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

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

LABORATORY REPORT

Name	:Mrs. MANPREET KAUR	Sex/Age	: Female/24 Years	Case ID	:30421600473
Ref By	:	Dis.Loc.	:	Pt ID	:
Bill. Loc.	:KOS DIAGNOSTIC LAB			Pt. Loc.	:
Registration Date & Time	: 07-Apr-2023 09:07	Sample Type	: Streck Tube - Blood	Ph #	:
Sample Date & Time	: 07-Apr-2023 09:07	Sample Coll.By	:	Ref Id	:
Report Date & Time	: 15-Apr-2023 19:51	Acc. Remarks	:	Ref Id 2	:

CHROME
The most preferred non-invasive prenatal test

PATIENT INFORMATION			
Pregnancy Type	Singleton	Collection date	06/04/2023
Gestational age	15 weeks	Fetal fraction	7.7%
Sample Quality	Optimal	Test performed	Chrome Comprehensive

INDICATION Non - Invasive Screening for Chromosomal Aneuploidies

RESULTS	NO ANEUPLOIDY DETECTED

CHROMOSOMES	RESULT	ZSCORE
Chromosome 21	No aneuploidy detected Low risk of fetus being affected with Trisomy 21	0.92
Chromosome 18	No aneuploidy detected Low risk of fetus being affected with Trisomy 18	-0.81
Chromosome 13	No aneuploidy detected Low risk of fetus being affected with Trisomy 13	-2.39
Sex chr abnormalities and Rare Autosomal Trisomies (RAT)	No aneuploidy detected. Low risk of rare autosomal trisomies, XO, XXX, XXY and XYY	**

*Zscore reference range is between -3 to +3.**Zscore is not applicable for sex chromosomal abnormalities.*

RECOMMENDATIONS

- The above results need to be interpreted in the context of all clinical findings.
- Further follow up with your health provider is recommended.
- Follow up genetic sonogram recommended. Invasive testing to be considered in the event of ultrasound anomalies.

EXPECTED TEST RESULTS

CHROME-NIPT analysis can yield any of the following three results:

- **No Aneuploidy Detected:** The probability that the fetus is affected with the specific chromosomal aneuploidy is low.
- **Aneuploidy Detected:** The probability that the fetus is affected with the specific chromosomal aneuploidy is high. Confirmatory testing via amniocentesis/CVS is recommended.
- **No Results:** 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

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Dr. Shiva Murarka
Ph.D. Sr. Scientist
(Molecular Genetics)

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NOTE:
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generated again.

TEST PERFORMANCE

Prenatal Chromosomal Aneuploidy Results for Chromosomes 13, 18, 21 & sex chromosomes		
Chromosome	**Risk**	**Sensitivity**
Chromosome 13	Low	99.99%
Chromosome 18	Low	99.99%
Chromosome 21	Low	99.99%
XO	Low	90.32%
XXY	Low	93.00%
XXX	Low	93.00%

Prenatal Chromosomal Aneuploidy for Other Chromosomes		
Chromosome	**Risk**	**Sensitivity**
Chromosome 1	Low	98.36%
Chromosome 2	Low	98.03%
Chromosome 3	Low	97.64%
Chromosome 4	Low	96.92%
Chromosome 5	Low	97.26%
Chromosome 6	Low	96.44%
Chromosome 7	Low	96.10%
Chromosome 8	Low	95.72%
Chromosome 9	Low	94.88%
Chromosome 10	Low	94.38%
Chromosome 11	Low	93.82%
Chromosome 12	Low	93.16%
Chromosome 14	Low	92.84%
Chromosome 15	Low	92.24%
Chromosome 16	Low	91.62%
Chromosome 17	Low	90.20%
Chromosome 19	Low	90.68%
Chromosome 20	Low	91.08%
Chromosome 22	Low	90.45%

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Principle

The test is capable of genome-wide aneuploidy detection over the whole fetal genome (23 pairs of chromosomes) and offers an interpretation of the results for Trisomy 13, Trisomy 18, Trisomy 21, sex chromosomes. This test confers an accuracy of up to 99% on the detection of fetal chromosome aneuploidy.

Methodology

(1) Extraction of cell free fetal DNA from the 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
The test employs a non-invasive for that utilizes whole-genome sequencing of cfDNA fragments derived from the maternal peripheral whole blood samples. The Next Generation Sequencing is performed using Illumina platform and analyzed through the CHROME analysis pipeline version 2.1.2.

TEST LIMITATIONS

- The NIPT CHROME COMPREHENSIVE analyzes all 23 chromosomes and NIPT CHROME FOCUS analyses chromosomes 13, 18, 21 and sex chromosomes for aneuploidy in singleton and twin gestations at gestational age of at least 9 weeks.
- The NIPT CHROME is a screening test; a low risk does not exclude the above evaluated disorders. It is not intended, neither validated for diagnosis nor for use in pregnancies with more than two fetuses, mosaicism, partial chromosomal aneuploidy, translocations or maternal aneuploidy.
- The NIPT CHROME is a screening test and the positive predictive value is not 100%. Hence confirmation of high risk results is recommended by invasive testing.
- A LOW RISK test result reduces the risk of fetal aneuploidy but it does not ensure an unaffected fetus. It also does not negate the possibility that the fetus may be affected with sub-chromosomal abnormalities, gene defects and birth defects. Need for an invasive testing may arise later in pregnancy.
- False positive and false negative results are known. Factors affecting test accuracy include confined placental mosaicism (reported results reflects placental changes rather than fetal status), maternal mosaicism, maternal neoplasms, vanishing twin and low fetal fraction.
- The lower limit of detection for singleton pregnancies is at fetal fraction of 2%. The lower limit of detection for twin pregnancies is at fetal fraction of 4%. The sensitivity is reduced in case of twin pregnancies with fetal fraction of 2-4%.
- The test is reportable for only certain multiple gestations but cannot differentiate between specific fetuses.
- The NIPT CHROME is a CAP (College of American Pathologists) and NABL accredited test.

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REFERENCES

- ACOG PRACTICE BULLETIN. Clinical Management Guidelines for Obstetrician–Gynecologists.2018.
- Causes of aberrant non-invasive prenatal testing for aneuploidy: A systematic review. Osamu Samura, Aikou Okamoto. 2020.
- Fetal fraction and noninvasive prenatal testing: What clinicians need to know.Lisa Hui,Diana W. Bianchi, Prenatal Diagnosis 2020.
- ACMG statement on noninvasive prenatal screening for fetal aneuploidy Anthony R. Gregg, S.J. Gross, R.G. Best, K.G. Monaghan, K. Bajaj, B.G. Skotko, B.H. Thompson and M.S. Watson. Genetics in Medicine 2013.

Important: On doing PNDT test, the undersigned hereby confirms that no sex chromosome information has been passed on to anyone in whatsoever manner

---------- End Of Report ----------

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