MaterniT™ GENOME

THE NEXT LEVEL IN NONINVASIVE PRENATAL TESTING

For many years, the only way to learn about a baby's chromosomes during pregnancy was with an invasive procedure, in which either fluid (amniocentesis) or a small sample of the placenta (chorionic villus sampling) is taken directly from the womb. These studies provide a great deal of information, but the procedures have an associated risk of miscarriage.

The MaterniT GENOME test is the only prenatal blood test available to date that can analyze every chromosome of your baby to identify extra or missing parts of chromosomes, or other whole chromosome changes. Many of these chromosome abnormalities can severely impact the health of a baby. Through the convenience of a blood draw performed as early as 10 weeks into your pregnancy, the MaterniT GENOME test offers comprehensive information about chromosomes for your pregnancy, without the risk of miscarriage associated with an invasive procedure.

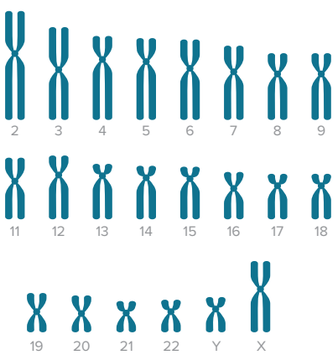
IS THE TEST RIGHT FOR ME?

The MaterniT GENOME test represents the latest scientific advancement in noninvasive prenatal testing. It can analyze every chromosome in the genome—the complete set of your baby's chromosomes. Your health care provider may discuss the benefits of the MaterniT GENOME test with you if:

- There are concerns about chromosome abnormalities in your pregnancy
- Ultrasound abnormalities have been identified
- You have had earlier abnormal screening results for this pregnancy
- You, your partner, or a prior pregnancy or child were identified with a chromosome abnormality
- You have received inconclusive results from another fetal DNA screening test
- You have asked to learn the most information you can about your baby's chromosomes without the risks associated with an invasive procedure

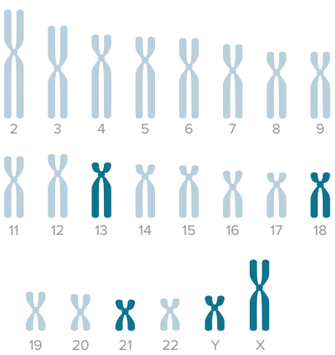
THE MATERNIT GENOME TEST

The MaterniT GENOME test analyzes all chromosomes, providing the most information available to date from a noninvasive prenatal test.



OTHER TESTS

Most noninvasive prenatal tests analyze just a few chromosomes to report common genetic information.



WHAT WILL THE RESULTS TELL ME?

The MaterniT GENOME test can identify common whole chromosome abnormalities like trisomy 21 (also known as Down syndrome), trisomy 18, or trisomy 13. Extra or missing pieces of chromosome material can also be found. Some of these smaller changes can be associated with rare conditions such as DiGeorge or Wolf-Hirschhorn syndromes, which often go undiagnosed at birth. Having information about such genetic conditions before birth can help ensure your baby receives the proper and necessary support.

The MaterniT GENOME test reports on many chromosome abnormalities and conditions, which include, but are not limited to:

Any trisomy or monosomy	Trisomy – extra copy of a chromosome is present (3 instead of 2) Monosomy – missing copy of a chromosome (1 instead of 2)
Sex chromosome abnormalities	Extra or missing sex-determining X or Y chromosome
Fetal sex	Reports as male or female
Partial chromosome abnormalities	Very small part of the chromosome is extra or missing
Many other chromosome changes throughout the genome	

HOW ARE RESULTS PROVIDED?

Results are typically available 5 days after your sample has been received in the laboratory. Results are communicated clearly—as a positive or a negative result.

A positive result means that a chromosomal abnormality has been identified. Genetic counseling is recommended following any positive test result to discuss the findings and review options for further confirmatory testing. To assist in understanding an abnormal result, the MaterniT GENOME test report also has an image of the chromosome change that illustrates what was discovered.

A negative result means that no chromosome changes were identified. Though highly reassuring, it is important to note that, like many tests during your pregnancy, a negative result does not mean your baby is unaffected, as the test cannot detect all possible abnormalities.

