen

Specimen Type

Tissue

Ordering Guidance

-For the most complete genetic evaluation on fresh bone marrow specimens, order MPCDS / mSMART, Plasma Cell Proliferative Disorder, FISH, Bone Marrow.

-For evaluation of high risk abnormalities plus CCND1/IGH fusion on fresh bone marrow specimens, order PCPDS / Plasma Cell Proliferative Disorder, FISH, Bone Marrow.

-For fixed cell pellet specimens, order MFCF / Myeloma, FISH, Fixed Cells.

-Testing will be changed to the appropriate test if this test is ordered on either of the previous specimen types.

Shipping Instructions

Advise Express Mail or equivalent if not on courier service.

Necessary Information

A reason for testing and pathology report are required in order for testing to be performed. Send information with specimen. Acceptable pathology reports include working drafts, preliminary pathology, or surgical pathology reports.

Specimen Required

Submit only 1 of the following specimens:

Specimen Type: Tissue

Preferred: Tissue block

Collection Instructions: Submit a formalin-fixed, paraffin-embedded (FFPE) tumor tissue block. Blocks prepared with alternative fixation methods may be acceptable; provide fixation method used.

Acceptable: Slides

Collection Instructions: For each probe set ordered, 2 consecutive, unstained, 5 micron-thick sections placed on positively charged slides, and 1 hematoxylin and eosin-stained slide.

Forms

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

Specimen Minimum Volume

See Specimen Required

Reject Due To

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

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Tissue	Ambient (preferred)		
	Refrigerated		

Clinical and Interpretive

Clinical Information

A plasmacytoma is a localized proliferation of plasma cells that are cytologically and immunophenotypically identical to the plasma cell clones seen in myeloma. There are 2 primary types of plasmacytomas; solitary plasmacytoma of bone (SPB) and extramedullary plasmacytoma (EP).

SPBs are a localized bone tumor comprised of plasma cells and account for about 5% of all plasma cell neoplasms. Common sites for SPBs are the vertebrae, ribs, skull, pelvis, femur, clavicle, and scapula. Patients often present with pathological fracture or bone pain near the lesion. Treatment is typically radiation therapy; at 10 years, 35% of patients appear to be cured, 55% develop myeloma, and 10% have local recurrence.

EPs are tumors of plasma cells that form in areas away from the bone and account for 3% to 5% of all plasma cell neoplasms. Approximately 80% of EPs occur in the upper respiratory tract. Less common locations include the gastrointestinal tract, bladder, testis, central nervous system, and skin. Treatment consists of radiation therapy. Regional recurrence develops in about 25% of patients, but development of myeloma is less frequent, occurring in only about 15% of patients.

Genetics of both types of plasmacytomas, while not extensively studied, appear to be the same as plasma cell myeloma.

Paraffin plasma cell fluorescence in situ hybridization (FISH) evaluation of bone marrow clot specimens is also important when a fresh bone marrow specimen is not available or is unsuccessful in the initial/diagnostic evaluation to document the genetic abnormalities associated with a patientâ€™s plasma cell clone.

Reference Values

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 a given probe set.

A positive result supports the diagnosis of a plasmacytoma or myeloma.

A negative result does not exclude the diagnosis of a plasmacytoma or myeloma.

Cautions

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

Fixatives other than formalin (eg, Prefer, Bouin) may not be successful for fluorescence in situ hybridization (FISH) assays. Although FISH testing will not be rejected due to non-formalin-fixation, results may be compromised.

Paraffin-embedded tissues that have been decalcified may be unsuccessful for FISH analysis. FISH studies will usually be attempted. The pathologist reviewing the hematoxylin and eosin-stained slide may find it necessary to cancel testing.

Supportive Data

Each probe was independently tested and verified on paraffin-embedded tissue specimens. Normal cutoffs were calculated based on the results of at least 25 normal specimens. For each probe set a series of chromosomally

abnormal specimens were evaluated to confirm each probe set detected the anomaly it was designed to detect.

Clinical Reference

1. Swerdlow S, Campo E, Harris NL, et al: WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues. IARC Press; 2017

2. Nolan KD, Mone MC, Nelson EW: Plasma cell neoplasms: review of disease progression and report of a new variant. Surg Oncol. 2005;14:85-90

3. Dingli D, Kyle RA, Rajkumar SV, et al: Immunoglobulin free light chains and solitary plasmacytoma of bone.Blood. 2006;108(6):1979-1983

Performance

Method Description

This test is performed using both commercially available and laboratory-developed probes. Deletion or monosomy of chromosomes 13 and 17 and copy number gain of 1q are detected using enumeration strategy probes. Centromere probes are used to detect chromosomal gain of chromosomes 3, 7, 9, and 15. Translocations involving *IGH* with *FGFR3*, *CCND1*, *CCND3, MAF*, and *MAFB* are detected using dual-color, dual-fusion fluorescence in situ hybridization (D-FISH) strategy probes. Rearrangement of *MYC and IGH* is detected using a break-apart strategy (BAP) probe. Formalin-fixed, paraffin-embedded tissues are cut at 5 microns and mounted on positively charged glass slides. The selection of tissue and the identification of target areas on the hematoxylin and eosin (H and E)-stained slide are performed by a pathologist. Using the H and E-stained slide as a reference, target areas are etched with a diamond-tipped etcher on the back of the unstained slide to be assayed. Each probe set is hybridized to the appropriate target areas and 2 technologists analyze 50 interphase nuclei each (100 total) with the results expressed as the percent abnormal nuclei.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

7 to 10 days

Specimen Retention Time

Slides and H&E used for analysis are retained by the laboratory in accordance to CAP and NYS requirements. Client provided paraffin blocks and extra unstained slides (if provided) will be returned after testing is complete.

Performing Laboratory Location

Rochester

Fees and 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 Regional Manager. For assistance, contact Customer Service.

Test Classification

This test was developed using an analyte specific reagent. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information

88271x2, 88291-DNA probe, each (first probe set), Interpretation and report

88271x2-DNA probe, each; each additional probe set (if appropriate)

88271x1-DNA probe, each; coverage for sets containing 3 probes (if appropriate)

88271x2-DNA probe, each; coverage for sets containing 4 probes (if appropriate)

88271x3-DNA probe, each; coverage for sets containing 5 probes (if appropriate)

88274 w/modifier 52-Interphase in situ hybridization, <25 cells, each probe set (if appropriate)

88274-Interphase in situ hybridization, 25 to 99 cells, each probe set (if appropriate)

88275-Interphase in situ hybridization, 100 to 300 cells, each probe set (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
PLASF	Plasma Cell Prolif, FISH, Ts	In Process

Result ID	Test Result Name	Result LOINC Value
52219	Result Summary	50397-9
52221	Interpretation	69965-2
52220	Result Table	93356-4
54593	Result	62356-1
CG753	Reason for Referral	42349-1
52222	Specimen	31208-2
52223	Source	31208-2
52224	Tissue ID	80398-1
52225	Method	49549-9
55033	Additional Information	48767-8
53823	Disclaimer	62364-5
52226	Released By	18771-6