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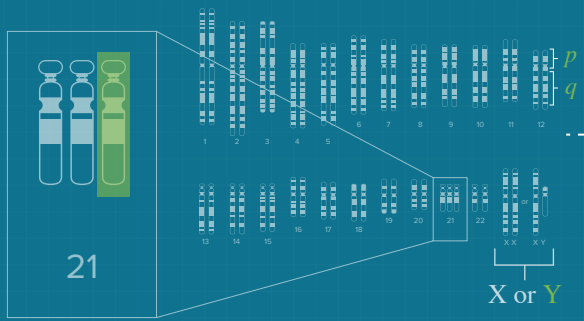

Clear results.
Meaningful answers.

MaterniT21™ PLUS

QUALITY OF SCIENCE

MaterniT21™ PLUS Lab Report

Sequenom Laboratories
3595 John Hopkins Court
San Diego, CA 92121
CLIA #: 05D2015356 CAP #: 7527138
877.821.7266

Final Report

Ordering Provider:	**Doe, John, MD**	Patient:	**Sample, Jane**
Provider Location:	**Grand Rapids**	DOB:	**09/13/1970**
Provider Phone:	**555-555-5555**	Patient ID:	**12345-01234**
Date Ordered:	**11/28/2014**	Specimen:	**1035600024**
Date Collected:	**11/29/2014**	Referral Clinician:	**Smith, Jane, GC**
Date Received:	**11/30/2014**	Lab Director:	**Juan-Sebastian Saldivar, MD**
Order ID:	**ORD12345-01234**	Date Reported:	**04/29/2013 6:00 PM PT**

Test Result for Chromosomes 21, 18 and 13	
Positive for Trisomy 21	This specimen showed an increased amount of chromosome 21 material (trisomy 21), such as may be found in pregnancies with Down syndrome. This specimen also showed an expected representation of chromosomes 18 and 13 material. Clinical correlation is suggested.
Test Result for Y Chromosome	
No Y chromosomal material detected	Consistent with a female fetus.

Test Method

Circulating cell-free DNA was purified from the plasma component of anti-coagulated maternal whole blood. It was then converted into a genomic DNA library for the determination of chromosome 21, 18, 13 representation and the presence of the Y chromosome.[1] Other chromosomal material, including fetal chromosome 22, 16, sex chromosome (X and Y) representation, and select regions (22q, 15q, 11q, 8q, 5p, 4p, 1p), was also evaluated and will only be reported as an Additional Finding when an abnormality is detected.

About the Test

The MaterniT21 PLUS test analyzes circulating cell-free DNA extracted from a maternal blood sample. The test is indicated for use in pregnant women with increased risk for chromosomal aneuploidy. Validation data on twin pregnancies is limited and the ability of this test to detect aneuploidy in a triplet pregnancy has not yet been validated.

Performance

The performance characteristics of the MaterniT21 PLUS laboratory-developed test (LDT) have been determined in a clinical validation study with pregnant women at increased risk for fetal chromosomal abnormality.[1,2,3]

Intended Use	Performance	Confidence Interval (95% CI)
Trisomy 21	Sensitivity: 99.1%	96.3-99.8%
	Specificity: 99.9%	99.6-99.9%
Trisomy 18	Sensitivity: >99.9%	92.4-100.0%
	Specificity: 99.6%	99.2-99.8%
Trisomy 13	Sensitivity: 91.7%	59.7-99.6%
	Specificity: 99.7%	99.3-99.9%
Y chromosome	Accuracy: 99.4%	99.0-99.6%

Limitations of the Test

DNA 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 presence of an Additional Finding should be referred for genetic counseling and offered invasive prenatal diagnosis for confirmation of test results.[4] 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.

Note

This test was developed and its performance characteristics determined by Sequenom Laboratories. It has not been cleared or approved by the U.S. FDA. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing and accredited by the College of American Pathologists.

References

1. Palomaki GE, et al. *Genet Med*. 2012;14(3):296-305.
2. Palomaki GE, et al. *Genet Med*. 2011;13(11):913-920.
3. Mazloom AR, et al. *Prenat Diag*. 2013;33(6):591-597.
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SEE ADDITIONAL FINDINGS

Test Result for Chromosomes 21, 18 and 13

Negative	This specimen showed an expected representation of chromosome 21, 18 and 13 material. Clinical correlation is suggested.

