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

Physician: Doctor, Example

Patient: Patient, Example

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

1p19q Deletion by FISH and IDH1 R132H Point Mutation by Immunohistochemistry with Reflex to IDH1 and IDH2 Mutation Analysis, Exon 4

ARUP test code 3002135

IDH1 R132H Point Mut by IHC with Reflex	Positive INTERPRETIVE INFORMATION: IDH1 R132H Point Mut by IHC with Reflex IDH1 R132H Point Mutation by Immunohistochemistry detects the presence of mutant IDH1 R132H protein expression in diffuse gliomas and can serve as a screening tool for molecular testing. A positive result indicates a probable IDH1 R132H mutation. A negative result indicates the tumor has no R132H mutation, which will automatically reflex to IDH1 and IDH2 gene sequencing, to detect less common IDH1 or IDH2 mutations not detected by the IHC test. This test is performed on paraffin-embedded, formalin-fixed tissue. Controls were run and performed as expected. Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: aruplab.com/CS
IDH1 Tissue Source	Brain
IDH1 R132H Mutation Reference Number	B88

1p/19q Deletion by FISH

ARUP test code 3001309

1p Result	Deleted
19q Result	Deleted Controls were run and performed as expected. This result has been reviewed and approved by [redacted]

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

1p/1q Ratio	0.57
1P Percent Deleted	74 %
Chromosome 1 Polysomy	Not Detected
19q/19p Ratio	0.60
19Q Percent Deleted	72 %
Chromosome 19 Polysomy	Not Detected
1P Total Cell Count	50
19Q Total Cell Count	50
Scoring Method	Manual
1p19q FISH Reference Number	B88
1p19q FISH Source	Brain

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

INTERPRETIVE INFORMATION: 1p/19q, FISH

Fluorescence in situ hybridization (FISH) analysis was performed on a section from a paraffin-embedded tissue block using differentially labeled fluorescent probes targeting 1p36/1q25 and 19p13/19q13 (Abbott Molecular). Cells were evaluated from regions of tumor identified on histopathologic review of a matching hematoxylin- and eosin-stained section. Controls performed appropriately.

This assay evaluates the average ratios of 1p to 1q and 19q to 19p, as well as the percentage of cells with a signal pattern consistent with a deletion (individual cell 1p/1q and 19q/19p ratios of 0.5 or lower). Based on the validation of this assay, 1p deletion is defined as a 1p/1q ratio below 0.80 combined with a deleted pattern in 24 percent or more of the scored cells, and 19q deletion is defined as a 19q/19p ratio below 0.80 combined with a deleted pattern in 26 percent or more of the scored cells.

Codeletion of 1p and 19q as the result of an unbalanced translocation is characteristic of oligodendrogliomas and a diagnostic feature according to the WHO Classification of Tumours of the Central Nervous System, Revised 4th Edition (2016). Codeletion is also predictive of a favorable response to combination chemotherapy. Isolated deletions of 1p or 19q are neither diagnostic nor predictive in a similar fashion. Polysomy, defined in this context as three or more signals for 1q and/or 19p in 30 percent or more of the tumor cells, suggests a less-favorable outcome in oligodendrogliomas. Based on the assay performance during test validation, the test is expected to detect 96 percent of 1p and 19q deletions in patients with oligodendrogliomas. Assay range and limit of detection were generated using normal and known positive cases respectively. Correlation with other laboratory data, especially histopathologic findings, is recommended for optimal risk stratification.

References:
1. Jenkins RB et al. A t(1;19)(q10;p10) Mediates the Combined Deletions of 1p and 19q and Predicts a Better Prognosis of Patients with Oligodendroglioma. Cancer Res 66 (20): 9852-9861, 2006.
2. Snuderl M et al. Polysomy for chromosomes 1 and 19 predicts earlier recurrence in anaplastic oligodendrogliomas with concurrent 1p/19q loss. Clin Cancer Res 15(20):6430-6437, 2009.
3. Wiens et al. Polysomy of chromosomes 1 and/or 19 is common and associated with less favorable clinical outcome in oligodendrogliomas: fluorescent in situ hybridization analysis of 84 consecutive cases. J Neuropathol Exp Neurol 71(7):618-624, 2012.
4. Clark K et al. How molecular testing can help (and hurt) in the workup of gliomas. Am J Clin Pathol 139(3):275-288, 2013.
5. Senetta R et al. A "weighted" fluorescence in situ hybridization strengthens the favorable prognostic value of 1p/19q codeletion in pure and mixed oligodendroglial tumors. J Neuropathol Exp Neurol 72(5):432-41, 2013.
6. Eckel-Passow JE et al. Glioma Groups Based on 1p/19q, IDH, and TERT Promoter Mutations in Tumors. N Engl J Med 25;372(26):2499-508, 2015.
7. Louis DN, Ohgaki H, Wiestler OD, Cavenee WK, Ellison DW, Figarella-Branger D, Perry A, Reifenberger G, von Deimling A, Eds. WHO Classification of Tumours of the Central Nervous System, Revised 4th Edition. Lyon, France: International Agency for Research on Cancer, 2016.

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.

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

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
IDH1 R132H Point Mut by IHC with Reflex	24-212-103982	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
IDH1 Tissue Source	24-212-103982	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
IDH1 R132H Mutation Reference Number	24-212-103982	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
1p Result	24-212-103982	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
19q Result	24-212-103982	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
1p/1q Ratio	24-212-103982	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
1P Percent Deleted	24-212-103982	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Chromosome 1 Polysomy	24-212-103982	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
19q/19p Ratio	24-212-103982	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
19Q Percent Deleted	24-212-103982	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Chromosome 19 Polysomy	24-212-103982	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
1P Total Cell Count	24-212-103982	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
19Q Total Cell Count	24-212-103982	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Scoring Method	24-212-103982	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
1p19q FISH Reference Number	24-212-103982	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
1p19q FISH Source	24-212-103982	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

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