




Certificate no.MC-3871

Name : F/O. POONAM	Lab ID : KT20700213067	CRM: 220898010012 
Age : NA	Sample Collection Date : 26-07-2022 16:00	
DOB : NA	Sample Receipt Date : 28-07-2022 10:00	
Gender : UNKNOWN	Reporting Date : 04-08-2022 18:26	
Referring Physician : Dr. MEENAL GARG	Location : Delhi	
Hospital Name : Biogene Labs India Private Limited		

Initial Report	<input checked="" type="checkbox"/>	Duplicate Report	<input type="checkbox"/>	Revised Report	<input type="checkbox"/>	Version No	<input type="text" value="1"/>
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CHROMOSOMAL MICROARRAY CYTOSCAN OPTIMA

Sample Type	: Product Of Conception
Quality of Sample	: Adequate
Gestational Age	: Not provided
Clinical Indication	: The submitted sample has been evaluated for the pathogenic CNV's.
Test Requested	: Aneuploidy

Interpretation	: No clinically significant deletions, duplications or other chromosomal abnormalities were found in the sample submitted for analysis.
Recommendation	: Clinical correlation is suggested and further genetic counselling is recommended.

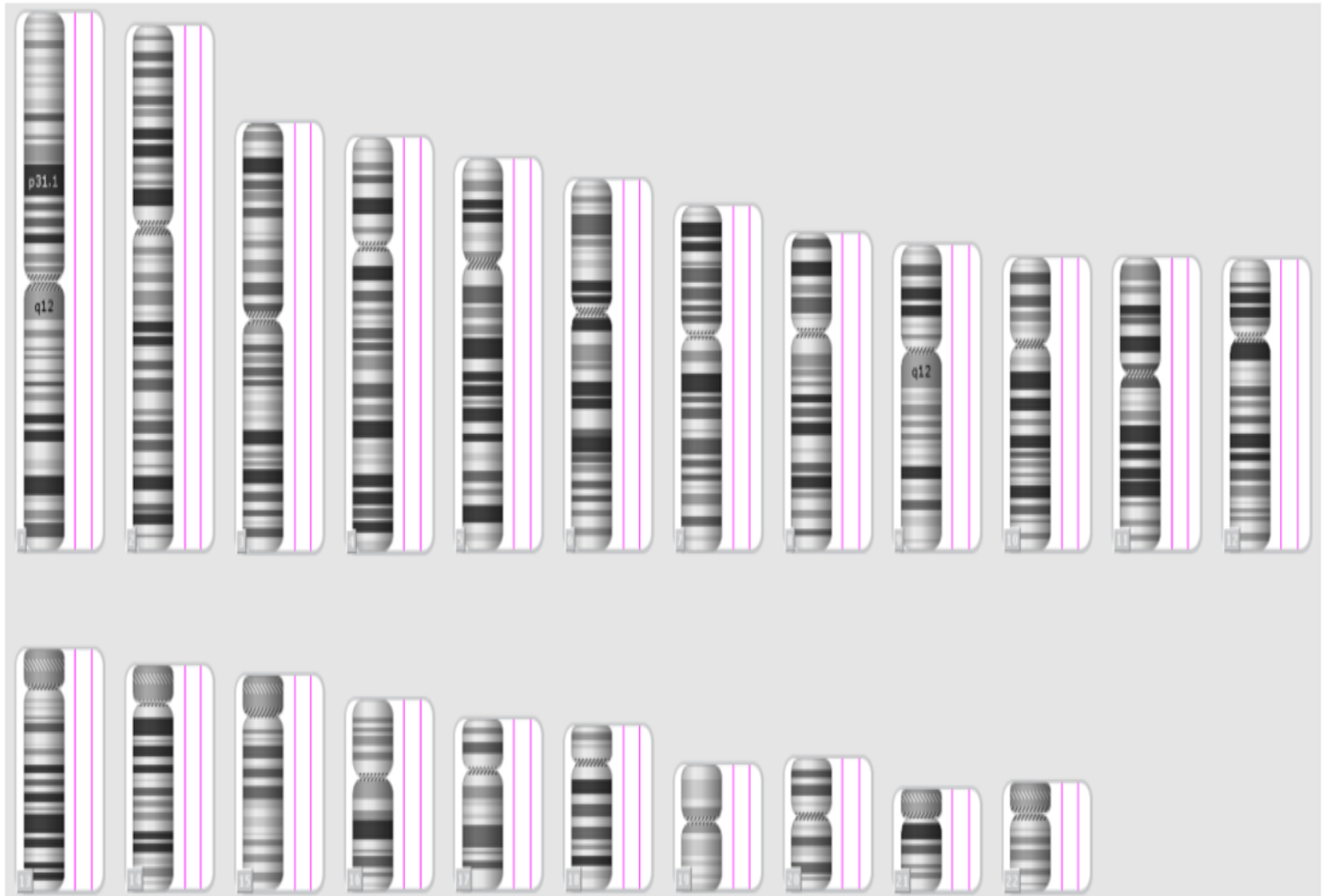


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KARYOVIEW



This is an electronically authenticated report.