Test Result for Y Chromosome

No Y chromosomal material detected	Consistent with a female fetus.

ADDITIONAL FINDINGS

This specimen showed a decreased representation of chromosome 4p	These findings are suggestive of a 4p deletion, affecting the 4p16.3 region associated with Wolf-Hirschhorn syndrome.

Wolf-Hirschhorn syndrome (4p minus) is caused by a deletion on the short arm of chromosome 4. The disorder is characterized by distinctive craniofacial anomalies, growth restriction, developmental delay, hearing loss and seizures. Incidence is estimated to be ~1/50,000 births. Most cases are not inherited and represent a *de novo* deletion.[1]

Test Method

Circulating cell-free DNA was purified from the plasma component of anti-coagulated maternal whole blood. It was then converted into a genomic DNA library for the determination of chromosome 21, 18, 13 representation and the presence of the Y chromosome.[2] Other chromosomal material, including fetal chromosome 22, 16, sex chromosome (X and Y) representation, and select regions (22q, 15q, 11q, 8q, 5p, 4p, 1p), was also evaluated and will only be reported as an Additional Finding when an abnormality is detected.

About the Test

The Materni1 PLUS test analyzes circulating cell-free DNA extracted from a maternal blood sample. The test is indicated for use in pregnant women with increased risk for chromosomal aneuploidy. Validation data on twin pregnancies is limited and the ability of this test to detect aneuploidy in a triplet pregnancy has not yet been validated.

Performance

The performance characteristics of the MaterniT21 PLUS laboratory-developed test (LDT) have been determined in a clinical validation study with pregnant women at increased risk for fetal chromosomal abnormality.[2,3,4]

Intended Use	Performance	Confidence Interval (95% CI)
Trisomy 21	Sensitivity: 99.1%	96.3-99.8%
	Specificity: 99.9%	99.6-99.9%
Trisomy 18	Sensitivity: >99.9%	92.4-100.0%
	Specificity: 99.6%	99.2-99.8%
Trisomy 13	Sensitivity: 91.7%	59.7-99.6%
	Specificity: 99.7%	99.3-99.9%
Y chromosome	Accuracy: 99.4%	99.0-99.6%

Limitations of the Test

DNA 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 presence of an Additional Finding should be referred for genetic counseling and offered invasive prenatal diagnosis for confirmation of test results.[5] 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.

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References

1. http://www.ncbi.nlm.nih.gov/books/NBK1183.
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SEE ADDITIONAL FINDINGS

Test Result for Chromosomes 21, 18 and 13

Negative	This specimen showed an expected representation of chromosome 21, 18 and 13 material. Clinical correlation is suggested.

Test Result for Y Chromosome

Y chromosomal material detected	Consistent with a male fetus.

ADDITIONAL FINDINGS

This specimen showed a decreased representation of chromosome 8q	These findings are suggestive of an 8q deletion, affecting the 8q24.1 region associated with Langer-Giedion syndrome.

Langer-Giedion syndrome (Tricho-rhino-phalangeal syndrome type II) is caused by a deletion on the long arm of chromosome 8. The disorder is characterized by bone anomalies and distinctive facies. Bone anomalies include exostoses, or benign bone tumors and epiphyses; facial characteristics may include sparse scalp hair and a bulbous nose. Developmental delay has also been reported. Most cases are not inherited and represent a *de novo* deletion.[1]

Test Method

Circulating cell-free DNA was purified from the plasma component of anti-coagulated maternal whole blood. It was then converted into a genomic DNA library for the determination of chromosome 21, 18, 13 representation and the presence of the Y chromosome.[2] Other chromosomal material, including fetal chromosome 22, 16, sex chromosome (X and Y) representation, and select regions (22q, 15q, 11q, 8q, 5p, 4p, 1p), was also evaluated and will only be reported as an Additional Finding when an abnormality is detected.

About the Test

The MateriT21 PLUS test analyzes circulating cell-free DNA extracted from a maternal blood sample. The test is indicated for use in pregnant women with increased risk for chromosomal aneuploidy. Validation data on twin pregnancies is limited and the ability of this test to detect aneuploidy in a triplet pregnancy has not yet been validated.

