

Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB: 12/5/1960
Gender: Male
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 00/00/0000 00:00

MGMT Promoter Methylation Detection by ddPCR

ARUP test code 3005956

Block ID test

MGMT METH Result

Low Level *

Low level MGMT promoter methylation was detected.

This result has been reviewed and approved by [REDACTED]

INTERPRETIVE INFORMATION: MGMT Promoter Methylation
Detection by ddPCR

CHARACTERISTICS: This assay is designed to detect MGMT promoter methylation. MGMT promoter methylation status is a prognostic biomarker in patients with high-grade gliomas and is useful in treatment decisions. For specific treatment recommendations, please refer to NCCN Clinical Practice Guidelines in Oncology for Central Nervous System Cancers (www.nccn.org).

METHODOLOGY: Genomic DNA is isolated from microscopically-guided dissection of tumor tissue followed by bisulfite conversion. Two droplet digital PCR reactions with conversion-specific primers and differentially labeled probes complementary to methylated and unmethylated MGMT promoter sequence are performed. Methylation status of CpG sites 75-78 is evaluated in reaction 1 and of CpG sites 79-82 in reaction 2. Percent methylation for each reaction is calculated as a ratio of methylated to all amplifiable alleles. The average percent methylation of both reactions is used for qualitative calls and reported as follows: average percent methylation of 0 to less than 5 percent is reported as "Not detected," 5 to less than 25 percent as "Low level," and equal or more than 25 percent as "Detected."

LIMITATIONS: Methylation at locations other than those listed above will not be detected.

ANALYTICAL SENSITIVITY: 5 percent methylation.

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.

MGMT METH Specimen

Tissue

H=High, L=Low, *=Abnormal, C=Critical

VERIFIED/REPORTED DATES				
Procedure	Accession	Collected	Received	Verified/Reported
Block ID	22-346-101140	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
MGMT METH Result	22-346-101140	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
MGMT METH Specimen	22-346-101140	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

END OF CHART

H=High, L=Low, *=Abnormal, C=Critical