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*****Example Report*****

Patient Age/Gender: Unknown Unknown
Printed: 18-Dec-19 14:56:04

Procedure	Result	Units	Ref Interval	Accession	Collected	Received	Reported/ Verified
Cytogenomic MIP Array, FFPE	Normal f		[Normal]	19-351-900102	17-Dec-19 15:55:00	17-Dec-19 15:55:00	18-Dec-19 07:41:18
EER Cytogenomic MIP Microarray, FFPE	See Note			19-351-900102	17-Dec-19 15:55:00	17-Dec-19 15:55:00	18-Dec-19 07:41:18
Block ID	MKS19-25398 1A			19-351-900102	17-Dec-19 15:55:00	18-Dec-19 13:46:00	18-Dec-19 13:46:42

17-Dec-19 15:55:00 Cytogenomic MIP Array, FFPE:

Specimen Received
Specimen Type: FFPE Tumor
Estimated Tumor Burden: 85 percent
Reason for Referral: Glioma
Test Performed: FFPE ARRAY

NORMAL MICROARRAY RESULT

Sex chromosome complement: XX (female)

Interpretation:
The FFPE microarray analysis showed no clinically significant DNA copy number changes or copy neutral loss of heterozygosity, and is consistent with a female chromosome complement.

Formalin-Fixed Paraffin-Embedded (FFPE) Molecular Inversion Probe Array was performed using the Affymetrix OncoScan FFPE Assay. This technology contains 220,000 probes across the genome for detection of copy number changes and loss of heterozygosity (LOH). Chromosome Analysis Suite, manufactured by Affymetrix, was used for the data analysis.

Patient hybridization parameters are normalized to a reference set derived from over 300 FFPE samples from unaffected tissues. Detected gains, losses and LOH are reported when found to have clear or suspected clinical relevance. Gains, losses and LOH devoid of relevant gene content or commonly detected in the general population may not be reported. Genomic linear positions correspond to the NCBI Genome Reference Consortium Human Build 37 (GRCh37/hg19).

The functional resolution of this assay varies across different samples and across the genome, dependent upon the size of the abnormality, probe density in the region, tumor content and quality of the DNA obtained. The limit of detection will range from approximately 400 kilobases genome-wide, with higher resolution in targeted regions containing cancer genes for samples with high tumor content (generally greater than 70 percent); to several megabases for samples with lower tumor content (30-40 percent). The limit of detection for LOH is approximately 3 megabases.

This test is used by ARUP Laboratories for the purpose of identifying DNA copy number gains and losses as well as copy-neutral LOH. This analysis will not detect all forms of polyploidy, balanced rearrangements (e.g., inversions and balanced chromosomal translocations), small deletions, point mutations, and some mosaic conditions. This technology cannot determine positional information regarding the genomic location of copy number alterations and may not be able to distinguish between mechanisms of origin for certain genomic aberrations. Validation of this assay was performed according to ACMG guidelines [American College of Medical Genetics and Genomics technical standards and guidelines: microarray analysis for chromosome abnormalities in neoplastic disorders. Cooley LD, Lebo M, Li MM, Slovak ML, Wolff DJ; Working Group of the American College of Medical Genetics and Genomics (ACMG) Laboratory Quality Assurance Committee. Genet Med. 2013 Jun;15(6):484-94]. While extensive efforts are made to analyze a variety of genomic alterations that may be encountered during clinical testing, analysis of all potential genomic aberrations is not practically feasible in a validation study.

This result has been reviewed and approved by Erica F. Andersen, Ph.D., FACMG

17-Dec-19 15:55:00 Cytogenomic MIP Array, FFPE:
INTERPRETIVE INFORMATION: Cytogenomic Molecular Inversion Probe Array, FFPE Tissue - Oncology
For detection of copy number alterations and loss of heterozygosity in FFPE specimens.

***** Abnormal, **#** = Corrected, **C** = Critical, **f** = Footnote, **H** = High, **L** = Low, **t** = Interpretive Text, **@** = Reference Lab

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: aruplab.com/CS