Performance

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Intended Use	Performance	Confidence Interval (95% CI)
Trisomy 21	Sensitivity: 99.1%	96.3-99.8%
	Specificity: 99.9%	99.6-99.9%
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Trisomy 13	Sensitivity: 91.7%	59.7-99.6%
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Y chromosome	Accuracy: 99.4%	99.0-99.6%

Limitations of the Test

DNA 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 presence of an Additional Finding should be referred for genetic counseling and offered invasive prenatal diagnosis for confirmation of test results.[5] 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.

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References

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Order ID:	**ORD12345-01234**	Date Reported:	**04/29/2013 6:00 PM PT**

SEE ADDITIONAL FINDINGS

Test Result for Chromosomes 21, 18 and 13

Negative	This specimen showed an expected representation of chromosome 21, 18 and 13 material. Clinical correlation is suggested.

Test Result for Y Chromosome

Y chromosomal material detected	Consistent with a male fetus.

ADDITIONAL FINDINGS

This specimen showed a decreased representation of the X chromosome	These findings are suggestive of a 45,X chromosomal abnormality, such as may be found in pregnancies with Turner syndrome.

Test Method

Circulating cell-free DNA was purified from the plasma component of anti-coagulated maternal whole blood. It was then converted into a genomic DNA library for the determination of chromosome 21, 18, 13 representation.[1] Other chromosomal material, including fetal chromosome 22, 16, sex chromosome (X and Y) representation, and select regions (22q, 15q, 11q, 8q, 5p, 4p, 1p), was also evaluated and will only be reported as an Additional Finding when an abnormality is detected.

About the Test

The MaterniT21 PLUS test analyzes circulating cell-free DNA extracted from a maternal blood sample. The test is indicated for use in pregnant women with increased risk for chromosomal aneuploidy. Validation data on twin pregnancies is limited and the ability of this test to detect aneuploidy in a triplet pregnancy has not yet been validated.

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Test Result for Chromosomes 21, 18 and 13

Negative	This specimen showed an expected representation of chromosome 21, 18 and 13 material. Clinical correlation is suggested.

Test Result for Y Chromosome

No Y chromosomal material detected	Consistent with a female fetus.

ADDITIONAL FINDINGS

This specimen showed a decreased representation of the X chromosome	These findings are suggestive of a 45,X chromosomal abnormality, such as may be found in pregnancies with Turner syndrome.

Test Method

Circulating cell-free DNA was purified from the plasma component of anti-coagulated maternal whole blood. It was then converted into a genomic DNA library for the determination of chromosome 21, 18, 13 representation and the presence of the Y chromosome.[1] Other chromosomal material, including fetal sex chromosome (X and Y) representation, was also evaluated and will only be reported as an Additional Finding when an abnormality is detected.

About the Test

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Order ID:	**ORD12345-01234**	Date Reported:	**04/29/2013 6:00 PM PT**

Test Result for Chromosomes 21, 18 and 13

Negative

This specimen showed an expected representation of chromosome 21, 18 and 13 material. Clinical correlation is suggested.

Test Method

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About the Test

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Limitations of the Test

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 34-40200R1.0 T8 071414

ABOUT THE COMPANY

Sequenom Laboratories, a wholly owned subsidiary of Sequenom, Inc., is a CAP-accredited and CLIA-certified molecular diagnostics laboratory dedicated to improving patient outcomes by offering revolutionary laboratory-developed tests for a variety of prenatal conditions. Sequenom Laboratories pioneered NIPT with the launch of its MaterniT21 PLUS test for fetal abnormalities, and offers a broad menu of prenatal tests.

ABOUT THE MATERNIT21 PLUS TEST

The MaterniT21™ PLUS test is a laboratory-developed test that was developed, validated and performed exclusively by Sequenom Laboratories in the USA. It has not been cleared or approved by the U.S. 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 CLIA to ensure the quality and validity of the tests. Sequenom Laboratories is certified under the U.S. Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing and accredited by the College of American Pathologists (CAP).

No test is perfect. DNA test results do not provide a definitive genetic risk in all individuals. Cell-free fetal 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.

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