

Patient ID SA00125398	Patient Name TESTINGRNA, SAMPLE REPORT	Birth Date 1977-10-08	Gender F	Age 42
Order Number SA00125398	Client Order Number SA00125398	Ordering Physician CLIENT, CLIENT	Report Notes	
Account Information C7028846 DLMP Rochester		Collected 27 Jan 2020 05:30		

MPCDS Pre-Analysis Cell Sorting, BM
MPCDS Pre-Analysis Cell Sort

1 MCR

Performed

ADDITIONAL INFORMATION

Flow cytometric cell selection was performed with antibodies to the following antigens: CD45, CD319, CD19, CD56, CD38, and CD138.

Specimen enrichment for certain cell types is necessary, in order to enhance the sensitivity of genetic/molecular abnormalities detection in the cell population of interest, and to avoid unwanted contamination from other cell types. Flow cytometric cell sorting is the most direct and robust method of obtaining a pure population for subsequent genetic/molecular analysis, through assessment of a characteristic combination of cell surface antigens.

Received: 28 Jan 2020 10:59

Reported: 28 Jan 2020 11:07

Performing Site Legend

Code	Laboratory	Address	Lab Director	CLIA Certificate
MCR	Mayo Clinic Laboratories - Rochester Main Campus	200 First Street SW, Rochester, MN 55905	William G. Morice M.D. Ph.D	24D0404292

Patient ID SA00125398	Patient Name TESTINGRNV, SAMPLE REPORT	Birth Date 1977-10-08	Gender F	Age 42
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mSMART Eval, PCPDs, FISH

mSMART Result Summary

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Standard-Risk

mSMART Evaluation

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Based on the mSMART algorithm, this patient is in the STANDARD RISK category. Plasma cell FISH studies were normal identified and the Monotypic Plasma Cells S-phase (MSMRT) result was <2.0% (reported separately).

The Mayo Stratification for Myeloma and Risk Adapted Therapy (mSMART 3.0) algorithm classifies patients into standard or high risk categories based on the results of 2 assays. The high risk group includes patients with any of the following defined by FISH: t(14;20), t(14;16), t(4;14), 1q duplication or 17p deletion (TP53 deletion) or patients with a Monotypic Plasma Cells S-phase (MSMRT) result of $\geq 2.0\%$. The standard risk group includes patients with all remaining results, including: Monotypic Plasma Cells S-phase (MSMRT) <2.0% and FISH abnormalities including hyperdiploidy (multiple trisomies), t(11;14), or t(6;14). This classification is best used for newly diagnosed multiple myeloma. The interpretation may not be appropriate in monoclonal gammopathy of undetermined significance (MGUS), amyloidosis, or smoldering myeloma (mSMART 3.0, www.msma.org/mm-treatment-guidelines.html).

Note: Due to the application of a new classification criteria (mSMART 3.0, www.msma.org/mm-treatment-guidelines.html), any follow up testing on samples previously positive for either a t(4;14), 1q duplication or monocytic plasma cell S-phase $\geq 2\%$ evaluated using the mSMART 2.0 algorithm will now be classified as HIGH RISK using the updated mSMART 3.0 algorithm. This adjustment in risk is due to a new classification criteria and does not imply disease progression.

Interpretation

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The result is within normal limits for the plasma cell FISH panel.

Since sufficient plasma cells were observed and no clonal abnormalities were identified by the FISH panel in this sample, this result may represent a plasma cell clone with unusual genetic abnormalities, polyclonal plasma cells, or a different plasmacytoid malignancy. Evaluation for mutations in MYD88 may be considered.

Result Table

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Abnormality Name	Result	#Abn	TotalCells
-17p13.1(TP53x1,D17Z1x2)	Normal	0	50
-17(TP53,D17Z1)x1	Normal	0	50
+1q22(TP73x2,1q22x3)	Normal	0	50
+1(TP73,1q22)x3	Normal	0	50
t(14;16) IGH/MAF fusion	Normal	0	50
t(4;14) FGFR3/IGH fusion	Normal	0	50
8q24.1(MYC sep)	Normal	0	50
-13q14(RB1x1,LAMP1x2)	Normal	0	50
-13(RB1,LAMP1)x1	Normal	0	50
+9CEN(D9Z1x3)	Normal	0	50
+15CEN(D15Z4x3)	Normal	0	50
+7CEN(D7Z1x3)	Normal	0	50
+3CEN(D3Z1x3)	Normal	0	50
14q32(IGH sep)	Normal	0	50
t(11;14) CCND1-XT/IGH-XT fusion	Normal	0	50
+11(CCND1-XTx3)	Normal	0	50

Result

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Interphase FISH is normal for all loci studied.

