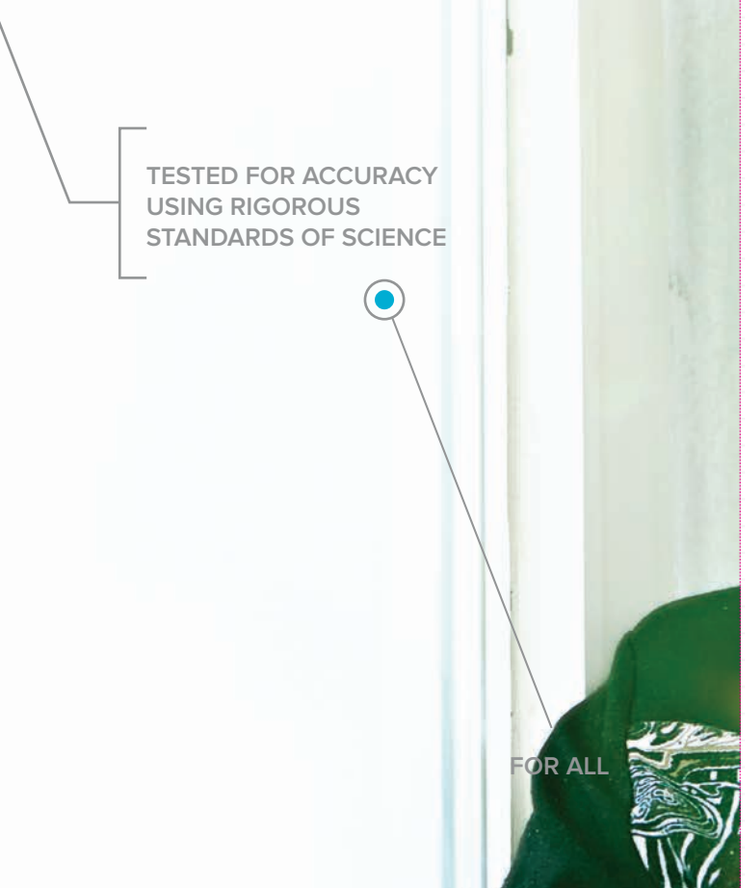
NONINVASIVE PRENATAL TESTING OPTIONS FOR ALL

Noninvasive prenatal testing (NIPT) was pioneered by Sequenom Laboratories in 2011, and since then, several hundred thousand pregnant women worldwide have benefited. Many have avoided potentially unnecessary invasive procedures while still gaining important information about the health of their pregnancies.

With our recent scientific advancements, we have enabled noninvasive prenatal testing to reach even more pregnant women looking for relevant genetic information about their pregnancy.

Sequenom Laboratories is the first provider to offer two distinct noninvasive prenatal testing choices with the MaterniT21 and the MaterniT21 PLUS laboratory-developed tests.



MaterniT21®

LABORATORY-DEVELOPED TEST

For those who want relevant information about common fetal trisomies, we have a test that meets that need. Pregnant women who would find value include:

- Those who want to know common genetic information
- Those with singleton or multiple gestations
- Those who desire high accuracy for trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome) and trisomy 13 (Patau syndrome)

SELECTIVE CONTENT

The MaterniT21 test was designed to mirror the common trisomies provided by current serum screening tests. Serum screening tests have highly variable detection rates and result in a 5% positive screen rate.[1]

The MaterniT21 test, performed as early as week 9 in your pregnancy, includes trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome), trisomy 13 (Patau syndrome) and fetal gender.

CLEAR, DIRECT RESULTS

- Positive or negative result for common fetal trisomies (13, 18, 21)
- Gender and fetal fraction reported

RELIABLE PERFORMANCE

- High detection rate of greater than 99% for trisomy 21 (Down syndrome) and trisomy 18 (Edwards syndrome), and greater than 91% for trisomy 13 (Patau syndrome)
- Similar trisomy information as prenatal serum screening
- Very low false positive rate compared to prenatal serum screening
- This test has a very low no-result rate (<1.0%) meaning you have less of a chance needing a retest
- Reports to a fetal fraction of 3%

Condition	MaterniT21 test[3,5] Number of samples identified
Trisomy 21	>99% (210 of 212)
Trisomy 18	>99% (59 of 59)
Trisomy 13	>91% (11 of 12)
Fetal gender	>99% accuracy

MaterniT21® PLUS

LABORATORY-DEVELOPED TEST

For those who want comprehensive answers without the risks associated with prenatal invasive procedures, a solution is available with the MaterniT21 PLUS test. Pregnant women who would find value include:

- Those seeking comprehensive information
- Those considered high risk (abnormal ultrasound findings, or family history)
- Those with single or multiple gestations
- Those who want detailed genetic information about rare chromosomal disorders

BREADTH OF CONTENT

This test, performed as early as week 9 in your pregnancy, provides a broad set of genetic information.

