

KOS Diagnostic Lab

(A Unit of KOS Healthcare)





PATIENT INFORMA	TION	1540	40
Pregnancy Type	Singleton	Collection date	26/03/2022
Gestational age	16 weeks 1 day	Fetal fraction	11.50%
Sample Quality	Optimal	Test performed	Chrome Comprehensive

INDICATION: Advanced Maternal Age, Abnormal Biochemical Screening

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RESULTS	NO ANEUPLOIDY DETECTED	
MESOLIS	NO ANEOFEOIDT DETECTED	

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

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 generated again.

Fortest performed on specimens received or collected from non-STMPL locations, it is presumed that the specimen belongs to the patient named or identified as labeled on the container/test request and such verification has been carried out at the point generation of the saids specimen by the sender.

STMPL will be responsible Only for the analytical part of test carried out. All other responsibility will be of referring Laboratory 1 of 3

NOTE:

This Sample was outsourced



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TEST TECHNOLOGY

Whole Genome Sequencing of cell free maternal DNA and analysis for fetal aneuploidy.

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%		
хо	Low	90.32%		
XXY	Low	93.00%		
XXX	Low	93.00%		

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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TEST LIMITATIONS

- The NIPT CHROME COMPREHENSIVE analyzes all 23 chromosomes for aneuploidy in singleton and twin gestations at gestational age of atleast 9 weeks.
- The NIPT CHROME COMPREHENSIVE 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 COMPREHENSIVE is a screening test and the positive predictive value is not 100%. Hence confirmation of Borderline or 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 CHROME-NIPT is a CAP (College of American Pathologists) accredited test.

DISCLAIMER! : NIPT is a screening test, a low risk does not exclude the above evaulated disorders.

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



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NOTE:

This Sample was outsourced to Microbiology & Molecular Biology Lab