

# **KOS Diagnostic Lab**

(A Unit of KOS Healthcare)



Dr. Vinay Chopra MD (Pathology & Microbiology) Chairman & Consultant Pathologist Dr. Yugam Chopra MD (Pathology) CEO & Consultant Pathologist

NAME: Ms. ARTI PRASAD Accession No.: 111169 Age/Gender: 30 Y/Female NT2400094 Specimen ID: Lab NO: 012410040013 Specimen: Maternal Blood Referred BY: Self Collected: 04/Oct/2024 02:57PM Remark: Registered: 04/Oct/2024 02:51PM Reported: 22/Oct/2024 08:20AM

## NIPT REPORT

### **NIPT-Assurety**

RESULTS

LOW RISK

FETAL FRACTION 8.6%

Chromosome		Results		Patient-specific PPV or Residual Risk*
Trisomy 13		Low Risk.	0	< 0.01% (1 in 10,000)
Trisomy 18		Low Risk.	0	< 0.01% (1 in 10,000)
Trisomy 21		Low Risk.	0	< 0.01% (1 in 10,000)
Sex Chromosomal Aneuploidies	-	Low Risk.	0	< 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.



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## NOTE:



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



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NOTE:

This Sample was outsourced



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- 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.
- 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:

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- 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.
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- 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 \*\*\*

The test results are subject conditions of reporting. (www.labassure.com/disclaimers)
This is a technical report and results need to be discussed with a qualified physician to correlate clinically and arrive at a diagnosis. In case of any discrepancy in the report, kindly contact the laboratory immediately.



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