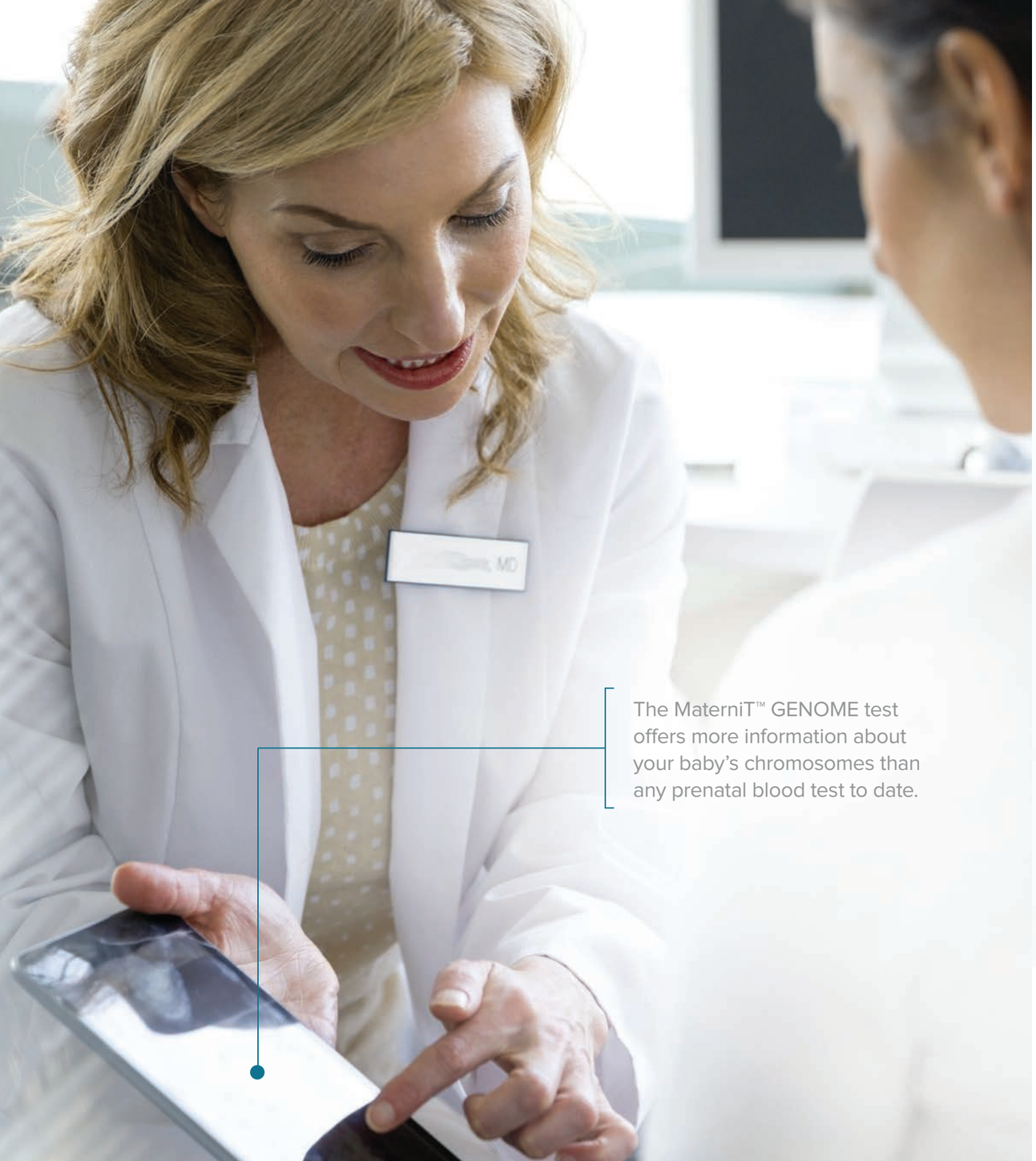
In some instances, one of the many chromosome targets analyzed may return an "uninformative" result. This does not necessarily indicate there is a problem with your pregnancy. Most commonly, it means that the amount of fetal DNA required for that particular result is insufficient and re-testing or alternative testing may be conducted.

Some chromosome changes are associated with known conditions, while other changes may be identified in chromosome regions that are not as well defined clinically. Also, in some cases, results may indicate chromosome changes from the placenta and not the baby. Your health care provider can explain your test results and may recommend a specialized procedure, such as amniocentesis or chorionic villus sampling, to confirm either positive or negative results. You may also be referred for genetic counseling, which can help provide the context necessary to understand your test results and plan for your pregnancy.

ARE THERE OTHER CHOICES IN THIS CLASS OF TESTS I SHOULD CONSIDER?

The MaterniT GENOME test is unique in the level of information it provides. No other noninvasive prenatal test can offer analysis of all fetal chromosomes.

As a pioneer and leader in fetal DNA testing, Sequenom Laboratories has significant experience in testing for fetal chromosome abnormalities from maternal blood. Should you wish to consider other options for fetal DNA testing, ask your health care provider about the MaterniT21 PLUS® or VisibiliT™ noninvasive prenatal tests.



