



LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003826 F 12/05/1988 34 Y

Referral Testing

Collected: 09/14/2023 14:36 Received: 09/14/2023 14:36

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: MLH1 Promoter Methylation, Positive, AB, ARRL

MLH1 promoter methylation was detected.

This result has been reviewed and approved by Anna Matynia, M.D.

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

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



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<u>Test Name</u>	<u>Result</u>	<u>Flag</u>	<u>Ref-Ranges</u>	<u>Units</u>	<u>Site</u>
intended for clinical purposes.					
Block ID	ABC12-34567				ARRL

Performed By: ARUP Laboratories
500 Chipeta Way
Salt Lake City, UT 84108
Laboratory Director: Jonathan R. Genzen, MD, PhD
CLIA Number: 46D0523979

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

Reported Date: 2023.09.14 14:37 MLH1

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

F314000009 Ordered By: KAJAL SITWALA, MD, PhD
WX0000003826 WX00000000002353
Printed D&T: 09/14/23 14:37

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