MAYO CLINIC LABORATORIES

NEW TEST

Notification Date: November 10, 2021
Effective Date: December 13, 2021

Myeloma, High Risk with Reflex Probes, Diagnostic FISH Evaluation, Fixed Cell Pellet

Test ID: MFCDF

Useful for:

Aiding in the diagnosis of new cases of multiple myeloma or other plasma cell proliferative disorders using a fixed cell pellet derived from bone marrow

Identifying prognostic markers based on the abnormalities found

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

Testing Algorithm:

This test includes a charge for the probe application, analysis, and professional interpretation of results for 3 probe sets (6 individual fluorescence in situ hybridization [FISH] probes). Additional charges will be incurred for all reflex or additional probe sets performed.

This test is designed for diagnostic bone marrow specimens from patients with multiple myeloma or other plasma cell proliferative disorders. Best results are obtained when the bone marrow demonstrates at least 20% involvement by a plasma cell proliferative disorder.
The FISH panel includes testing for the following abnormalities using the FISH probes listed:

For **diagnostic** samples, the following probes will be evaluated:
17p-, TP53/D17Z1
1q gain, TP73/1q22
14q32 rearrangement, IGH break-apart
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 fusion
t(14;16)(q32;q23), IGH/MAF fusion
t(4;14)(p16.3;q32), FGFR3/IGH fusion
t(14;20)(q32;q12), IGH/MAFB fusion

For **follow-up** samples, the following probes will be evaluated if sufficient plasma cells are identified:
If a previous diagnostic sample was uninformative for a probe set, attempts may be made to achieve results for the missing probe on a subsequent sample.
17p-, TP53/D17Z1
1q gain, TP73/1q22
8q24.1 rearrangement, MYC break-apart

Reflex Tests:

Test ID	Reporting Name	Available Separately	Always Performed
MFCDB	Probe, Each Additional (MFCDF)	No (Bill Only)	No

Methods:
Fluorescence In Situ Hybridization (FISH)

Reference Values:
An interpretive report will be provided.

Specimen Requirements:

Specimen Type: Fixed Cell Pellet - Bone marrow

Container/Tube: Sterile container

Specimen Volume: 1 Fixed cell pellet

Collection Instructions:

1. Place specimen in a sterile container with a 3:1 methanol/glacial acetic acid (or similar) fixative.

Note:
A reason for testing and a flow cytometry and/or a bone marrow pathology report should be sent 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. If this information is not provided, an appropriate indication for testing may be entered by Mayo Clinic Laboratories.

Specimen Stability Information:

Specimen Type	Temperature	Time
Fixed Cell Pellet Bone Marrow	Ambient (preferred)	
	Refrigerated	

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.

CPT Code:
88271x6, 88275x3, 88291 x1-FISH Probe, Analysis, Interpretation; 3 probe sets

88271x2, 88275x1-FISH Probe, Analysis; each additional probe set (if appropriate)

Day(s) Performed: Monday through Friday **Report Available:** 7 to 10 days

Questions
Contact Joshua Couchene Laboratory Technologist Resource Coordinator at 800-533-1710.