First Name: Mrs. Sapna	Lab ID: 012205280186
Last Name: Bikal	Test Requested: NIPT
DOB/Age: 27/F	Sample Collection Date: 2022-05-28
Clinician Name: NA	Sample Receipt Date: 2022-05-29
Hospital Name: Shweta Path Labs	Report Date: 2022-06-17
Location: Haryana	Sample Type: Peripheral Venous blood
Pregnancy Status: Spontaneous	Sample Quality: Optimal
Pregnancy Type: Singleton	Gestational Age: NA
Clinical Indication: Routine Screening for aneuploidy detection	

Non-Invasive Prenatal Screening Report

Results

Chromosomes	Risk	Z score	Test Results	Reference interval
Chromosome 21		1.37	Low Risk	-6<Z score<2.8
Chromosome 18		0.08	Low Risk	-6<Z score<2.8
Chromosome 13		-0.28	Low Risk	-6<Z score<2.8
Sex Chromosomes			Low Risk	
Other Chromosomes			Low Risk	

Fetal Fraction: 19.80%

Interpretation

Non-Invasive Prenatal Test performed on cell free DNA isolated from maternal plasma showed low risk for the aneuploidies tested. Review the results in correlation with other clinical findings.

Dr. Bhawna Dubey PhD
Chief Scientific Officer

Dr. Rahul Dev Singh, MD (Path)
Consultant Pathologist

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Ancillary Information

Chromosomes	Risk	Z score	Test Results	Reference interval
Chromosome 1		1.07	Low Risk	-6<Z score<6
Chromosome 2		-0.52	Low Risk	-6<Z score<6
Chromosome 3		-0.68	Low Risk	-6<Z score<6
Chromosome 4		-0.63	Low Risk	-6<Z score<6
Chromosome 5		-0.29	Low Risk	-6<Z score<6
Chromosome 6		0.13	Low Risk	-6<Z score<6
Chromosome 7		-0.32	Low Risk	-6<Z score<6
Chromosome 8		-0.05	Low Risk	-6<Z score<6
Chromosome 9		0.65	Low Risk	-6<Z score<6
Chromosome 10		-0.07	Low Risk	-6<Z score<6
Chromosome 11		0.07	Low Risk	-6<Z score<6
Chromosome 12		0.76	Low Risk	-6<Z score<6
Chromosome 14		0.37	Low Risk	-6<Z score<6
Chromosome 15		-0.70	Low Risk	-6<Z score<6
Chromosome 16		0.61	Low Risk	-6<Z score<6
Chromosome 17		1.28	Low Risk	-6<Z score<6
Chromosome 19		0.77	Low Risk	-6<Z score<6
Chromosome 20		-0.42	Low Risk	-6<Z score<6
Chromosome 22		-1.08	Low Risk	-6<Z score<6

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Sex Chromosomes Aneuploidies	Risk	Z score	Test Results	Reference interval
XO		-0.69	Low Risk	-3<Z score<3
XXY/XYY		-0.69	Low Risk	
XXX		-0.69	Low Risk	

Provenance information:

The Sage^{TM} methodology: prenatal test screens the maternal blood sample for chromosome aneuploidy in placental DNA using the following methodology:

1. Extraction of cell-free placental DNA from the maternal blood sample.
2. High throughput sequencing of the extracted cell-free placental DNA by Next Generation Sequencing (NGS) for determination of chromosomal aneuploidy.

Test Method:

Maternal blood sample is collected from the pregnant woman (>10 weeks gestation). Circulating cell-free placental DNA was purified from the plasma component of maternal whole blood. cfDNA was then used to prepare genomic DNA library, followed by Next Generation Sequencing on Ion Torrent S5 NGS system. Raw data generated is analyzed by Sage NIPT pipeline for determination of chromosomal aneuploidy.

Additional Information

1. The method is intended for use in pregnant women who are at least 10 weeks pregnant.
2. The test is suitable for both singleton and twin pregnancies, but the accuracy may be slightly lower in twin pregnancies due to multiple sources of fetal DNA.
3. Non-Invasive Prenatal Screening (NIPS) test can detect the aneuploidies in the autosomes, Sex chromosomes (XO, XXX, XXY/XYY).
4. This test confers an accuracy and sensitivity of 99% on the detection of fetal aneuploidy for chromosomes 13, 18 and 21.
5. This test is validated on peripheral blood collected from pregnant women in cfDNA BCT, stored/ received at ambient temperature.

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Limitations of the test:

- NIPS is a screening test and not a diagnostic test and the results should be reviewed in correlation with other clinical findings.
- High-risk results should be confirmed through further invasive diagnostic tests and should be referred for genetic counselling.
- Pregnant women with a negative test result, does not ensure an unaffected pregnancy.
- The test is not validated for mosaicism, triploids, partial trisomy, translocations, inversions or UPD.
- The test is not reportable for known multiple gestations.
- Improper collection, insufficient sample volume in Streck tubes, improper collection tubes, storage and transportation can affect the results.

As per Prenatal Diagnostic Techniques (Regulations and Prevention of Misuse) Amendment Act 2002, sex determination shall not be done for all prenatal samples at BioServe Biotechnologies (India) Pvt Ltd.

References:

1. Bianchi DW, Platt LD, Goldberg JD, et al. Genome-wide fetal aneuploidy detection by maternal plasma DNA sequencing. Obstet Gynecol. 2012;119(5):890-901.
2. Lo YM. Non-invasive prenatal diagnosis by massively parallel sequencing of maternal plasma DNA. Open Biol. 2012;2(6):120086.
3. Chiu RW, Lo YM. Noninvasive prenatal diagnosis empowered by high-throughput sequencing. PrenatDiagn. 2012;32(4):401-
4. ACOG/SMFM Joint Committee Opinion No. 545, Dec 2012

END OF REPORT

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