MAYO
Mayo Medical Laboratories
1-800-533-1710

NEW TEST ANNOUNCEMENT
NOTIFICATION DATE: August 8, 2012
EFFECTIVE DATE: September 10, 2012

IDH1/IDH2 MUTATION ANALYSIS BY PYROSEQUENCING PARAFFIN
Test ID: 61207

USEFUL FOR: Supporting a diagnosis of grade II or III astrocytoma, oligodendroglioma, oligoastrocytoma or secondary glioblastoma

Stratifying prognosis of gliomas

METHODOLOGY: Polymerase Chain Reaction (PCR) and Pyrosequencing

REFERENCE VALUES: Negative

SPECIMEN REQUIREMENTS:
Preferred: Formalin-fixed, paraffin-embedded (FFPE) tissue block with a minimum of 40% tumor cell population
Alternate: Unstained slides with a minimum of 40% tumor population; slides may be stained and/or scraped

Collection Instructions:
1. Process all fresh or frozen specimens into FFPE blocks prior to submission.
2. When a FFPE block is not available or processing cannot be performed, a frozen specimen shipped on dry ice will be accepted and will be processed by the laboratory into a FFPE block prior to testing.
3. If submitting slides, a minimum of ten, 4- to 5-micron thick, unstained slides are required.
Additional Information:
1. A quality specimen is essential for evaluation. Submit only tissue containing tumor cells; minimal tissue is required for evaluation.
2. Special stains performed outside Mayo Medical Laboratories and included with the case may be repeated and charged at the reviewing pathologist's discretion. Testing requested by referring physician may not be performed if deemed unnecessary by Mayo Clinic pathologist.

SPECIMEN STABILITY INFORMATION:

Specimen Type	Temperature	Time
Varies	Ambient (preferred)	
	Refrigerated	

CAUTIONS: Reliable results are dependent on adequate specimen collection and processing. This test has been validated on formalin-fixed, paraffin-embedded tissues; other types of fixatives are discouraged. Improper treatment of tissues, such as decalcification, may cause PCR failure. False-negative results may occur in heterozygous tumor specimens when tumor cells comprise <40% of the cell population.

Clinical diagnosis or therapy should not be based solely on this assay. The results should be considered in conjunction with clinical information and additional diagnostic tests.

This test is designed to detect mutations in codon 132 of the IDH1 gene and codon 172 of the IDH2 gene and does not detect mutations in other areas of these genes.

Results should be interpreted only in context of histological analysis.

FEE: Please contact your Regional Manager for your account's fee information.

CPT CODE:
83891 - Isolation or extraction of highly purified nucleic acid
83892 - Enzymatic digestion
83896 x 4 - Nucleic acid probe, each
83898-x 2 - Amplification, target, each nucleic acid sequence
83904-x 2 - Mutation identification by sequencing, single segment
83907- Lysis of cells prior to nucleic acid extraction
83912- Interpretation and report
88387-Macroscopic examination, dissection, and preparation of tissue for non-microscopic analytical studies (eg, nucleic acid-based molecular studies); each tissue preparation (eg, a single lymph node)

DAY(S) SET UP: Monday through Friday; 8 a.m. – 4:30 p.m.

ANALYTIC TIME: 3 days

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager or
Leah Saint-Fort, MML Laboratory Technologist Resource Coordinator
Telephone: 800-533-1710