

LABORATORY REPORT

QC ACCOUNT (WARDE) 300 W. TEXTILE ANN ARBOR MI 48108 **EXAMPLE, REPORT**

WX0000000237 F 12/05/1988 36 Y

Referral Testing

Collected: 09/18/2025 09:37 Received: 09/18/2025 09:37

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

MLH1 Promoter Methylation

MLH1 PCR, Source Tissue ARRL
MLH1 Promoter Methylation Positive AB

TEST INFORMATION: MLH1 Promoter Methylation, Paraffin

MLH1 methylation is common in sporadic microsatellite unstable tumors, like colorectal cancer and endometrial cancer, and rarely occurs in Lynch syndrome (hereditary non-polyposis colon cancer or HNPCC). Therefore, the presence of MLH1 methylation suggests that the tumor is sporadic and not associated with Lynch syndrome. However, since there have been rare reports of Lynch syndrome-associated MLH1 methylation, all results should be interpreted within the clinical context. The lack of MLH1 methylation in a mismatch repair deficient tumor suggests that it may be associated with Lynch syndrome, and germline evaluation is suggested. Finally, low level MLH1 methylation is not reported as positive, since it does not correlate with MLH1 inactivation and microsatellite instability.

METHODOLOGY: DNA is isolated from tumor tissue microdissected from prepared slides. DNA is treated with sodium bisulfite, followed by amplification of a segment of the MLH1 promoter region using methylation specific real-time PCR. The MLH1 methylation level is calculated by comparison to the amplification of a reference gene.

LIMITATIONS: Methylation at locations other than those covered by the primers and probes will not be detected. Results of this test must always be interpreted within the clinical context and other relevant data, and should not be used alone for a diagnosis of malignancy. This test is not intended to detect minimal residual disease.

ANALYTICAL SENSITIVITY: Methylation levels below 10 percent are reported as negative.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Block ID 12345

Performed By: ARUP Laboratories

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

E118000008 WX0000000237 Printed D&T: 09/18/25 09:37 Ordered By: CLIENT CLIENT WX000000000000336

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 1 OF 2



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500 Chipeta Way

Salt Lake City, UT 84108

Laboratory Director: Jonathan R. Genzen, MD, PhD

CLIA Number: 46D0523979

Reported Date: 09/18/2025 09:37 MLH1P

Performing Site:

ARRL: ARUP REFERENCE LAB 500 Chipeta Way Salt Lake City UT 841081221

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Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 2 OF 2