LABORATORY REPORT

Redcliffe labs

Gestation Age: 13 Weeks 1 Day as per LMP

Patier	Gender:	Center Code
Patien	Clinician	Sample Colle
Patien	Pregnanc	Sample Rece
Age: 3	Hospital I	Report Relea

Test Performed:-NIPT- All Chromosome Test

Clinical Indication:

Advised to be screened for NIPT.

TEST RESULTS

***Fetal fraction: 10.41%**

ANEUPLOIDIES	RESULTS	Z-Score	Risk
Down syndrome (Trisomy 21)	Low Risk:Result consistent with two copies of chromosome 21	-2.07	
Edwards syndrome (Trisomy 18)	Low Risk:Result consistent with two copies of chromosome 18	-0.74	
Patau syndrome (Trisomy 13)	Low Risk:Result consistent with two copies of chromosome 13	-0.05	
Sex Chromosomes	Low Risk		

About this test:

This screening test evaluates whether your pregnancy is at increased risk for certain types of chromosomal disorders. Because this is a screen, false positives and false negatives can occur. The estimated fetal fraction of DNA present in this sample is one component of Redcliffe Lab's non-invasive screening algorithm.

*If the fetal fraction is lower than 3.5%, the accuracy of the test may be reduced. To ensure the accuracy of the results, we would recommend a re-sampling of the maternal blood one or two weeks later.

CLINICAL COMMENTS

This result shows a low risk group for all chromosomes based on the Z score.

EXPECTED TEST RESULTS

NIPT analysis can yield any of the following results:

- Low Risk : The probability that the fetus is affected with the specific chromosomal aneuploidy is low.
- High Risk : The probability that the fetus is affected with the specific chromosomal aneuploidy is high confirmatory testing via amniocentesis/CVS is recommended.
- Borderline: Further confirmatory test recommended (Amniocentesis or other confirmatory tests)
- Inconclusive : Due to unavoidable reasons a result could not be generated on the given maternal sample therefore repeat sampling is advised. Invasive testing is recommended if a NO RESULT is generated again.

Performed by
Himanshu Saini
Senior Scientific Officer
Clinical-Genomics

Reviewed by
Aayushi Gupta
DBT-HSSC Certified
Genetic Counsellor

Approved by
Dr. Himani Pandey
Postdoc-SGPGIMS Lucknow
Lab Head-Clinical Genomics

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Patient Name:

PRENATAL CHROMOSOMAL ANEUPLOIDY RESULTS FOR OTHER CHROMOSOMES

CHROMOSOME	RISK	Test Results	Z-SCORE	Sensitivity(%)
CHROMOSOME 1	●	Low Risk	-0.44	99.9
CHROMOSOME 2	●	Low Risk	1.05	99.9
CHROMOSOME 3	●	Low Risk	-0.19	99.9
CHROMOSOME 4	●	Low Risk	0.21	99.9
CHROMOSOME 5	●	Low Risk	0.68	99.9
CHROMOSOME 6	●	Low Risk	-0.08	99.9
CHROMOSOME 7	●	Low Risk	1.74	99.9
CHROMOSOME 8	●	Low Risk	-0.75	99.9
CHROMOSOME 9	●	Low Risk	0.42	99.9
CHROMOSOME 10	●	Low Risk	-2.13	99.9
CHROMOSOME 11	●	Low Risk	0.12	99.9
CHROMOSOME 12	●	Low Risk	1.21	99.9
CHROMOSOME 14	●	Low Risk	-0.41	99.9
CHROMOSOME 15	●	Low Risk	0.12	99.9
CHROMOSOME 16	●	Low Risk	-0.03	99.9
CHROMOSOME 17	●	Low Risk	-1.19	99.9
CHROMOSOME 19	●	Low Risk	0.66	99.9
CHROMOSOME 20	●	Low Risk	-0.23	99.9
CHROMOSOME 22	●	Low Risk	0.99	99.9

*Risk Description: ●Low Risk Group ●Borderline Group ●High Risk Group

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931-126-1989 genee@redcliffelabs.com www.redcliffelabs.com

Redcliffe Life Sciences Pvt. Ltd. (Unit of Redcliffe Life Sciences inc,USA) H-55,Sector-63,Noida, Uttar Pradesh, 201301

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Patient Name:

METHODOLOGY

NIPT is a simple, non-invasive and low-risk method which offers screening of maternal blood sample for genome-wide aneuploidy detection over the whole fetal DNA (23 pairs of chromosomes) and offers an interpretation of the results for Trisomy 13, Trisomy 18, Trisomy 21, sex chromosomes using following methodology.

1.Extraction of cell free fetal DNA from the component plasma of maternal blood sample.

2. High throughput sequencing of the extracted cell free fetal DNA.

3. Calculation of molecular mass of fetal DNA in all chromosomes.

TEST LIMITATIONS

1. The results of this test are for reference only, not for the final diagnosis. Cell-free fetal DNA does not replace the accuracy and precision of prenatal diagnosis with Amniocentesis or Chorionic Villus Sampling (CVS).

2. If the test result is at high risk, genetic counseling and invasive prenatal diagnosis are needed.

3. If the test result is at low risk, the fetus has a low risk of developing the target disease of this screening, hence unaffected pregnancy.However, the possibility of other abnormalities cannot be excluded, and systematic ultrasound examinations and other prenatal examinations should be conducted.

4. The accuracy and quality of the test may be affected by low fetal fraction <3.5%, maternal or fetal mosaicism, or other causes (micro-deletions, chromosome re-arrangements, translocations, inversions, unbalanced translocations, uniparental disomy). The possibility of false positive or false negative cannot be ruled out.

5. The accuracy and quality of the test may be also be affected by high data noise due to improper blood sample collection, handling, storage, or transportation.

6. This test is not applicable for cases with gestational age <10+0 weeks, received allogeneic blood transfusion, A family history of genetic diseases or a high risk of genetic diseases in the fetus, transplantation and allogeneic cell therapy within 1 year or a pregnancy with malignant tumor.

7. The patient must provide complete, accurate and detailed personal information. Redcliffe labs shall not be responsible for the interruption of testing services and inaccurate results caused by inaccurate information or other misleading factors provided by the patient.

8. The test results in this report are only responsible for the samples submitted for inspection.

REFERENCES

Jiang, Fetal., Noninvasive Fetal Trisomy (NIFTY) test: an advanced noninvasive prenatal diagnosis methodology for fetal autosomal and sex chromosomal aneuploidies. BMC Med Genomics, 2012. 5: p. 57.

Chiu, R.W., et al., Noninvasive prenatal diagnosis of fetal chromosomal aneuploidy by massively parallel genomic sequencing of DNA in maternal plasma. BMJ. 2011;342:c7401.

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Chen, S., et al., A method for noninvasive detection of fetal large deletions/duplications by low coverage massively parallel sequencing. Prenatal Diagnosis, 2013. 33(6): p. 584-590.

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***AS PER THE ACCORDNACE WITH "PC & PNDT ACT-1994 & AMENDENTS",SEX OF THE FETUS HAS NEITHER BEEN DETECTED NOR DISCLOSED**

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Conditions for Reporting

1. It is presumed that specimen belongs to patient named or identified, such verification being carried out at the point of generation of said specimen.

2. A test might not be performed due to following reasons:
    a. Specimen Quantity not sufficient (Inadequate collection/spillage during transit).
    b. Specimen Quality not acceptable (Hemolysis/clotted/lipemic).
    c. Incorrect sample type.

3. In any of the above case a fresh specimen will be required for testing and reporting.

4. Partial representation of report is not allowed.

5. The reported tests are for the notification of the referring doctor, only to assist him/her in the diagnosis and management of the patient.

6. This report is not valid for Medico Legal Purpose.

7. Applicable Jurisdiction will be of "Delhi" for any dispute/claim concerning the test(s) & results of the test(s).

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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.