

Limitations of the test

- CHROME is indicated for use in pregnant women with increased risk for chromosomal aneuploidy & does not replace the accuracy and precision of prenatal diagnosis with Amniocentesis or Chorionic Villus Sampling (CVS)
- Pregnant women with a positive diagnosis test result should be referred to genetic counseling & offered invasive prenatal diagnosis for confirmation of test results
- However, a negative test result does not ensure an unaffected pregnancy
- Not all chromosomal abnormalities can be detected due to placental, maternal, fetal mosaicism, or other causes (micro-deletions, chromosome re-arrangements, translocations, inversions, unbalanced translocations, uniparental disomy)

CHROME

The most preferred non-invasive prenatal test



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CHROME

The most preferred non-invasive prenatal test

NEW AGE PREGNATAL SCREENING FOR THE NEW GENERATION

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COLLEGE of AMERICAN PATHOLOGISTS

*AT SELECT LABORATORIES

The Science Behind CHROME

Cell-free DNA fragments (cfDNA) are short fragments of DNA, which can be found circulating in the blood. During pregnancy, cfDNA fragments originating from both the mother and the fetus are present in maternal circulation.

The test requires taking a small maternal blood sample. This is then analysed with our proprietary genetic sequencing technology and bioinformatics to screen for any chromosomal abnormality in the fetus.

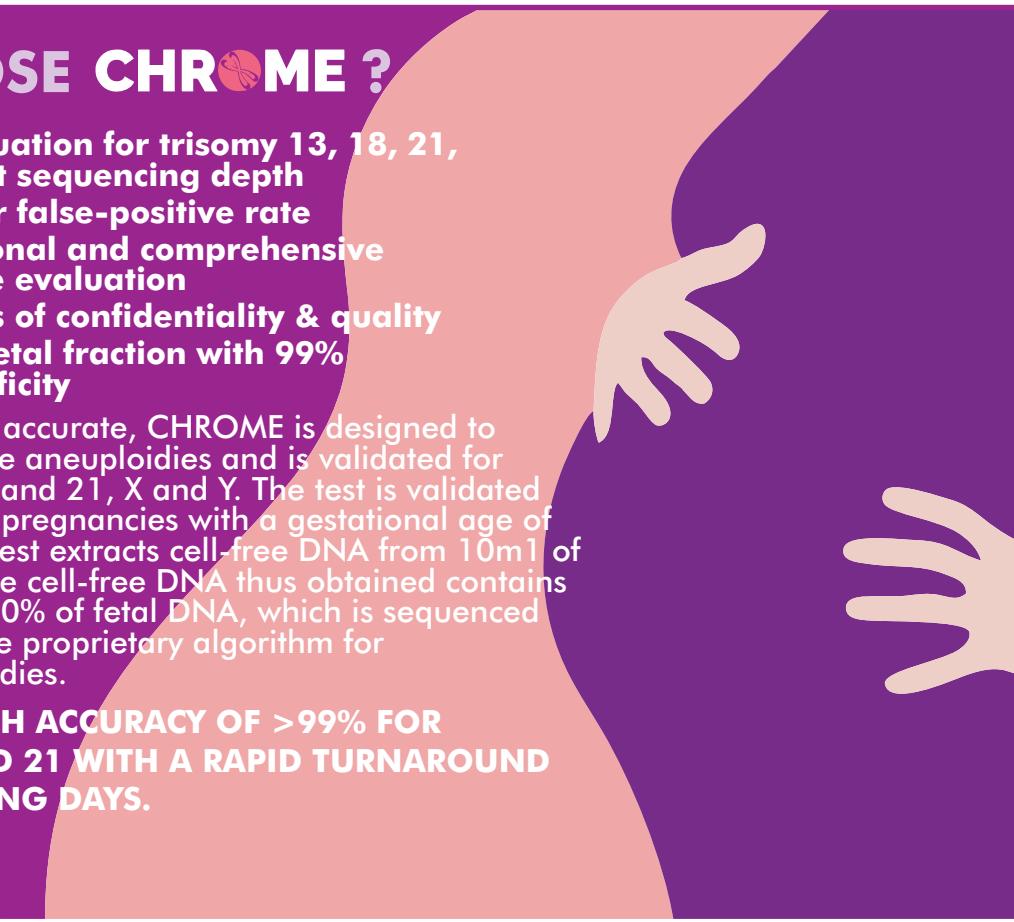
The technology behind CHROME allows for highly accurate results with detection rates of over 99.5% for the three most common trisomy conditions present at birth (Down Syndrome, Edwards Syndrome and Patau Syndrome).

WHY CHOOSE CHROME ?

- Reliable risk evaluation for trisomy 13, 18, 21, X & Y due to great sequencing depth
- Significantly lower false-positive rate
- Part of a professional and comprehensive prenatal medicine evaluation
- Highest standards of confidentiality & quality
- Reporting at 2% fetal fraction with 99% sensitivity & specificity

Non-invasive & highly accurate, CHROME is designed to screen for chromosome aneuploidies and is validated for chromosomes 13, 18, and 21, X and Y. The test is validated for singleton and twin pregnancies with a gestational age of at least 9 weeks. The test extracts cell-free DNA from 10ml of the mother's blood. The cell-free DNA thus obtained contains approximately 4% to 10% of fetal DNA, which is sequenced and analyzed using the proprietary algorithm for chromosome aneuploidies.

CHROME HAS A HIGH ACCURACY OF >99% FOR TRISOMY 13, 18 AND 21 WITH A RAPID TURNAROUND TIME OF 5-7 WORKING DAYS.



CHROME Is Ideal In The Following Cases

- Pregnant women from 9 weeks gestation
- Singleton or twin pregnancies (Sample collection recommended after 8 weeks in vanishing twin)
- IVF, Donor egg or, Surrogate pregnancies

For other specific genetic disorders, an alternative genetic test may be more appropriate.

Sample Collection

Specialized tubes known as "Streck tubes" are made available at hospitals or doctor's clinics for collecting the blood. These tubes are a 10 ml blood collection tube with a formaldehyde-free preservative stabilizing nucleated blood cells. Please refer to our Protocol Guidelines for Sample Collection & Handling.

The CHROME Test Results

An example of the final report is shown to understand the test results:

Detection Rate

	Overall Stats	Chr13 Stats	Chr18 Stats	Chr21 Stats
Sensitivity	99.99%	99.99%	99.99%	99.99%
Specificity	99.69%	99.99%	99.99%	99.99%
Negative Predictive Value	99.99%	99.99%	99.99%	99.99%
Accuracy	99.70%	99.99%	99.99%	99.99%

CHROME Is Unsuitable If The Mother

- Has cancer
- Received stem cell therapy
- Has received blood transfusion, organ transplantation, immunotherapy radiotherapy in the last 3 months