

SAMPLE MOLECULAR (FISH) REPORT

DIAGNOSIS:

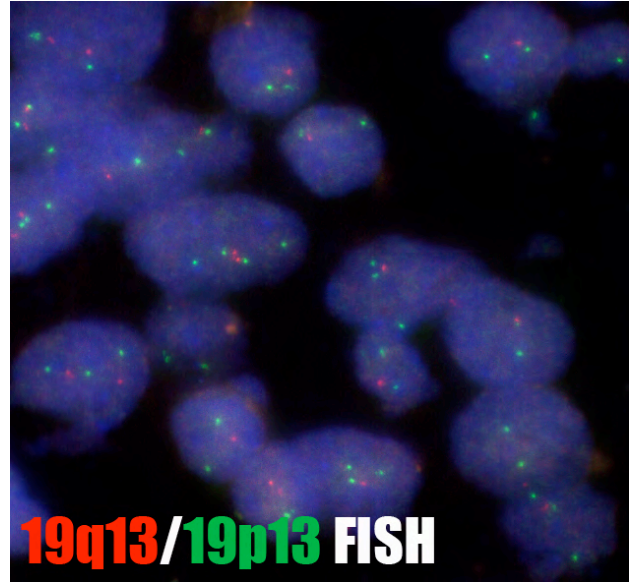
ABC Hospital A06-5019 (Block B1)

Brain, left parietal lobe, second lesion, biopsy: Anaplastic oligodendroglioma with the following features:

1. **Positive for loss of 1p36** by fluorescence in situ hybridization (FISH).
2. **Positive for loss of 19q13** by fluorescence in situ hybridization (FISH).

COMMENTS:

Gliomas are the most common primary neoplasm of the central nervous system and can have strikingly different clinical behaviors and responses to therapy. Distinguishing between different subtypes is often less than perfect with significant inter-observer variability. Although attempts have been made to define clinical and histologic features that correlate with a favorable prognosis, none has been sufficiently reliable at predicting response to adjuvant chemotherapy. However, recent studies have shown that loss of 1p36 and 19q13 is associated with an oligodendroglial phenotype, favorable response to chemotherapy and overall prolonged survival.¹⁻³ Fluorescence in situ hybridization (FISH) studies provide a direct method for identifying loss of 1p36 and 19q13 in formalin-fixed, paraffin-embedded tissue sections. Loss of 1p36 and 19q13 is performed by assessing the ratio of 1p36 and 19q13 to their corresponding reference genes, 1q25 and 19p13, respectively, and by assessing the number of nuclei showing clear 1p36 and 19q13 deletion, according to guidelines defined by the International Society of Pediatric Oncology.¹⁻⁴



REFERENCES:

1. Burger PC et al. Mod Pathol. 2001 Sep;14(9):842-53
2. Smith JS et al. J Clin Oncol. 2000 Feb;18(3):636-45
3. Gelpi E et al. Mod Pathol. 2003 Jul;16(7):708-15
4. Ambros PF et al. Med Pediatr Oncol. 2001 Dec;37(6):492-504

SPECIMEN INFORMATION:

A1 = A06-5019, B1, 1 block

RECEIVED FOR THE FOLLOWING:

1p19q deletion study by FISH.

FLUORESCENCE IN SITU HYBRIDIZATION FINDINGS:

Deparaffinized tissue sections, following digestion/pretreatment along with appropriate positive/negative controls, are incubated with a Vysis detection system, an analyte specific reagent containing 2 pairs of probes performed on two separate tissue sections: the first probe pair set includes a probe to the 1p36 region (Spectrum Orange™) and the second to the 1q25 region (Spectrum Green™), and the second probe pair set involves a probe to the 19q13 region (Spectrum Orange™), with a second to the 19p13 region (Spectrum Green™). Quantitative analysis of both probe pair sets is performed manually on areas of the paraffin tissue sections selected by the pathologists. Slides are analyzed by the pathologist with the assistance of the MetaSystems™ Metafer scanning system, which has an extended focus/tile sampling methodology, and the ability to analyze 3D distance between FISH signals. The threshold for positivity is established from a group of reactive and neoplastic cases. A positive case is defined as a case in which the ratio of 1p36/1q25 and 19q13/19p13 is less than 0.84 and 0.90, respectively (3 standard deviations below the

Dr. Pathologist MD
ABC Hospital
Anywhere, WA 98102



PP2006-XXXXX-XX
PATIENT: Doe, John
DATE OF BIRTH: July 1, 1980
AGE: 26 GENDER: M
RECEIVED: July 1, 2006
DATE OF REPORT: July 4, 2006

mean of a negative control group of cases). In addition, the percentage of nuclei showing loss of 1p36 and 19q13 is calculated and positive cases show greater than 19.0% and 20.1% of nuclei with deletion of 1p36 and/or 19q13 (i.e., 2:1, 3:1, 4:1, 4:2 - 3 standard deviations above the mean of a negative control group of cases with a mean of 11.8% for loss of 1p36 and 9.5% for loss of 19q13).

Block B1 (Surgery Date: 06/29/2006) -Brain (PP2006XXXXX A1)

Dual Color Probe Sets	Results
1p36/1q25 ratio	0.56
Percentage of nuclei showing loss of 1p36	66.0%
19q13/19p13 ratio	0.61
Percentage of nuclei showing loss of 19q13	46.5%

*****ELECTRONICALLY SIGNED*****

Steven J. Kussick, M.D., Ph.D.
Pathologist

In compliance with CMS regulations, the pathologist's signature on this report indicates that the case has been personally reviewed, and the diagnosis made or confirmed by the Pathologist.

NOTE: Some of the tests reported here may have been developed and performance characteristics determined by PhenoPath Laboratories. They have not been cleared or approved by the U.S. Food and Drug Administration (FDA). However, the FDA has determined that such clearance or approval is not necessary. Pursuant to the requirements of CLIA, this laboratory has established and verified the accuracy and precision of all tests, and additional information about these tests is available upon request. PhenoPath Laboratories is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical laboratory testing.