

FOR MULTIPLE MYELOMA PATIENTS, COMPREHENSIVE FISH TESTING CAN HELP REVEAL A CLEARER PICTURE¹



Comprehensive FISH testing in patients with Multiple Myeloma may offer additional insight and knowledge about their disease.¹

In Multiple Myeloma, accuracy in test results matters. Plasma cell enrichment may help enhance the sensitivity of the FISH panel, may help reduce false negatives, and may inform a more personalised care approach.¹⁻³

FISH=fluorescence in situ hybridization.

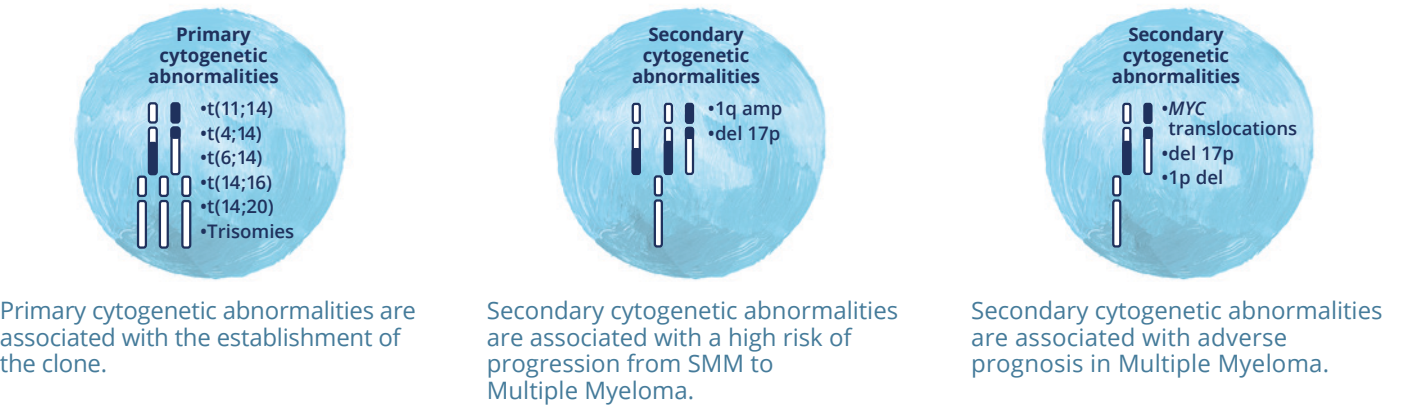
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FISH HELPS IDENTIFY GENETIC ABNORMALITIES⁴

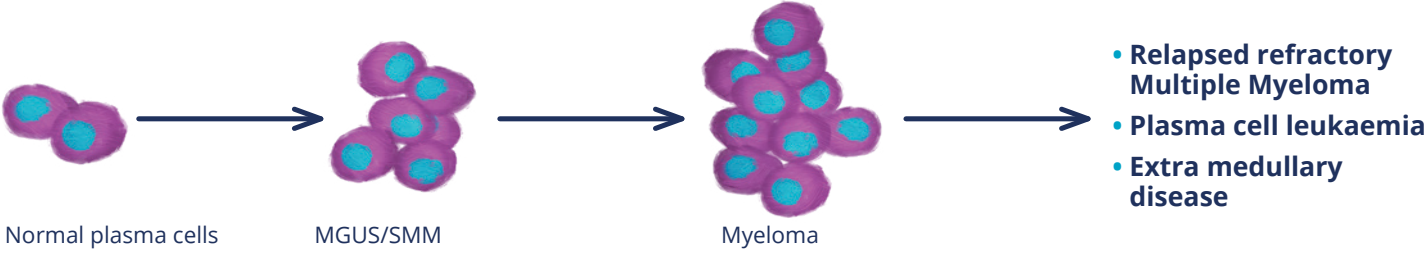
Multiple Myeloma is a treatable but incurable blood cancer that occurs when the bone marrow produces clonal plasma cells. It is the second most common haematologic malignancy worldwide.²

FISH can help identify IgH translocations, which emerge when normal plasma cells transition to a premalignant state. Knowledge of these IgH translocations is important for patient prognosis and risk stratification.³⁻⁶

EHA-ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up for Multiple Myeloma recommend karyotype and FISH for detection of del 17p, t(4;14), t(14;16), t(11;14), and ampl 1q/ gain 1q.⁷



The frequency and extent of karyotypic abnormalities can help determine disease stage, prognosis, and response to disease management.⁴



IgH translocations provide insight into prevalence and risk^{3,4}

Over 90% of the translocations observed in all Multiple Myeloma cases involve chromosome 14. Most recurrent translocations involving chromosome 14 are regarded as primary cytogenetic events that initiate tumour development.^{8,9}

IgH translocations are observed in 50%-70% of all Multiple Myeloma cases⁸

Translocations of IgH locus that appear most often⁸

Translocation	Gene(s)	Prevalence
t(11;14)(q13;q32)	CCND1	15% to 20%
t(4;14)(p16;q32)	FGFR3 and MMSET	10% to 15%
t(14;16)(q32;q23)	MAF	2% to 5%
t(6;14)(p21;q32)	CCND3	2%
t(14;20)(q32;q12)	MAFB	1%

t(11;14) is the most common translocation. This aberration can be identified early and is stable throughout disease progression.

IgH=immunoglobulin heavy-chain gene; MGUS=monoclonal gammopathy of undetermined significance; SMM=smoldering multiple myeloma.

PLASMA CELL ENRICHMENT INCREASES FISH SENSITIVITY AND ACCURACY^{3,10,11}



Plasma cell enrichment is a pre-analytical processing step that enhances FISH testing sensitivity by separating and isolating plasma cells.^{3,11,12}

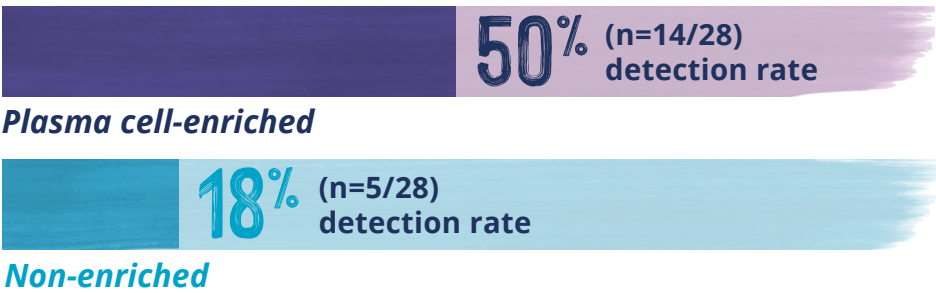


Plasma cell enrichment prior to FISH helps enhance the detection of cytogenetic abnormalities, which may help improve appropriate stratification of a patient's risk with a plasma cell neoplasm.^{4,6,10}

For these reasons, it is important that plasma cell enrichment is performed prior to FISH testing

See the prognostic value of enhanced sensitivity and accuracy^{1,10}

The percentage of cytogenetic abnormalities detected in enriched vs non-enriched samples¹



Comprehensive cytogenetic testing with PCE can foster personalised patient care

Many existing FISH diagnostic panels may not include key translocations like t(11;14) nor be plasma cell enriched.¹⁰

Multiple Myeloma patients could benefit from comprehensive FISH testing with PCE at diagnosis and/or relapse to identify key translocations.³⁻⁶

FISH testing with plasma cell enrichment may help provide enhanced testing sensitivity, reduced false negatives, and a personalised care approach.^{1,2}



Plasma cell enrichment prior to FISH can help foster personalised care^{2,3}:

- Reveal presence of IgH translocations
- Contribute to patient risk assessment



Potential benefits of personalised care^{2,13}:

- Improved cost effectiveness
- Increased patient confidence
- Opportunity to tailor management strategies

Plasma cell enrichment is recommended to enrich bone marrow samples prior to FISH testing.

EHA-ESMO Clinical Practice Guidelines recommend the use of plasma cell enrichment at diagnosis.⁷

The International Myeloma Working Group recommends FISH testing with plasma cell enrichment or cytoplasmic immunoglobulin-enhanced FISH to reduce the risk of low sensitivity for detection of chromosome abnormalities.¹⁴

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FISH testing with plasma cell enrichment may help provide^{1,3}:

- Enhanced testing sensitivity
- Reduced false negatives
- Personalised care approach

Together with FISH testing, plasma cell enrichment can improve detection of cytogenetic abnormalities by almost 3x¹

50% detection rate
(n=14/28)
Plasma cell-enriched

18% detection rate
(n=5/28)
Non-enriched

Plasma cell enrichment prior to FISH enhances sensitivity of the test to minimise false negatives and improve accuracy^{1,11}

Numerous global institutions and clinical practice guidelines recommend the use of plasma cell enrichment in their diagnostic recommendations for Multiple Myeloma^{7,14-18}

EHA-ESMO Clinical Practice Guidelines

International Myeloma Working Group (IMWG)

Revised International Staging System (R-ISS) for Multiple Myeloma

National Comprehensive Cancer Network® (NCCN®) Guidelines for Multiple Myeloma

College of American Pathologists (CAP)

ACMG Technical Standards for Clinical Genetics Laboratories

See NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for MM, Version 3.2023, for complete recommendations and principles. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. Comprehensive FISH testing=plasma cell enrichment prior to FISH. FISH=fluorescence in situ hybridization.

References: 1. Lu G, Muddasani R, Orlowski RZ, et al. Plasma cell enrichment enhances detection of high-risk cytogenomic abnormalities by fluorescence in situ hybridization and improves risk stratification of patients with plasma cell neoplasms. *Arch Pathol Lab Med*. 2013;137(5):625-631. 2. Kumar SK, Mikhael JR, Buadi FK, et al. Management of newly diagnosed symptomatic multiple myeloma: updated Mayo Stratification of Myeloma and Risk-Adapted Therapy (mSMART) consensus guidelines. *Mayo Clin Proc*. 2009;84(12):1095-1110. 3. Hartmann L, Biggerstaff JS, Chapman DB, et al. Detection of genomic abnormalities in multiple myeloma: the application of FISH analysis in combination with various plasma cell enrichment techniques. *Am J Clin Pathol*. 2011;136(5):712-720. 4. Rajan AM, Rajkumar SV. Interpretation of cytogenetic results in multiple myeloma for clinical practice. *Blood Cancer J*. 2015;5(10):e365. doi:10.1038/bcj.2015.92. 5. Pratt G. Molecular aspects of multiple myeloma. *J Clin Pathol: Mol Pathol*. 2002;55(5):273-283. 6. Mayo Clinic. mSMART3.0: Classification of Active MM. Updated February 2023. https://static1.squarespace.com/static/5b44f08ac258b493a25098a3/t/63ed594327268576fe783442/1676499267755/RiskStrat+3.0_Feb2023.pdf. Accessed April 10, 2023. 7. Dimopoulos MA, Moreau P, Terpos E, et al. Multiple myeloma: EHA-ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *HemaSphere*. 2021;5(2):1-12. 8. Saxe D, Seo EJ, Bergeron MB, Han JY. Recent advances in cytogenetic characterization of multiple myeloma. *Int J Lab Hematol*. 2019;41(1):5-14. 9. Avet-Loiseau H, Malard F, Campion L, et al. Translocation t(14;16) and multiple myeloma: is it really an independent prognostic factor? *Blood*. 2011;117(6):2009-2011. 10. Yu Y, Brown Wade N, Hwang AE, et al. Variability in cytogenetic testing for multiple myeloma: a comprehensive analysis from across the United States. *JCO Oncol Practice*. 2020;16(10):e1169-e1180. 11. Miller C, Yesil J, Derome M, et al. A comparison of clinical FISH and sequencing based FISH estimates in multiple myeloma: an MmrF compass analysis. *Blood*. 2016;128(22):374. doi.org/10.1182/blood.V128.22.374.374. 12. Sexton S, Chouinard T, Yung J-F. Plasma cell enrichment: manual versus automated methods. *NeoGenomics*. July 11, 2022. <https://neogenomics.com/sites/default/files/literature/plasma-cell-enrichment-manual-versus-automated-methods1.pdf>. Accessed April 10, 2023. 13. Mathur S, Sutton J. Personalized medicine could transform healthcare. *Biomed Rep*. 2017;7(1):3-5. 14. Fonseca R, Bergsagel PL, Drach J, et al. International Myeloma Working Group molecular classification of multiple myeloma: spotlight review. *College of American Pathologists*. 2015. www.cap.org/cancerprotocols. Accessed April 10, 2023. 15. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma V.3.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed April 10, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. 16. Khoury JD, Dogan A, Foucar K, et al. Protocol for the examination of specimens from patients with plasma cell neoplasms. *College of American Pathologists*. 2015. www.cap.org/cancerprotocols. Accessed April 10, 2023. 17. Palumbo A, Avet-Loiseau H, Oliva S, et al. Revised International Staging System for multiple myeloma: a report from International Myeloma Working Group. *J Clin Oncol*. 2015;33(26):2863-2869. 18. Technical standards for clinical genetics laboratories. 2021 revision. American College of Medical Genetics and Genomics (ACMG) website. https://www.acmg.net/PDFLibrary/Updated_Section_E.pdf. Updated 2021. Accessed April 10, 2023.

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