Reason for Referral

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Plasma cell proliferative disorder (PCPD)

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Specimen

Bone Marrow

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Source

Left posterior iliac crest

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Method

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Locus and probes	[Strategy;#Nuclei;Class]
1p36.3(TP73), 1q22	[COPY#;50;LDT]
3CEN(D3Z1), 7CEN(D7Z1)	[COPY#;50;ASR]
4p16.3(FGFR3), 14q32(IGH)	[DFISH;50;ASR]
8q24(5'MYC,3'MYC)	[BAP;50;ASR]
9CEN(D9Z1), 15CEN(D15Z4)	[COPY#;50;ASR]
11q13(CCND1-XT), 14q32(IGH-XT)	[DFISH;50;ASR]
13q14(RB1), 13q34(LAMP1)	[COPY#;50;ASR]
14q32(3'IGH,5'IGH)	[BAP;50;LDT]
14q32(IGH), 16q23(MAF)	[DFISH;50;ASR]
17p13.1(TP53), 17CEN(D17Z1)	[COPY#;50;ASR]

Probe strategies include: DFISH=dual color, double fusion;
BAP=break-apart probe; COPY#=region gain and loss.

Disclaimer

Applicable to Analyte Specific Reagent (ASR) and Laboratory Developed Tests (LDT). 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 U.S. Food and Drug Administration. This FISH test does not rule out other chromosome abnormalities.

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Released By

Linda B. Baughn, Ph.D.

MCR

Received: 28 Jan 2020 10:59

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mSMART Algorithmic Testing, BM

Final Diagnosis

(2) MCR

Bone marrow, flow cytometric immunophenotyping:

1. Plasma cells express: monotypic kappa cytoplasmic immunoglobulin light chains, CD38 and CD138. They do not express: CD19 or CD45.

Comment:

S-phase of $\geq 2\%$ is associated with less favorable prognosis in patients with myeloma. It implies high-risk by mSMART stratification, in the absence of cytogenetic abnormalities. Correlation with plasma cell FISH results is recommended. For further details please see msmart.org.

Plasma cells, (monoclonal/monotypic and polyclonal/polytypic) are detected by immunoglobulin light chain restriction, surface immunophenotype, and DNA content. If present, the light chain expressed by the monotypic plasma cells is indicated. The percentage of clonal plasma cells estimated by flow cytometry is affected by specimen processing and antigen loss with specimen aging. Manual differential counting remains the accepted standard for determining the bone marrow plasma cell percentage.

The percentage of monotypic plasma cells in S-phase of the cell cycle is determined by quantitative DNA analysis. The DNA index is a calculated value. The presence of more than one value indicates the presence of cell populations with differing DNA contents within the monotypic plasma cells.

Method:

Plasma cell analysis was performed with antibodies to the following antigens: CD19, CD38, CD45, CD138, kappa and lambda cytoplasmic immunoglobulin light chains and DAPI.

Reviewed by: SHANDA VOELTZ

FISH STUDIES

Based on flow cytometric analysis ($\geq 0.1\%$ monotypic plasma cells), additional cytogenetic studies are being performed. See separate report for results.

Monotypic Plasma Cells:

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Monotypic kappa plasma cells present.

Reference Value
None detected.

Monotypic PC per Total Events

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12.21 %

Monotypic Plasma Cells S-phase

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2.2 %

Monotypic Plasma Cells DNA Index

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1.24

Reference Value
0.95–1.05

Monotypic Plasma Cells DNA Ploidy

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Hyperdiploid

Reference Value
Diploid

Polytypic PC per Total Events

MCR

0.1 %

Polytypic PC per All Plasma Cells

MCR

< 5.0 %

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Test
Environment
ETCF1 Template

Laboratory Notes

- 1 This test was developed and its performance characteristics 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.
- 2 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.

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