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Source of Tissue: Skin Biopsy
Indications: Left Upper Back; R/O Melanoma
Date Reported FISH: 05/16/2011 7:50 AM

ACCESSION: 000000-2011

Obtained: 05/11/2011

Received: 05/12/2011

PRACTICE: ABC PRACTICE
PHYSICIAN: JOHN SMITH, MD
123 STATE STREET
ANYWHERE, NY 12345

PATIENT: JOHN DOE
123 STATE AVENUE
ANYWHERE, NY 12345

Age: 72 DOB:02/03/1939
Sex: Male SS#: 123-45-6789
Acct: 12345

Account # 1234-5678-90



Rte
9

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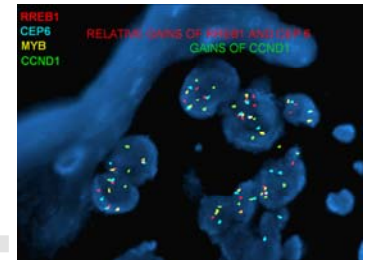
FINAL DIAGNOSIS:

ABNORMAL, 90% OF CELLS EXHIBIT RELATIVE GAINS OF RREB1/CEP 6 AND 53.3% OF CELLS EXHIBIT GAINS OF CCND1

FISH ANALYSIS DATA

Assay #	Probe Region	Chromosome or Locus	Normal Percentage	Normal Reference Range	No. of Cells Scored
1	Melanoma Panel	CCND1 (11q13.3)	46.6%	62% - 100%	60
1	Melanoma Panel	D6Z1 (6p11.1-q11)	10%	45% - 100%	60
1	Melanoma Panel	MYB (6q23.3)	28.3%	60% - 100%	60
1	Melanoma Panel	RREB1 (6p24.3-p25)	0%	71% - 100%	60

FISH



ISCN RESULT:

nuc ish(RREB1x3~8)[60],(D6Z1x3~5)[54/60],(MYBx3~5)[43/60],(CCND1x3~4)[32/60]

INTERPRETATION:

Interphase fluorescence in situ hybridization (FISH) was completed on the submitted formalin fixed paraffin embedded left upper back biopsy using a panel of four locus specific identifier probes for the following loci: CCND1 (11q13), MYB (6q23), RREB1 (6p25) (Empire Genomics, Buffalo NY), and D6Z1 (CEP 6) (Abbott Molecular, Des Plains IL). FISH results were as follows: 54/60 cells (90%) were identified to have relative gains of both the RREB1 and CEP 6 loci. This finding satisfies the abnormal criteria of >55% of the cells having relative gains of these loci (Morey et al. Pathology 2009, pp. 383-387). Relative gains of RREB1/CEP6 have been observed in patients with melanocytic tumors (Morey et al. Pathology 2009, pp. 383-387). In addition, there were 32/60 cells (53.3%) identified to have 3~4 copies of the CCND1 locus. Gains of the CCND1 locus in >38% of the tissue have been observed in patients with melanoma (Gerami et al. Am J Surg Path 2009 pp1146-1156). MYB appeared to be present in normal copy number relative to the centromere of chromosome 6. These are ABNORMAL results. These four loci have been identified to have variations in copy number, and can be associated with malignant melanoma (Morey et al. Pathology 2009, pp. 383-387). In this case, two of the established abnormal criteria have been satisfied for deeming the case abnormal. These findings should be interpreted in association with other clinical and laboratory findings.

Process and limitations of use:

- The malignant melanoma FISH assay is not an FDA-approved FISH test designed to aid in the detection of chromosomal abnormalities related to the development of malignant melanoma. This FISH assay is intended for use as an adjunct to traditional diagnostic procedures and should not be used as the sole basis for the diagnosis of new cancers or for the surveillance of tumor recurrence.
- A positive result by the malignant melanoma FISH assay requires analysis of a minimum of 30 interphase cells that fit the criteria of being morphologically abnormal under a counterstain and that these cells show gains of CCND1 in >38%, or gains of RREB1 in >29%, or relative gains of RREB1/CEP6 in >55%, or relative loss of MYB/CEP6 in >40% of the interphase cells examined.
- This FISH test was developed and its performance determined by the Acupath Cytogenetics Laboratory. Although it has not been cleared or approved by the U.S. Food and Drug Administration, the FDA has determined that such clearance or approval is not necessary. Pursuant to the requirements of CLIA '88, however, this laboratory has established and verified the test's accuracy and precision, therefore, this test is used for clinical purposes.
- The Spitz Nevus FISH assay is not an FDA-approved FISH test designed to aid in the detection of chromosomal abnormalities related to the development of Spitz Nevi. This FISH assay is intended for use as an adjunct to traditional diagnostic procedures and should not be used as the sole basis for diagnosis.
- A positive result for the Spitz Nevus FISH assay requires 30% of the tissue to exhibit greater than three-fold the normal diploid copy number for the HRAS locus. Increases in HRAS locus have been observed in specimens that were diagnosed as Spitz nevus.

Electronically signed by: **GEORGE HOLLENBERG, M.D.**

George Hollenberg, M.D., Medical Director