

SAMPLE MOLECULAR (FISH) REPORT

DIAGNOSIS:

ABC Hospital A06-11111 (Block A1)

Lung mass, transbronchial biopsies: **Positive** for EGFR high polysomy by fluorescence in situ hybridization (FISH).

SPECIMEN INFORMATION:

A1 = A06-11111, A1, 1 block

RECEIVED FOR THE FOLLOWING:

EGFR by FISH

FLUORESCENCE IN SITU HYBRIDIZATION FINDINGS:

Deparaffinized sections of tissue, following digestion and pretreatment of the tissue, and along with appropriate positive and negative controls, are incubated with Vysis probes containing 2 separate probes: a locus-specific EGFR (7p12 SpectrumOrange™) and a chromosome 7-centromeric probe (7p11.1-q11.1 SpectrumGreen™). Morphometric image analysis is performed using a MetaSystems™ image analysis system and Metafer 4 application software as well as manual counting of at least 60 non-overlapping nuclei. EGFR positivity for fluorescence in situ hybridization is defined as (1) EGFR CEP-7 ratio of ≥ 2.0 , (2) ≥ 15 copies of EGFR per nucleus in $> 10\%$ of nuclei, or (3) \geq four copies of EGFR in $\geq 40\%$ of nuclei (high polysomy).

REFERENCES:

1. Cappuzzo F, Hirsch FR, et al. Epidermal growth factor receptor gene and protein and gefitinib sensitivity in non-small-cell lung cancer. J Natl Cancer Inst. 2005 May 4;97(9):643-55.
2. Hirsch FR, Varella-Garcia M, et al. Epidermal growth factor receptor in non-small-cell lung carcinomas: correlation between gene copy number and protein expression and impact on prognosis. J Clin Oncol. 2003 Oct 15;21(20):3798-807. Epub 2003 Sep 2.

Block A1 (Surgery Date: 6/29/06) -Lung (PP2006XXXX A1)

POSITIVE FOR EGFR HIGH POLYSOMY BY FISH

DNA Target	Probe	Mean # of signals/nuclei
EGFR	EGFR/SpectrumOrange	3.67
Chromosome 7-centromere	CEP -7/SpectrumGreen	3.47

EGFR to CEP-7 ratio = 1.10

High Polysomy (\geq four copies of EGFR in $\geq 40\%$ of nuclei) present in 55% of cells counted.

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

Todd Barry, 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.