The MaterniT™ GENOME test offers more information about your baby's chromosomes than any prenatal blood test to date.

ABOUT THE TEST

The MaterniT GENOME test is a laboratory-developed test that was developed, validated and performed exclusively by Sequenom Laboratories. The test has not been cleared or approved by the US Food and Drug Administration (FDA). Although laboratory-developed tests to date have not been subject to US FDA regulation, certification of the laboratory is required under the Clinical Laboratory Improvement Amendments (CLIA) to ensure the quality and validity of the test. Sequenom Laboratories is certified under CLIA as qualified to perform high complexity clinical laboratory testing and is accredited by the College of American Pathologists.

No test is perfect. While the results of the MaterniT GENOME test are highly accurate, discordant results, including inaccurate fetal sex prediction, may occur due to: placental, maternal, or fetal mosaicism or neoplasm; vanishing twin; prior maternal organ transplant; or other causes. Cell-free DNA (cfDNA) testing does not replace the accuracy and precision of prenatal diagnosis with CVS or amniocentesis. A patient with a positive MaterniT GENOME test result should be referred for genetic counseling and offered invasive prenatal diagnosis for confirmation of test results. A negative MaterniT GENOME test result does not ensure an unaffected pregnancy. An uninformative result may be reported, the causes of which may include, but are not limited to, insufficient sequencing coverage, noise or artifacts in the region, amplification or sequencing bias, or insufficient fetal fraction. The MaterniT GENOME test is not intended to identify pregnancies at risk for neural tube defects or ventral wall defects. cfDNA testing for whole chromosome abnormalities (including sex chromosomes) and for subchromosomal abnormalities could lead to the potential discovery of both fetal and maternal genomic abnormalities that could have minor, or no, clinical significance. Evaluating the significance of a positive or a non-reportable test result may involve both invasive prenatal testing and additional studies on the mother. Such investigations may lead to detection of maternal chromosomal or subchromosomal abnormalities, which on occasion may be associated with benign or malignant maternal neoplasms. cfDNA testing may not accurately identify fetal triploidy, balanced rearrangements, or the precise location of subchromosomal duplications or deletions; these may be detected by prenatal diagnosis with CVS or amniocentesis. The ability to report results may be impacted by maternal body mass index (BMI), maternal weight, and/or maternal systemic lupus erythematosus (SLE). The results of this testing, including the benefits and limitations, should be discussed with a qualified health care provider. Pregnancy management decisions, including termination of the pregnancy, should not be based on the results of this test alone.

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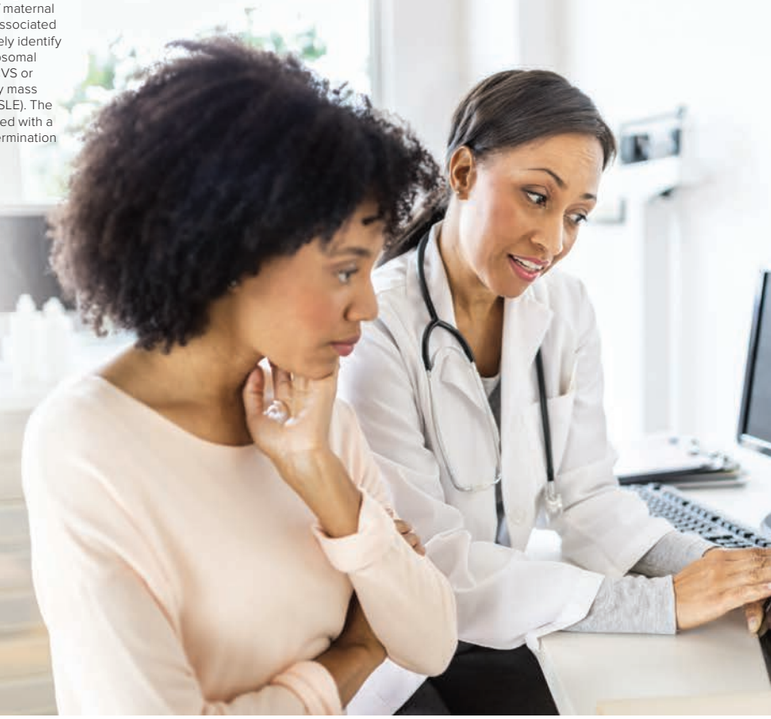
THE SCIENCE OF UNPARALLELED INFORMATION



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The only prenatal blood test that analyzes every chromosome of your developing baby.

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