

Patient Information

Patient Name: Jane Doe
 Date of Birth: 11/08/1975
 Maternal Age at EDD: 37
 Gestational Age: 11 weeks/0 days
 Maternal Weight: N/A
 Patient ID: P99457
 Medical Record #: M84555
 Collection Kit: 254233-2-N
 Accessioning ID: C47695
 Case File ID: 159466

Test Information

Ordering Physician: Dr. Matthew Goodbirth,
 M.D. (G123456)
 Clinic Information: Natera, Inc.
 Additional Reports: N/A
 Report Date: 02/01/2013
 Samples Collected: 01/31/2013
 Samples Received: 02/01/2013
 Mother Blood

ABOUT THIS SCREEN: Panorama™ is a screening test, not diagnostic. It evaluates genetic information in the maternal blood, which is a mixture of maternal and placental DNA, to determine the chance for specific chromosome abnormalities. The test does NOT tell with certainty if a fetus is affected, and only tests for the conditions ordered by the healthcare provider. A low risk result does not guarantee an unaffected fetus.

FINAL RESULTS SUMMARY: EGG DONOR/SURROGATE
Result
HIGH RISK for Trisomy 21

Fetal Sex
Male

Fetal Fraction
8.3%


This is a screening test only. Genetic counseling and diagnostic testing should be offered to further evaluate these findings.

Panorama analyzes DNA from the placenta. In some cases placental DNA can differ from that of the fetus; therefore, no irreversible decisions should be made based upon results of this screening test alone.

RESULT DETAILS: ANEUPLOIDIES

Condition tested ¹	Result	Risk Before Test ²	Risk After Test ³
Trisomy 21	High Risk	1/152	9/10
Trisomy 18	Low Risk	1/111	<1/10,000
Trisomy 13	Low Risk	1/357	<1/10,000

1. Reporting for Monosomy X, Triploidy, and microdeletion syndromes is not available for egg donor and surrogate pregnancies. Excludes cases with evidence of fetal and/or placental mosaicism. 2. Based on maternal age, gestational age, and/or general population, as applicable. References available upon request. 3. Risk after test for aneuploidy incorporates results from the Panorama algorithm and data from a published study of 17,885 women [Dar et al. Am J Obstet Gynecol. 2014. Nov;211(5):527.e1-27.e17] and are reported as PPV (high risk) and NPV (low risk). Maternal age is utilized in this calculation, however the "risk after test" may not reflect the actual PPV for this patient, as additional risk factors, including but not limited to; results of other screening, ultrasound findings, personal/family history, are not included in the risk assessment.

Approved By:  Susan Zneimer, Ph.D., FACMGG, Laboratory Director

IF THE ORDERING PROVIDER HAS QUESTIONS OR WISHES TO DISCUSS THE RESULTS, PLEASE CONTACT US AT 650-249-9090 #3. Ask for the NIPT genetic counselor on call.

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OVERALL TEST SPECIFICATIONS FOR PANORAMA

The information in the table below relates to the general performance of the test.

Sensitivity is the ability to correctly identify a truly high risk case as high risk. For example, in a group of Trisomy 21 cases, Panorama will correctly identify more than 99% of those cases.

Specificity is the ability to correctly identify an unaffected case as low risk.

Positive Predictive Value is the likelihood the result says high-risk and the fetus is actually affected. For example, when Panorama shows a high-risk result for Trisomy 21, there is a 91% chance that the fetus is affected by Trisomy 21. In other words, 9% of the time, you may get a high-risk result when the fetus is not affected by Trisomy 21.

Negative Predictive Value is the likelihood the result says low-risk and the fetus is truly not affected.

Condition	Sensitivity (95% CI)	Specificity (95% CI)	Positive Predictive Value	Negative Predictive Value
Trisomy 21 ^{1,2,3,4}	>99% (CI 97.8-99.9)	>99% (CI 99.7-100)	91%	>99.99%*
Trisomy 18 ^{1,2,3,4}	98.2% (CI 90.4-99.9)	>99% (CI 99.7-100)	93%	>99.99%*
Trisomy 13 ^{1,2,3,4}	>99% (CI 87.2-100)	>99% (CI 99.8-100)	38%	>99.99%*
Female	>99.9% (CI 99.4-100)	>99.9% (CI 99.5-100)		
Male	>99.9% (CI 99.5-100)	>99.9% (CI 99.4-100)		

- Nicolaides KH et al. Prenat Diagn. 2013 June;33(6):575-9
- Pergament E et al. Obstet Gynecol. 2014 Aug;124(2 Pt 1):210-8
- Ryan A et al. Fetal Diagn Ther. 2016;40(3):219-223
- Dar P et al. Am J Obstet Gynecol. 2014 Nov;211(5):527.e1-527.e17

* Ongoing clinical follow-up is performed to ensure the NPV does not fall below the quoted value but follow up is not obtained for all low risk calls.

Test specifications above are applicable to singleton and monozygotic twin pregnancies only. For additional information, please visit: www.natera.com/panorama-test/test-specs

Testing Methodology: DNA isolated from the maternal blood, which contains placental DNA, is amplified at specific loci using a targeted PCR assay, and sequenced using a high-throughput sequencer. Sequencing data is analyzed using Natera's proprietary algorithm to determine the fetal copy number for chromosomes 13, 18, 21, X, and Y, thereby identifying whole chromosome abnormalities at these locations, and if ordered, the microdeletion panel will identify microdeletions at the specified loci only. If a sample fails to meet the quality threshold, no result will be reported for the specified chromosome(s). The test requires sufficient fetal fraction to produce a result. Fetal fraction is determined using a proprietary algorithm incorporating data from single nucleotide polymorphism-based next-generation sequencing. Estimates of fetal fraction may differ when measured by different laboratories and/or methodologies.

Disclaimers: This test has been validated on women with a singleton, twin or egg donor pregnancy of at least nine weeks gestation. A result will not be available for higher order multiples and multiple gestation pregnancies with an egg donor or surrogate, or bone marrow transplant recipients. Complete test panel is not available for twin gestations and pregnancies achieved with an egg donor or surrogate. For twin pregnancies with a fetal fraction value below the threshold for analysis, a sum of the fetal fractions for both twins will be reported. Findings of unknown significance will not be reported. As this assay is a screening test and not diagnostic, false positives and false negatives can occur. High risk test results need diagnostic confirmation by alternative testing methods. Low risk results do not fully exclude the diagnosis of any of the syndromes nor do they exclude the possibility of other chromosomal abnormalities or birth defects, which are not a part of this test. Potential sources of inaccurate results include, but are not limited to, mosaicism, low fetal fraction, limitations of current diagnostic techniques, or misidentification of samples. This test will not identify all deletions associated with each microdeletion syndrome. This test has been validated on full region deletions only and may be unable to detect smaller deletions. Microdeletion risk score is dependent upon fetal fraction, as deletions on the maternally inherited copy are difficult to identify at lower fetal fractions. Test results should always be interpreted by a clinician in the context of clinical and familial data with the availability of genetic counseling when appropriate. The Panorama prenatal test was developed by Natera, Inc., a laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA). This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA).