IPSC Name	**: I G I B i 0 1 1 - A**	Lab ID	:	
		Sample Collection Date	:	
Age	: NA	Sample Receipt Date	:	
DOB	: NA	Reporting Date	:	
Gender	: UNKNOWN	Location	:	
Referring Physician	:			
Hospital Name	:			

Initial Report	☐	Duplicate Report	☐	Revised Report	☐	Version No	1

CHROMOSOMAL MICROARRAY CYTOSCAN 750K

Sample Type : Extracted DNA

Quality of Sample : Adequate

Clinical Indication : To evaluate chromosomal aneuploidies in the sample submitted for CMA analysis.

Test Requested : Aneuploidy/Microdeletion/Micro Duplication

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.

KARYOVIEW

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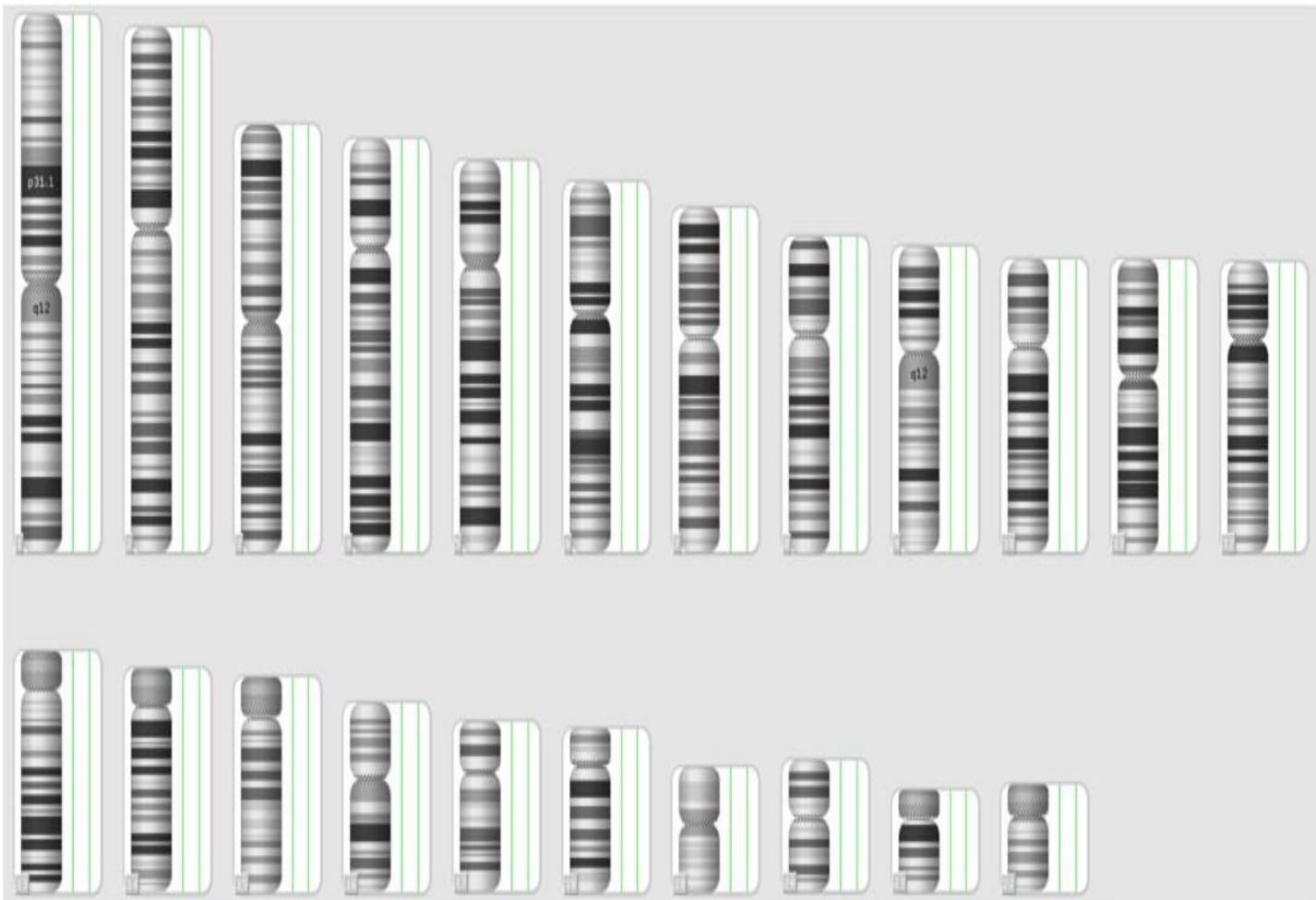

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List of Syndromes	Result
Autosomal Aneuploidies	
Trisomy 21 (Down syndrome)	Negative
Trisomy 18 (Edwards syndrome)	Negative
Trisomy 13 (Patau syndrome)	Negative
Other autosomal aneuploidies	Negative
Sex Chromosome Aneuploidies	
Monosomy X (Turner syndrome)	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 microarray technology. This microarray consists of 750,000 markers for copy number analysis which consist of 550,000 unique non-polymorphic probes and approximately 200,000 SNPs (single nucleotide polymorphism) that fully genotype with greater than 99% accuracy. This microarray and associated software (Chromosome Analysis Suite) is designed by Affymetrix. The cut-off filter setting for the CMA test analysis is 100kbp for clinically relevant gain/loss and greater than 5MB size for Loss of Heterozygosity (LOH). 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.

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:

1. This technique specifically detects copy number variations, which include both gains and losses, as well as regions of heterozygosity. Other forms of polyploidy, as well as balanced chromosome rearrangements such as inversions and balanced chromosomal imbalances, point mutations, small deletions, and certain mosaic conditions, will not be detectable. It is important to consider more than just chromosomal microarray results when making clinical decisions, and it is necessary to correlate these results with other clinical findings such as patient history and ultrasound findings.
2. 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 interpreted and consultation with the medical professional to explain the findings and implications. Lifecell will not be liable for any direct, indirect, consequential, special, exemplary, or any other damages.
3. 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.
4. The ability to detect mosaicism depends on the size and type of genomic imbalance. Typically, if there is a genotype mixture caused by mosaicism (different cell lines from the same person) or chimerism (cell lines from different people), it will be identified when it constitutes more than 20-30 percent of the sample.
5. The results specifically pertains to the examined sample and may not accurately represent the fetal chromosome constitution in instances of confined placental mosaicism or when the sample is contaminated with maternal cells.
6. Despite taking all necessary precautions during DNA-based tests, the technical error rate for all types of DNA analysis is approximately 2% . Therefore, it is crucial to interpret all results within this context before taking any action based on these results.
7. The report is generated within a specific timeframe known as the turnaround time (TAT) once received the sample received at the lab. However, the actual TAT may differ based on the complexity of the requested test(s) and information provided along with the sample. LifeCell is not responsible for delays due to incomplete information and or any technical requirements during sample handing over/testing/reporting.
8. In certain rare cases, genetic tests may not provide accurate results, for example, when the quality of the sample given to Lifecell is not optimal. If a test performed by Lifecell fails due to unforeseen or unknown reasons beyond our control, Lifecell cannot be held responsible for any incomplete, potentially misleading, or incorrect results that were not foreseeable beforehand.
9. Lifecell Pvt. Ltd has validated the test and determined its performance characteristics in accordance with the CAP/ACMG and NABL guidelines. 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.
10. The present report comprises genetic analysis of the sample provided. It is important to note that this report cannot be accurately interpreted without information regarding clinical features and other laboratory reports, investigations. The information contained herein should not be considered a substitute for professional medical advice or diagnosis. It is highly recommended to consult with a qualified healthcare professional or medical specialist for a comprehensive evaluation and interpretation of your specific medical condition.

This document is for clinical interpretation and not for medico-legal purpose.

Senior Manager

Lab Director

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