## Reveal(R) POC Paraffin

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The whole genome chromosome SNP microarray (Reveal) analysis was normal. No significant changes in the 2.695 million region specific SNP and structural targets were detected within the thresholds and specifications indicated below. No admixture of fetal and maternal DNA was noted.

Methodology.

SNP microarray analysis was performed using the Affymetrix OncoScan FPPE platform which uses over 220,000 SNP probes with a median spacing of 2.5 kb, within genes of the highest clinical relevance. <100 ng of total genomic DNA extracted was incubated with the annealed MIP (Molecular Inversion Probe) probe. Amplified MIP product were digested with HAEIII and hybridized to the Affymetrix OncoScan Array. Data was analyzed using Chromosome Analysis Suite. The analysis is based on the GRCh37/hg19 assembly.

Positive evaluation criteria include:

- DNA copy gain/loss within or including a known clinincally significant cancer related gene (530 in database) of 50 Kb or greater.
- DNA copy number loss of >1 Mb or gain >2 Mb outside known clinical oncology significant regions with at least one OMIM annotated gene of possible clinical significance.
- Contiguous allele homozygosity >8Mb through the telomere of a single chromosome is consistent with acquired copy-neutral loss of heterozygosity (CN-LOH). These regions designate clonal evolution associated with the acquisition of homozygosity for a gene mutation within the homozygotic stretch. Candidate gene(s) will be indicated.

Truly balanced chromosome alterations will not be
detected by this analysis. The threshold for mosaicism is variable, depending on the size of segment. Empiric studies have detected whole chromosome 22 mosaicism below 10.0%. CNVs cited in the Database of Genomic Variants are not reported.

This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug administration.

Director Review

| Comment: | STUART SCHWARTZ, PhD, FACMG |

| PDF | 01 |

| 01 | YU | LabCorp RTP | 1904 TW Alexander Drive Ste C, RTP, NC 27709-0153 |
| 02 | TG | LabCorp RTP | 1912 TW Alexander Drive, RTP, NC 27709-0160 |

Dir: Arundhati Chatterjee, MD

For inquiries, the physician may contact Branch: 866-762-4344 Lab: 888-735-4087
LCLS Specimen Number: 038-225-9001-0
Patient Name: SAMPLE REPORT, 511997
Date of Birth:
Gender: N
Patient ID:
Lab Number: YU18-10014 G
Indications:

Test: Oncoscan(TM) Array POC FFPE
Genotyping Targets: 222000

MICROARRAY RESULT: NORMAL FEMALE

INTERPRETATION:

arr[hg19](1-22,X)x2

The whole genome chromosome SNP microarray (Reveal) analysis was normal. No significant changes in the 2.596 million region specific SNP and structural targets were detected within the thresholds and specifications indicated below. No admixture of fetal and maternal DNA was noted.

Methodology
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Positive evaluation criteria include:
* DNA copy gain/loss within or including a known clinically significant cancer related gene (530 in database) of 50 Kb or greater.
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Truly balanced chromosome alterations will not be detected by this analysis. The threshold for mosaicism is variable, depending on the size of segment. Empiric studies have detected whole chromosome 22 mosaicism below 10.41. CNVs cited in the Database of Genomic Variants are not reported.

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LCLS Specimen Number: 038-225-9001-0
Patient Name: SAMPLE REPORT, 511997
Date of Birth: 
Gender: N
Patient ID: 
Lab Number: YU18-10014 G

Account Number: 90001325
Ordering Physician: 
Specimen Type: PARAFFIN EMBEDDED
Client Reference: 
Date Collected: 02/06/2018
Date Received: 02/07/2018

STUART SCHWARTZ, PhD, FACMG

Arundhati Chatterjee, MD
Medical Director
Stuart Schwartz, PhD
National Director of Cytogenetics

Technical component performed by Laboratory Corporation of America Holdings,
1904 TW Alexander Drive, RTP, NC, 27709-0153  (800) 345-4363
Professional Component performed by LabCorp CLIA 3401608914, 1904 TW Alexander Dr, Research Triangle Park, NC 27709, Medical Director, Arundhati Chatterjee, MD.
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