

Patient Name :	Bill Date :
DOB/Age/Gender :	Sample Collected :
Patient ID / UHID :	Sample Received :
Referred By :	Report Date :
Sample Type :	Barcode No :
Client :	Report Status :

TEST NAME

IDH mutations

SPECIMEN INFORMATION

Received 06 paraffin blocks labelled as G25441/22 A, B, C, D, E & F.

CLINICAL HISTORY

Suggestive of diffuse glioma - low grade.

METHODOLOGY

Polymerase Chain Reaction - Sequencing

DIAGNOSIS

MOLECULAR TEST	INTERPRETATION	IDH1 & IDH2 Molecular Mutation Tested	Results
IDH1 Mutations ✓ Exon 4- Mutant Wild Type Not Amplified	Positive	IDH1 132	Mutant
IDH2 Mutations ✓ Exon 4- Mutant Wild Type Not Amplified	Negative	IDH2 172	Wild Type

COMMENTS

- There is presence of IDH1 codon 132 (R132C) mutation in the given specimen.
- A positive test indicates the presence of an IDH1 or IDH2 mutation and supports a diagnosis of grade II or III astrocytoma, oligodendroglioma, oligoastrocytoma or secondary glioblastoma. It is important to note that IDH1 and IDH2 mutations have been found in a variety of other tumors.
- IDH1 codon 132 and IDH2 codon 172 mutations have been identified in more than 70% of brain tumors diagnosed as grade II and III astrocytoma, oligodendroglioma, oligoastrocytoma and secondary glioblastomas. These mutations are rarely found in other brain tumors and non-brain tumors. The ordering physician is responsible for the diagnosis and management of disease and decisions based on the data provided.
- False-negative results may occur in specimens when tumor cells comprise <40% of the cell population. Tumor cells are routinely enriched by macrodissection to avoid false-negative results. Clinical diagnosis and/or therapy should not be based solely on this assay. The results should be considered in conjunction with clinical information, histologic evaluation, and/or additional diagnostic tests.

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COMMENTS

Assay Description And Methodology:

Formalin-fixed, paraffin embedded tumor tissue sections are deparaffinized and DNA is extracted using the DNeasy Blood and Tissue Kit (Qiagen, Valencia, CA). Mutated IDH oncogenes are detected using Sequencing based PCR kit. Mutation of IDH1 appears to be a very strong prognostic factor in diffuse gliomas & mutations of the related IDH2 gene were also detected in astrocytic and oligodendroglial gliomas lacking IDH1 mutations.

Intended Use:

This test is intended to be used and be interpreted in conjunction with all other available clinical and laboratory information. Diagnosis of glioma; patients with glioma or AML for whom prognosis/risk stratification is sought. The test is validated for use with CRC FFPE tissue specimens that contain at least 40% tumor area, or that can be enriched to that tumor content in the course of a histological specimen review. The test has not been validated on other specimen types or other human malignancies.

Disclaimer:

This test is performed using an in-house developed and validated test. The assay is designed to perform the reactions at the specified analytical sensitivity given that the template DNA is not heavily fragmented and does not contain materials that could inhibit the amplification reaction

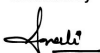
REFERENCES

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2. Innis MA, DH Gelfand, JJ Sninsky, and TJ White (eds.) 1990 PCR Protocols: A Guide to Methods and Applications. San Diego, California: Academic Press.
3. McPherson MJ, SG Moller, R Beynon, and C Howe 2000 PCR: Basics from Background to Bench. Heidelberg: Springer-Verlag.
4. Parsons DW, Jones S, Zhang X, et al. An integrated genomic analysis of human glioblastoma multiforme. Science. 2008;321:1807–1812.
5. Balss J, Meyer J, Mueller W, et al. Analysis of the IDH1 codon 132 mutation in brain tumors. Acta Neuropathol. 2008;116:597–602.
6. Bleeker FE, Lamba S, Leenstra S, et al. IDH1 mutations at residue p.R132 (IDH1(R132)) occur frequently in high-grade gliomas but not in other solid tumors. Hum Mutat. 2009;30:7–11.

NOTE- **This test is processed and validated at the partner lab of Redcliffe Labs.

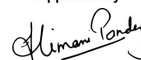
*** End of Report ***

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2. It is to be presumed that the tests performed pertain to the specimen/sample attributed to the Customer's name or identification. It is presumed that the verification particulars have been cleared out by the customer or his/her representation at the point of generation of said specimen / sample. It is hereby clarified that the reports furnished are restricted solely to the given specimen only.
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