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List of Syndromes	Result
Autosomal Aneuploidies	
Trisomy 21 (Down syndrome)	Negative
Trisomy 18 (Edwards syndrome)	Negative
Trisomy 13 (Patau syndrome)	Negative
Other autosomal aneuploidies	Negative
Sex Chromosome Aneuploidies	
Monosomy X (Turner syndrome)	Negative
XYY (Jacobs syndrome)	Negative
XXY (Klinefelter syndrome)	Negative
XXX (Triple X syndrome)	Negative
Euploidy	
Triploidy	Negative
Clinically significant Genome-wide copy number variations	
Duplications (Gains)	Negative
Deletions (Losses)	Negative

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ABOUT THE TEST


Chromosomal microarray analysis (CMA) was performed using Affymetrix CytoScan Optima microarray. This microarray offers whole-genome coverage for accurate detection of chromosomal abnormalities with increased probe coverage targeting 396 relevant regions for prenatal and miscarriage applications. This microarray and associated software (Chromosome Analysis Suite) is designed by Affymetrix and used for the purpose of identifying DNA copy number gains and losses associated with chromosomal imbalances. The filter settings for the CMA test analysis are 500kbp for clinically relevant losses and 1MB for gains. For LOH regions using the following criteria: Imprinted chromosomes - Interstitial >8MB, Terminal >5MB and Non-imprinted chromosomes >10MB. The test cannot detect balanced chromosomal rearrangements, single gene disorders due to point mutations or low-grade mosaicism (<20%) for chromosomal abnormalities. The test will not elucidate the chromosomal mechanism of a genetic imbalance. The laboratory follows the ACMG guidelines (South et. al., Constitutional Microarray Guidelines, Genetics in Medicine, Vol 15, Number 11, Nov 2013) for reporting of CMA findings. DNA for the experiment was isolated from the provided sample using a commercial kit that works on silica-membrane-based DNA purification. Genome version used is Hg 19 for the ChAS and the DGV database is used for analysis. List of the regions of LOH found in the sample are available on request.

REFERENCES:

- 1.Lu, Xinyan, Chad A. Shaw, Ankita Patel, Jiangzhen Li, M. Lance Cooper, William R. Wells, Cathy M. Sullivan et al. "Clinical implementation of chromosomal microarray analysis: summary of 2513 postnatal cases." PLoS One 2, no. 3 (2007): e327.
- 2.Dugoff, Lorraine, Mary E. Norton, Jeffrey A. Kuller, and Society for Maternal-Fetal Medicine (SMFM). "The use of chromosomal microarray for prenatal diagnosis." American journal of obstetrics and gynecology 215, no. 4 (2016): B2-B9.
- 3.South, Sarah T., Charles Lee, Allen N. Lamb, Anne W. Higgins, and Hutton M. Kearney. "ACMG Standards and Guidelines for constitutional cytogenomic microarray analysis, including postnatal and prenatal applications: revision 2013." Genetics in Medicine 15, no. 11 (2013): 901.
- 4.Armour, Christine M., Shelley Danielle Dougan, Jo-Ann Brock, Radha Chari, Bernie N. Chodirker, Isabelle DeBie, Jane A. Evans et al. "Practice guideline: joint CCMG-SOGC recommendations for the use of chromosomal microarray analysis for prenatal diagnosis and assessment of fetal loss in Canada." Journal of medical genetics 55, no. 4 (2018): 215-221.



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DISCLAIMER:

As per joint CCMG-SOGC guidelines (2018) for the use of CMA analysis for prenatal diagnosis and assessment of fetal loss, variants of uncertain clinical significance (VOUS) smaller than 500 Kb deletion or 1 Mb duplication will not be reported. This report is for the tissue sample provided as per request from the doctor. Clinical interpretation of given test result should be evaluated within the context of the patient's medical history and other diagnostic laboratory test results. All investigations have their limitations which are imposed by the limits of sensitivity & specificity of individual assay procedures as well as the quality of the specimen received by the laboratory. This is not a diagnostic test and so not to be considered as a purpose of diagnosis of any diseases. This test is meant for only understanding chromosomal aberrations and their clinical relevance, this test detects the chromosomal abnormalities only under its limit of resolution. This report must be given only in the presence of medical professional to explain the findings and implications. Company will not be liable for any direct, indirect, consequential, special, exemplary, or any other damages.

As per the PRE-NATAL DIAGNOSTIC TECHNIQUES (REGULATIONS & PREVENTION OF MISUSE) AMENDMENT ACT 2002, sex determination shall not be done for all prenatal samples.

Shivendra kumar M.Sc.

Lab Head Molecular Genetics

Dr.Nimisha Gupta MD(Pathology).