LABORATORY REPORT

Redcliffe labs

Patient Name	:	Bill Date	:
DOB/Age/Gender	:	Sample Collected	:
Patient ID / UHID	:	Sample Received	:
Referred By	:	Report Date	:
Sample Type	:	Barcode No	:
Client	:	Report Status	:

CYTOGENETICS REPORT

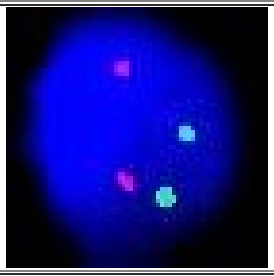
Karyotyping: Products Of Conception (POC) Reflex Testing To FISH

METHODOLOGY/KIT Interphase Fluorescence in-situ Hybridization (FISH) method; ANEUVYSION Multicolor DNA Probe Kit (FDA Approved) for Aneuploidy Detection of Chromosome 13, 18, 21 & X and Y.

SAMPLE DESCRIPTION Sample Volume and sample quality was Optimum for FISH Test

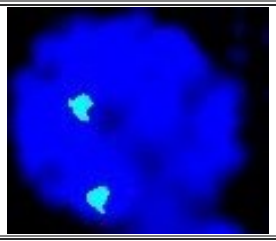
CLINICAL INDICATION Recurrent Pregnancy Loss

First hybridization-LSI probe- AneuVysion Multicolor DNA Probe FISH

	GREEN	ORANGE	NO OF CELLS ANALYZED	INTERPRETATION
				
Signals per cell	Two	Two	50	Normal

2 Green and 2 orange signals in each cell show normal (Diploid) status for the chromosome 13 and 21 respectively

Second Hybridization-CEP probe-AneuVysion Multicolor DNA Probe FISH

	AQUA	GREEN/ ORANGE SEX CHROMOSOME	NO OF CELLS ANALYZED	INTERPRETATION
				
Signals per cell	Two	Two	50	Normal

2 Aqua signals in each cell show normal (Diploid) status for the chromosome 18 respectively (Sex chromosome signals cannot be shown as per preconceptional and prenatal diagnostic, PNDT Act)

SUMMARY OF RESULTS: **NO ANEUPLOIDY DETECTED for chromosome 13, 18, 21 and Sex chromosomes**
(FISH is not intended for use as a standalone test for making clinical decisions)

NOMENCALTURE: **nuc ish 13q14(RB1X2),18p11.1-q11.1(D18X1X2),21q22.13q22.2(D21S259X2,D21S341X2,D21S342X2) [50]**
(As per International System of Human Cytogenomic Nomenclature, ISCN, 2020)
[Sex of Fetus not Revealed as per PNDT Act]

CLINICAL INTERPRETATION: The case is considered as informative NORMAL (NEGATIVE) with normal/disomic signal pattern for chromosome 13, 18, 21 and sex chromosomes observed in more than 95% of the total cells screened.

Dr. Ashish Fauzdar
PhD (Genetics), AIIMS
Head of Clinical Genomics & Cytogenetics

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Sample Type	:	Barcode No	:
Client	:	Report Status	:

Interpretation Guidelines:
Informative Normal: A case is classified as informative normal for specific chromosomes (autosomes/sex chromosome) if more than 90% of the cells showed normal disomic signal pattern.

Informative Abnormal: A case is classified as informative abnormal if more than 60% of the nuclei show aberrant/abnormal signal pattern for specific chromosomes (autosomes/sex chromosome)

Uninformative: A case is considered as uninformative whenever 10-60% of nuclei shows aberrant signals. In these case additional 200 nuclei are scored and conclusive interpretable results are obtained after routine cytogenetics analysis on more than 20 metaphase

Intended Use:

The AneuVysion (Vysis CEP 18, X, Y alpha satellite LSI 13 and 21) Multicolor probe panel is intended to use CEP18/X/Y probe to detect alpha satellite sequences in the centromere regions of chromosome 18, C and Y and LSI 13/21 probe to detect the 13q14 region and 21q22.13 and 21q22.2 region. The AneuVysion Kit is indicated for identifying and enumerating chromosome 13, 18, 21 X and Y via FISH in metaphase cells and interphase nuclei obtained from amniotic fluid in subjects with presumed high-risk pregnancies. It is not intended to be used as a standalone assay for making clinical decision. FISH Assay is a prenatal genetic test to be used in conjunction with fetal karyotype analysis to provide detection on trisomy 13, 18, 21 (Down's Syndrome) and sex chromosome abnormalities (such as Klinefelter and Turner syndromes).

Limitation of Test:
1. FISH is used to quickly rule out the common numerical chromosomal abnormalities i.e., Trisomy 13, 18, 21 and sex chromosomes disorder in rapid turn-around time. The FISH test does not provide information about any chromosome other than loci mentioned in this report and kit insert
2. No other numerical and structural chromosome abnormalities like translocations, deletions and abnormalities of other chromosomes cannot be ruled out by FISH. Reliability of the FISH test report is 99%.
3. A negative result does not exclude the presence of chromosome alterations other than the one screened for and imposes
4. The FISH results should be further verified and confirmatory gold standard karyotype test diagnostic tests through conventional culture techniques or through a DNA based chromosome microarray test.
5. The report relates only to the specimen submitted to the lab which was verified and confirmed at the time of specimen collection.

Reference:

1. An International System for Human Cytogenetic Nomenclature (2020). Karger Publishers. **2.** American College of Medical Genetics. Technical and clinical assessment of fluorescence in-situ hybridization: an ACMG/ASHG position statement. I. Technical consideration. Genet Med. 2000;2(6):356-361 **3.** ANEUVYSION Multicolor DNA Probe Kit, Abott Molecular (FDA Approved).

Comments:
Sex of the fetus shall not be revealed as per Pre-conception and Pre-Natal Diagnostic Techniques (PC & PNDT Act & Rules). Redcliffe Life Sciences Pvt. Ltd. is registered in District Gautam Budh Nagar, Uttar Pradesh, India under the Pre-Conception, and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act (PCPNDT Act), 1994 Govt. of India; vide Reg No. GBN/336

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Terms and Conditions of Reporting

1. The presented findings in the Reports are intended solely for informational and interpretational purposes by the referring physician or other qualified medical professionals possessing a comprehensive understanding of reporting units, reference ranges, and technological limitations. The laboratory shall not be held liable for any interpretation or misinterpretation of the results, nor for any consequential or incidental damages arising from such interpretation.

2. It is to be presumed that the tests performed pertain to the specimen/sample attributed to the Customer's name or identification. It is presumed that the verification particulars have been cleared out by the customer or his/her representation at the point of generation of said specimen / sample. It is hereby clarified that the reports furnished are restricted solely to the given specimen only.

3. It is to be noted that variations in results may occur between different laboratories and over time, even for the same parameter for the same Customer. The assays are performed and conducted in accordance with standard procedures, and the reported outcomes are contingent on the specific individual assay methods and equipment(s) used, as well as the quality of the received specimen.

4. This report shall not be deemed valid or admissible for any medico-legal purposes.

5. The Customers assume full responsibility for apprising the Company of any factors that may impact the test finding. These factors, among others, includes dietary intake, alcohol, or medication / drug(s) consumption, or fasting. This list of factors is only representative and not exhaustive.