ISO 9001 : 2008 CERTIFIED LAB

KOS Diagnostic Lab
(A Unit of KOS Healthcare)

KOS™
EXCELLENCE IN HEALTHCARE & DIAGNOSTICS

Dr. Vinay Chopra
MD (Pathology & Microbiology)
Chairman & Consultant Pathologist

Dr. Yugam Chopra
MD (Pathology)
CEO & Consultant Pathologist

LABORATORY REPORT

Name	:Mrs. NARESH RANI	Sex/Age	: Female/35 Years	Case ID	:40121600081
Ref By	:DR. VINAY CHOPRA	Dis.Loc.	:	Pt ID	:
Bill. Loc.	:KOS DIAGNOSTIC LAB			Pt. Loc.	:
Registration Date & Time	: 02-Jan-2024 09:44	Sample Type	: Product Of Conception Material	Ph #	:
Sample Date & Time	: 02-Jan-2024 09:44	Sample Coll.By	:	Ref Id	:
Report Date & Time	: 12-Jan-2024 19:58	Acc. Remarks	:	Ref Id 2	:

CYTO-ONE (ADVANCED) - MICROARRAY

Clinical History

CytoOne-Microarray prenatal analysis requested from POC sample/ Clinical indications not available

Results

Final Result	**46 chromosome complement detected. No sex chromosomal abnormality.**

Interpretation

No clinically significant aneuploidies or copy number variations (CNVs) were detected within the detection limit of CytoOne (Advanced)- Microarray.

Recommendation

- **Kindly correlate clinically.**
- **Low level of mosaicism may not be detected by microarray, FISH is recommended for the same.**

For specimens received from non NCGM locations, it is presumed that it belongsto the patient as identified on the labels of the container/Test Requisition Formand it has been verified as per GCLP (Good Clinical Lab Practices) by the referrer atthe time of collection of the specimen. NCGM's responsibility is limited to theanalytical part of the assay performed.

Priyanka

Dr. Priyanka Dube
PhD Bio Chem.

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COLLEGE of AMERICAN PATHOLOGISTS

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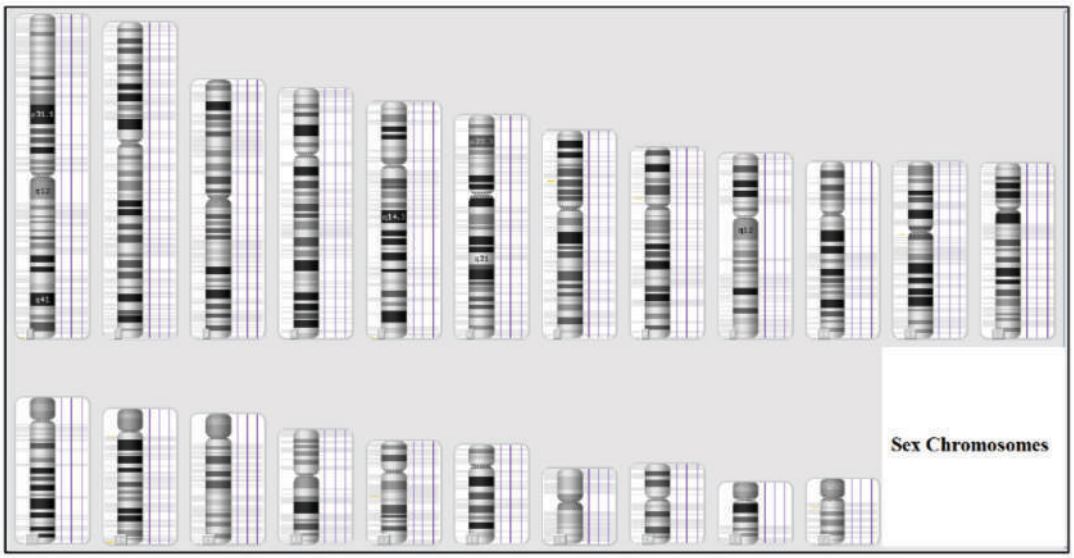
Karyoview



Gain Loss LOH

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Test Information

- Cyto-One (Advanced)Microarray is a cytogenetic method which detects copy number variants with a much higher resolution than conventional cytogenetic analysis. This technology, which does not require staining or cell culture, uses specially designed chips to study the DNA from various sample types such as Blood, Amniotic Fluid, Tissue, Product of Conception, Dried Blood Spot etc. It is used to detect gains and losses of DNA throughout the human genome or for detection of loss of heterozygosity of SNPs. Previous research indicates that more than 60% of first trimester miscarriages occurred due to chromosomal anomalies including aneuploidies, triploidy, uniparental disomy (UPD), etc. Traditional cytogenetic analysis of these samples is challenging due to high degrees of maternal cell contamination and culture failure, results in long turn-around time.
- Chromosomal microarray analysis (CMA) was performed using an Illumina Bead Array technology. This microarray consists of 1000K oligonucleotide probes across the genome. Genomic DNA (200 ng) was amplified with MA1 and MA2 then fragmented by FMS. The infinium chemistry Optimized Whole Genome Amplification reaction to reduces GC bias by up to 1000 fold amplification. The fragmented products of size 300 to 600bp were hybridized on Bead chip, and then scanned. Data was analyzed using Genome studio 2.0. The analysis is based on the Human reference genome (GRCh37/hg 19).
- The test has been performed by the laboratory with the assumption that counseling regarding its utility as well as limitations has been conveyed by the referring clinician to the patient/ guardian/family and consent for the same has been obtained after relevant pre-test counseling.

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Positive evaluation criteria

- Deletions smaller than 200KB and duplications smaller than 400 KB may not be reviewed. Detected copy number variations (CNVs) are reported when found to have clear or suspected clinical relevance; CNVs devoid of relevant gene content or reported as common findings in the general population may not be reported. Genomic linear positions are given relative to NCBI build 37 (hg19).

Regions of Homozygosity (ROH) or Loss of Heterozygosity(LOH) General Guidelines

1. Regions of homozygosity are reported when a single LCSH is greater than 8-15 Mb (dependent upon chromosomal location and likelihood of imprinting disorder), or when the total autosomal LCSH proportion is greater than 3% (only autosomal LCSH greater than 5 Mb are considered for this estimate). Please contact STMPL for the details regarding the LOH regions.
2. When >10% of the autosomal genome shows ROH, the proband may be the product of 1st or 2nd degree relatives (Rehder et al., 2013).
3. ROH may be of clinical significance if both parents are heterozygous carriers of a recessive pathogenic variant in the same gene located within one of the homozygous regions. These types of pathogenic variants cannot be determined by this assay and require clinical assessment.

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Limitations

- This test will detect gain or loss of genomic material at a resolution mentioned below.
  - I. CYTO-ONE BASIC- MICROARRAY- 2 MB for Duplication and 1 MB for Deletion.
  - I. CYTO-ONE ADVANCED- MICROARRAY- 200 KB for Deletion and 400 KB for Duplication.
- It will NOT detect predefined point mutations. It will NOT detect balanced translocations, low level mosaicism, inversions, small indels, epigenetic alterations and low frequency mutations that may be responsible for the clinical phenotype. In cases where the microarray report does not explain the clinical phenotype alternate tests may be required based on the clinician's discretion.
- This test will not detect the regions those are not represented on the array. Interpretation of the genomic copy number changes which have unknown clinical significance can be complicated to conclude any result.
- The test results should be interpreted only in conjunction with the patient's clinical history.
- **Maternal cell contamination is recommended in amniotic fluid, Chorionic Villous sample and products of conception obtained from placental tissue. Maternal cell contamination if present would interfere with result interpretation.**
- The accuracy and quality of the test may be affected by improper sample collection, storage and transportation.

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- In cases where any of the QC parameters fail during the process, the referring institute will be informed. Every attempt will be made to ensure the QC checks are within acceptable limits, but in cases where on account of technical difficulties or other causes this is not possible, testing for those samples will be ceased.
- Sex Chromosome information will not be provided in prenatal samples.
- **In accordance to the Pre-Conception and Pre-Natal Diagnostic Testing (PC-PNDT) Act, 2003, lab does not disclose the gender of the fetus.**
- All laboratory test procedures have an error rate of 2% and hence caution is recommended while interpreting test results.
- For test performed on specimens received or collected from non-NCGM locations, it is presumed that the specimen belongs to the patient named or identified as labeled on the container/test request and such verification has been carried out at the point of generation of the said specimen by the sender.

References

1. Silva M et al., European guidelines for constitutional cytogenomic analysis. European Journal of Human Genetics (2019) 27:1-6
2. Levy B., et al. Genomic imbalance in products of conception: single-nucleotide polymorphism chromosomal microarray analysis. Obstetrics and Gynecology 124(2 Pt 1):202–209 (2014).
3. Wang B. T., et al. Abnormalities in spontaneous abortions detected by G-banding and chromosomal microarray analysis (CMA) at a national reference laboratory. Molecular Cytogenetics 7:33 (2014). eCollection 2014. doi:10.1186/1755-8166-7-33
4. S.T. South, C. Lee, A.N. Lamb, A.W. Higgins, H.M. Kearney, Working Group for the American College of Medical Genetics and Genomics Laboratory Quality Assurance Committee. ACMG Standards and Guidelines for constitutional cytogenomic microarray analysis, including postnatal and prenatal applications: revision 2013. Genet Med. 2013;15:901-909 Crossref
5. Fruhman G, Van den Veyver IB. Applications of array comparative genomic hybridization in obstetrics. ObstetGynecolClin North Am 2010;37:71-85.

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6. Conlin LK, Thiel BD, Bonnemann CG, et al. Mechanisms of mosaicism, chimerism and uniparentaldisomy identified by single nucleotide polymorphism array analysis. Hum Mol Genet 2010;19:1263-75.

7. PCPNDT Act: Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (PNDT), was amended in 2003 to The Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection).

---------- End Of Report ----------

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