

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

Physician: Doctor, Example

Patient: Patient, Example

DOB: 3/30/2017
Gender: Female
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 00/00/0000 00:00

MYCN (N-MYC) Gene Amplification by FISH

ARUP test code 3001307

MYCN FISH Result Not Amplified

MYCN/CEP2 FISH Ratio 1.0

Average MYCN Signal Number per Cell 1.7

Average CEP2 Signal Number per Cell 1.8

Total Cell Count 40

Scoring Method Manual

MYCN FISH Reference Number PCS22-5428 A3

MYCN FISH Source Not provided

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

Unless otherwise indicated, testing performed at:

INTERPRETIVE INFORMATION: MYCN (N-MYC), FISH

Fluorescence in situ hybridization (FISH) analysis for MYCN gene amplification was performed on a section from a paraffin embedded tissue block using differentially labeled fluorescent probes targeting the MYCN gene and the chromosome 2 centromere (CEP2) (Abbott Molecular). Cells were evaluated from regions of tumor identified on histopathologic review of a matching hematoxylin and eosin stained section. Controls performed appropriately.

MYCN amplification (MYCN/CEP2 ratio of 2.0 or greater) is considered a feature of high-risk disease and an indicator of poor prognosis in neuroblastoma. Amplification is also seen in SHH-activated and group 4 medulloblastomas with implications for prognosis and therapy response. Based on the assay performance during test validation, the test is expected to detect MYCN amplification status correctly in 100 percent of patients. Assay range and limit of detection were generated using normal and known positive cases respectively.

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
MYCN FISH Result	22-333-400135	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
MYCN/CEP2 FISH Ratio	22-333-400135	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Average MYCN Signal Number per Cell	22-333-400135	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Average CEP2 Signal Number per Cell	22-333-400135	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Total Cell Count	22-333-400135	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Scoring Method	22-333-400135	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
MYCN FISH Reference Number	22-333-400135	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
MYCN FISH Source	22-333-400135	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

Unless otherwise indicated, testing performed at: