NAME:	**Mrs. NEHA BHAU**	Accession No.:	112018
Age/Gender:	28 Y/Female	Specimen ID:	NT2400101
Lab NO:	012410240026	Specimen:	Maternal Blood
Referred BY:	Self	Collected:	24/Oct/2024 03:35PM
Remark:		Registered:	24/Oct/2024 03:33PM
		Reported:	08/Nov/2024 06:14PM

NIPT REPORT

NIPT-Assurety

RESULTS

LOW RISK

FETAL FRACTION	14.6%

Chromosome		Results		Patient-specific PPVor Residual Risk*
Trisomy 13		Low Risk.	O	< 0.01% (1 in 10,000)
Trisomy 18		Low Risk.	O	< 0.01% (1 in 10,000)
Trisomy 21		Low Risk.	O	< 0.01% (1 in 10,000)
Sex Chromosomal Aneuploidies	-	Low Risk.	O	< 0.01% (1 in 10,000)

CLINICAL COMMENT

NIPT is a screening test and hence, there are possibilities for false positives and false negatives. Certain fetal, placental and maternal conditions can influence the result. Based solely on this test result, no irreversible clinical decisions should be made, and clinical correlations is highly recommended. For all high risk results, invasive diagnostic test along with appropriate genetic counselling is suggested.The confidence of the test is based on fetal fraction together with other quality metrics.The performance of the test decreases with lower fetal fractions.

NOTE:- THIS SAMPLE WAS OUTSOURCED

Tara Nath
Quality Manager

Mr. Brijesh
Authorised Signatory
PhD(P)

DR. S. KUMAR
MBBS, MD
Consultant Pathologist

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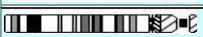
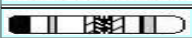
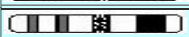
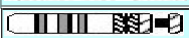
Chromosome		Results		Patient-specific PPV or Residual Risk*
Chromosome 1		Low Risk.	O	< 0.01% (1 in 10,000)
Chromosome 2		Low Risk.	O	< 0.01% (1 in 10,000)
Chromosome 3		Low Risk	O	< 0.01% (1 in 10,000)
Chromosome 4		Low Risk	O	< 0.01% (1 in 10,000)
Chromosome 5		Low Risk	O	< 0.01% (1 in 10,000)
Chromosome 6		Low Risk	O	< 0.01% (1 in 10,000)
Chromosome 7		Low Risk	O	< 0.01% (1 in 10,000)
Chromosome 8		Low Risk	O	< 0.01% (1 in 10,000)
Chromosome 9		Low Risk	O	< 0.01% (1 in 10,000)
Chromosome 10		Low Risk	O	< 0.01% (1 in 10,000)
Chromosome 11		Low Risk	O	< 0.01% (1 in 10,000)
Chromosome 12		Low Risk	O	< 0.01% (1 in 10,000)
Chromosome 14		Low Risk	O	< 0.01% (1 in 10,000)
Chromosome 15		Low Risk	O	< 0.01% (1 in 10,000)
Chromosome 16		Low Risk	O	< 0.01% (1 in 10,000)
Chromosome 17		Low Risk	O	< 0.01% (1 in 10,000)
Chromosome 19		Low Risk	O	< 0.01% (1 in 10,000)
Chromosome 20		Low Risk	O	< 0.01% (1 in 10,000)
Chromosome 22		Low Risk	O	< 0.01% (1 in 10,000)

TEST DESCRIPTION

1. The NIPT test is a screening test and is not diagnostic. It works by isolating the cfDNA (including both maternal and fetal DNA) from a maternal blood sample and performing low coverage whole genome sequencing using countseq enrichment next generation sequencing technology. The unique reads of each chromosome are calculated and compared to an optimal reference control sample. Data is analyzed using Cordon proprietary bioinformatics algorithms and an assessment is produced for the conditions tested only. Tests should always be ordered by a qualified healthcare professional and results reviewed with the patient. The test must not be used as the sole basis for diagnosis or other pregnancy management decision.
2. *The positive predictive value (PPV) represents the risk for the pregnancy to be affected with the indicated chromosome anomaly in view of a positive result. The residual risks provided represent the remaining chance that the pregnancy is affected with the indicated chromosome anomaly in view of a negative result.
3. This is a screening test; therefore, false positive and false negative results can occur. No irreversible decision should be made based on these findings only. Clinical correlation with ultrasound findings and history is indicated. If definitive diagnosis is desired, chorionic villus sampling or amniocentesis is necessary.
4. The test results are released under the presumption that the sample belongs to the patient named or identified in the bill/test request form.

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NIPT REPORT

5. Limitations: Possible sources of error include sample mix-up, trace contamination, bone marrow transplantation, chimerism or mosaicism, maternal neoplasm and technical errors.

DISCLAIMER

In small percentage of cases, sample recollection maybe requested based on certain circumstances and technical limitations, this is done in order to provide a result. However, in very few cases the test may not give correct result due to quality of the sample, or the test fails for unknown reasons which cannot be foreseen. In such situations, the company shall not be responsible for partial or even wrong result. The health care providers should interpret and explain the test results to the patients. Further recommendations should also be suggested.The test was developed,its performance characteristics were determined and validation was performed by Cordon Genomics.

REFERENCES:

1. Bianchi DW, Platt LD, Goldberg JD, Abuhamad AZ, Sehnert AJ, Rava RP. Genome-wide fetal aneuploidy detection by maternal plasma DNA sequencing. Obstet Gynecol 2012, 119(5):890-901.
2. Gil MM, Accurti V, Santacruz B, Plana MN, Nicolaides KH. Analysis of cell-free DNA in maternal blood in screening for aneuploidies: updated meta-analysis. Ultrasound Obstet Gynecol 2017;50:302-14.
3. Gravholt CH, Juul S, Naeraa RW, Hansen J. Prenatal and postnatal prevalence of Turner's syndrome : a registry study. BMJ. 1996;312:16-21.
4. Illumina, Inc. Analytical Validation of the verifi® prenatal test: Enhanced Test Performance for Detecting Trisomies 21, 18, and 13 and the Option for Classification of Sex Chromosome Status. 2012.
5. Simpson LL. Twin-twin transfusion syndrome. Am J Obstet Gynecol. Elsevier; 2013;208: 3-18.
6. Snijders RJM, Sundberg K, Holzgreve W, Henry G, Nicolaides KH. Maternal age and gestation-specific risk for trisomy 21. Ultrasound Obstet Gynecol 1999;13:167-70.
7. Snijders RJM, Sebire NJ, Cuckle H, Nicolaides KH. Maternal age and gestation age-specific risks for chromosomal defects. Fetal Diag Ther 1995;10:356-67.
8. Qiao L, Yu B, Liang Y, Zhang C, Wu X, Xue Y, Shen C, He Q, Lu J, Xiang J, Li H, Zheng Q, Wang T. Sequencing shorter cfDNA fragments improves the fetal DNA fraction in noninvasive prenatal testing. American J of Obstet and Gynecol 2019;221(4):345.E1-345.E11.

*** End Of Report ***

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