Demographics

PATIENT	SPECIMEN	PHYSICIAN
Name: John Doe	**Specimen ID:** ADM45A5789	**Name:** Dr. Gene
Patient ID: JL00032342	**Source Specimen ID:** SS-22-45454 1A	**Affiliation:** Cancer Genetics Institute
Source Patient ID: 45345234	**1° Tumor Site:** Brain	
D.O.B: 11/02/1960	**Specimen Site:** Brain	
Gender: Male	**Neoplastic Content:** 90%	
Submitted Diagnosis: Glioblastoma, WHO grade 4	**Collection Date:** 03/15/2022	
	Received Date: 03/20/2022	

JAX MGMT Promoter Methylation Final Result

MGMT Promoter Methylated

Test Methods and Limitations

As necessary (for FFPE blocks or unstained slides), specimens are sectioned and stained using Fisher Chemical Eosin Y and Richard-Allan Scientific™ Hematoxylin Stain (Modified Mayer). Slides are digitally scanned on the Leica Aperio CS2 Scanner for remote pathologist review of neoplastic content, tissue type, tumor area, and specimen quality (Remote Testing Site: LBH07).

The JAX MGMT Promoter Methylation Assay utilizes a quantitative PCR (qPCR) followed by high-resolution melt analysis (HRM) to identify MGMT promoter methylation. Genomic DNA is extracted from FFPE tissues (minimum 30% neoplastic content) and bisulfite treated using the EZ DNA Methylation-Gold Kit (Zymo). The bisulfite-treated DNA is amplified via qPCR followed by a melting analysis on an Applied Biosystems™ QuantStudio™ 7. The area under the curve (AUC) is calculated for the HRM derivative plots for both methylated and unmethylated peaks and the ratio of methylated to unmethylated is calculated. Specimens are interpreted as "MGMT Promoter Unmethylated" if the methylated/unmethylated ratio falls within the validated unmethylated range. Specimens with ratios above a 15% methylated control are interpreted as "MGMT Promoter Methylated". Specimens with ratios between unmethylated and the 15% methylated control are interpreted as "Indeterminate". Review of digital data, results, and/or clinical report was performed at the following remote testing sites: MKH11.

Disclaimers

Decisions on patient care must be based on the independent medical judgment of the treating physician, taking into consideration all relevant information about the patient's condition, including patient medical and family history, physical examinations, information from other diagnostic tests, and patient preferences. A treating physician's decisions should not be based on a single test, such as this test, or the information contained in this report alone. Results of this test must always be interpreted in the context of all relevant clinical and pathological data and should not be used alone for diagnosis or patient care decisions. Genetic counseling is recommended to discuss the implications of these test results.

This test was developed and its performance characteristics determined by The Jackson Laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). This test may be used for clinical purposes and should not be regarded as purely investigational or for research only. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) as qualified to perform high complexity clinical testing. The Jackson Laboratory makes no promises or guarantees that a healthcare provider, insurer or other third-party payor, whether private or governmental, will reimburse a patient for the cost of this test.

Melissa Kelly, PhD, HCLD/CC(ABB), Clinical Laboratory Director

03/24/2022
Date