

Patient ID SA00155799	Patient Name TESTINGRNV, MRDMM	Birth Date 1985-05-15	Sex M	Age 37
Order Number SA00155799	Client Order Number SA00155799	Ordering Physician CLIENT,CLIENT	Report Notes	
Account Information C7028846 DLMP Rochester		Collected 12 Dec 2022 06:00		

Multiple Myeloma MRD by Flow, BM

Final Diagnosis

1 MCR

Bone marrow, flow cytometric immunophenotyping:

Monotypic lambda plasma cells identified (MRD= 0.0011% or 11 cells/million).

Reviewed by: SHANDA VOELTZ

ASSAY DESCRIPTION, METHOD AND LIMITATIONS

This assay is intended for post-therapeutic assessment of patients with plasma cell neoplasms, when in complete remission. Specimens with low cellularity and specimens from patients treated with therapeutic antibodies may interfere with this assay's sensitivity. Based on current literature guidelines, specimens with mast cells <0.002% and B-cell precursors <0.05% of non-aggregated events may suggest hemodilution (PMID: 28104919). Specimens with >5% plasma cells may show false-negative staining due to antigen excess, and plasma cells may not be accurately identified. Correlation with clinical and other laboratory studies is recommended.

Plasma cell analysis was performed with antibodies to the following antigens: Myeloma MRD panel: CD138, CD27, CD38, CD56, CD45, CD19, CD117, CD81, kappa and lambda cytoplasmic immunoglobulin light chains.

Quality Assessment: Specimen received within validated guidelines.

% Minimal Residual Disease (MRD)

MCR

0.0011 %

% Normal Plasma Cells (of total PC)

MCR

87.4 %

Non-Aggregate Events

MCR

9125677

Total Plasma Cell Events

MCR

801

Poly PC Events

MCR

700

Abnormal PC Events

MCR

101

% B-cell Precursors

MCR

0.150 %

% Mast Cells

MCR

0.008 %

Validated Assay Sensitivity

MCR

1.0 x10⁽⁻⁵⁾

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



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Lower Limit of Quantitation (LLOQ)

MCR

2.0×10^{-6}

LLOQ is defined as a minimum of 20 abnormal PC events detected in 10 million non-aggregate events, based on literature and internal validation data.

Patient / Sample Theoretical LOQ

MCR

2.19×10^{-6}

LOQ is calculated as a minimum of 20 abnormal PC events divided by the actual number of non-aggregate events collected for this sample.

Received: 12 Dec 2022 13:32

Reported: 12 Dec 2022 15:13

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.

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