ARUP LABORATORIES
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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	10/6/1962
Gender:	Female
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	00/00/0000 00:00

EGFR Gene Amplification by FISH

ARUP test code 3001310

EGFR FISH Result	Not Amplified ISCN: nuc ish(EGFRx1-4,CEP7x1-5)[50/50] Controls were run and performed as expected. This result has been reviewed and approved by [redacted] 2000 Circle of Hope, RM 3100 Salt Lake City, UT 84112
EGFR/CEP7 FISH Ratio	1.0
Average EGFR Signal Number per Cell	2.2
Average CEP7 Signal Number per Cell	2.1
Total Cell Count	50
Scoring Method	Manual
EGFR FISH Reference Number	SU22-7099 B1
EGFR FISH Source	Brain Tumor

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

INTERPRETIVE INFORMATION: EGFR, FISH

Fluorescence in situ hybridization (FISH) analysis for EGFR gene amplification was performed on a section from a paraffin embedded tissue block using differentially labeled fluorescent probes targeting the EGFR gene and the chromosome 7 centromere (CEP 7) (Agilent Technologies). Cells were evaluated from regions of tumor identified on histopathologic review of a matching hematoxylin- and eosin-stained section. Controls performed appropriately.

Based on the assay performance during test validation, the test is expected to detect EGFR amplification status correctly in 100 percent of patients. Assay range and limit of detection were generated using normal and known positive cases respectively.

EGFR gene amplification (EGFR/CEP7 ratio of 2.0 or greater) is observed in a variety of tumor types. In gliomas, EGFR amplification is associated with higher grade tumors, especially primary glioblastomas. EGFR amplification status has been correlated with a worse outcome in anaplastic astrocytoma, and may also be used as a prognostic marker or to predict tumor response to targeted therapy in certain other tumor types.

Reference:
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.

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
EGFR FISH Result	22-160-401041	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
EGFR/CEP7 FISH Ratio	22-160-401041	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Average EGFR Signal Number per Cell	22-160-401041	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Average CEP7 Signal Number per Cell	22-160-401041	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Total Cell Count	22-160-401041	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Scoring Method	22-160-401041	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
EGFR FISH Reference Number	22-160-401041	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
EGFR FISH Source	22-160-401041	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