

|                     |                    |
|---------------------|--------------------|
| 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 :    |

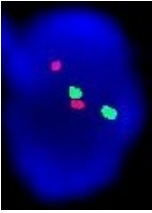
**CYTOGENETICS REPORT**  
**Aneuploidy Five Probes (13, 18, 21, X & Y) By FISH**

**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

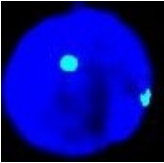
**CLINICAL INDICATION** Triple screening test positive for Trisomy 21

**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, PNDDT 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 PNDDT 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.



  
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 Head of Clinical Genomics & Cytogenetics

|                   |   |                  |   |
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| Referred By       | : | Report Date      | : |
| 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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