- Trisomy 21 (Down syndrome)
- Trisomy 18 (Edwards syndrome)
- Trisomy 13 (Patau syndrome)
- Fetal gender
- 45,X (Turner syndrome)
- 47,XXY (Klinefelter syndrome)
- 47,XXX (Triple X syndrome)
- 47,XYY (XYY syndrome)
- Trisomy 16
- Trisomy 22
- 22q (DiGeorge syndrome)
- 5p (Cri-du-chat syndrome)
- 1p36 deletion syndrome
- 15q (Prader-Willi/Angelman syndromes)
- 11q (Jacobsen syndrome)
- 8q (Langer-Giedion syndrome)
- 4p (Wolf-Hirschhorn syndrome)

CLEAR, DIRECT RESULTS

- Positive or negative result for common fetal trisomies (13, 18, 21)
- Gender and fetal fraction reported
- Additional Findings for all other chromosomal abnormalities

EXCELLENT PERFORMANCE

- Highly accurate for the broad array of information that this test offers
- This test has a very low no-result rate (<1.0%) meaning you have less of a chance needing a retest
- Reports to a fetal fraction of 3%

Condition	MaterniT21 PLUS test[3,4,5,6] Number of samples identified
Trisomy 21	>99% (210 of 212)
Trisomy 18	>99% (59 of 59)
Trisomy 13	>91% (11 of 12)
Fetal gender	>99% accuracy
Fetal sex aneuploidies	>96% (25 of 26 combined)
Select microdeletions	>94% (17 of 18)

REFERENCES

1. Screening for fetal chromosomal abnormalities. ACOG Practice Bulletin; Number 77, January 2007.
2. Kim S, et al. Application of risk-score analysis to low-coverage sequencing data for noninvasive detection of trisomy 21 and trisomy 18. Poster presented at the 18th International Conference on Prenatal Diagnosis and Therapy; July 2014; Brisbane, Australia.
3. Palomaki GE, et al. DNA sequencing of maternal plasma reliably identifies trisomy 18 and trisomy 13, as well as Down syndrome: An international collaborative study. Genet Med. 2012;14(3):296-305.
4. Mazloom AR, Dzakula Z, Oeth P, Wang H, et al. Noninvasive prenatal detection of sex chromosomal aneuploidies by sequencing circulating cell-free DNA from maternal plasma. *Prenat Diagn.* 2013;33(6):591-597.
5. Canick JA, et al. DNA sequencing of maternal plasma to identify Down syndrome and other trisomies in multiple gestations. *Prenat Diagn.* 2012;32(8):730-734.
6. Zhao C, et al. Detection of fetal subchromosomal abnormalities by sequencing CCF from maternal plasma. Poster presented at the ACMG Annual Clinical Genetics Meeting; March 2014; Nashville, TN.

No test is perfect. These test results do not provide a definitive genetic risk in all individuals. Cell-free DNA does not replace the accuracy and precision of prenatal diagnosis with CVS or amniocentesis. A patient with a positive test result or an Additional Finding should be referred for genetic counseling and offered invasive prenatal diagnosis for confirmation of test results. A negative test result does not ensure an unaffected pregnancy. The absence of an Additional Finding does not indicate a negative result. While results of this testing are highly accurate, not all chromosomal abnormalities may be detected due to placental, maternal or fetal mosaicism, or other causes. Sex chromosomal aneuploidies are not reportable for known multiple gestations. The health care provider is responsible for the use of this information in the management of their patient.

The tests were developed by, and its performance characteristics were determined by Sequenom Laboratories. The tests have not been cleared or approved by the U.S Food and Drug Administration. Although laboratory-developed tests to date have not been subject to U.S. FDA regulation, certification of the laboratory is required under the Clinical Laboratory Improvement Amendments (CLIA) to ensure the quality and validity of the tests. Sequenom Laboratories is CAP accredited and certified under CLIA to perform high-complexity clinical laboratory testing.

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THE SCIENCE OF

KNOWLEDGE FOR ALL

MaterniT21® PLUS
Clearly advanced.

MaterniT21®
Simply relevant.

Delivering noninvasive prenatal testing options for your pregnancy

sequenom Laboratories