MAYO CLINIC LABORATORIES

TEST CHANGE

Notification Date: September 23, 2025
Effective Date: October 27, 2025

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

Test ID: MFCDF

Explanation:
On the effective date, the lab will discontinue the limited progression panel for secondary abnormalities and instead evaluate for the presence of both primary and secondary high-risk cytogenetic abnormalities to align with current guidelines.

Current Algorithm	New 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. 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. This test is designed for diagnostic bone marrow specimens from patients with multiple myeloma, or other plasma cell proliferative disorders, when either a fixed cell pellet or a bone marrow sample exceeding 96 hours post-collection is available. Best results are obtained when the bone marrow demonstrates at least 20% involvement by a plasma cell proliferative disorder. This test is performed using either the diagnostic or follow-up analysis algorithm. The diagnostic high-risk myeloma 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	This test includes a charge for 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. 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. This test is designed for diagnostic bone marrow specimens from patients with multiple myeloma, or other plasma cell proliferative disorders, when either a fixed cell pellet or a bone marrow sample exceeding 96 hours post-collection is available. Best results are obtained when the bone marrow demonstrates at least 20% involvement by a plasma cell proliferative disorder. The high-risk myeloma 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:

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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

Use of the follow-up analysis testing algorithm is determined by the results of either previous MFCDF / Myeloma, High Risk with Reflex Probes, Diagnostic FISH Evaluation, Fixed Cell Pellet, PCPDS / Plasma Cell Proliferative Disorder, High Risk with Reflex Probes, Diagnostic FISH Evaluation, Bone Marrow or MPCDS / mSMART, Plasma Cell Proliferative Disorder, FISH, Bone Marrow testing reported by this laboratory.

The follow-up high-risk myeloma 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

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.

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. Any additional probes will have the results included within the final report and will be performed at an additional charge.

Questions

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