

PATIENT INFORMATION

Patient Name: TEST TEST
Date of Birth: 1991-11-15
Estimated Due Date: 2022-04-15
Maternal Age at EDD: 30
Gestational Age: 18 Weeks / 0 Days
Maternal Weight: -
Health Card #: -
Order ID: AUC72
Sample ID: A72
Accessioning ID: 3_PANO_SING_BASIC_LDOR

PROVIDER INFORMATION

Ordering Physician: TEST TEST
Genetic Counsellor: -
Additional Reports: -
Test Requested: Panorama Prenatal Test
Report Date: 2022-03-21
Samples Collected: 2021-11-12
Samples Received: 2021-11-15
Maternal 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 REPORT SUMMARY

Result	Fetal Sex	Fetal Fraction
HIGH RISK for Trisomy 21	Female	5.6%

Genetic counselling and diagnostic testing should be offered to further evaluate these findings.

This is a screening test only. The Panorama risk score reflects analysis of DNA from the placenta. The placental DNA may not accurately reflect the status of the fetus; therefore, no irreversible decisions should be made based upon the results of this screening test alone.

RESULT DETAILS

Condition Tested ¹	Result	Risk Before Test ²	Risk After Test ³
Trisomy 21	HIGH RISK	4/1,000	95/100
Trisomy 18	Low Risk	2/1,000	<1/10,000
Trisomy 13	Low Risk	5/10,000	<1/10,000
Monosomy X	Low Risk	4/1,000	<1/10,000
Triploidy/Vanishing Twin	Low Risk		

1. 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 population study of over 1 million women (2) and are reported as PPVs (high risk) and NPVs (low risk). Maternal age and fetal fraction are utilized in this calculation. *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.


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 of at least 2.8% to produce a result. Fetal fraction refers to the percentage of fetal (placental) DNA in the maternal plasma compared to the amount of maternal DNA. 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.

Condition	Sensitivity (95% CI)	Specificity (95% CI)	Positive Predictive Value	Negative Predictive Value
Trisomy 21 ^{1,2}	>99% (CI 97.8-99.9)	>99% (CI 99.7-100)	95%	>99.99%*
Trisomy 18 ^{1,2}	98.2% (CI 90.4-99.9)	>99% (CI 99.7-100)	91%	>99.99%*
Trisomy 13 ^{1,2}	>99% (CI 87.2-100)	>99% (CI 99.8-100)	68%	>99.99%*
Monosomy X ^{1,2}	94.7% (CI 74.0-99.9)	>99% (CI 99.7-100)	78%	>99.99%*
Triploidy ^{3,4}	>99% (CI 66.4-100)	>99% (CI 99.5-100)	5.3%	>99.99%*
XXX, XXY, XYY ^{5 **}	73.1% (CI 61.0-85.1)	99.9% (CI 99.90-99.99)	86.4%	99.87%
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)		

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 positive and false negatives can occur. High risk test results need diagnostic confirmation by alternative testing methods, such as chorionic villus sampling (CVS) or amniocentesis. 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 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 for deletions of 0.5Mb or greater within the 22q11.2 A-D region. This test has been validated on full region deletions only for 1p36 deletion syndrome, Cri-du-chat syndrome, Prader Willi syndrome and Angelman syndrome and may be unable to detect smaller deletions. Microdeletion risk score may be 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 the clinical and familial data with the availability of genetic counselling when appropriate. The Panorama prenatal test was developed by Natera, Inc., 201 Industrial Road Suite 410, San Carlos, CA 94070., 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).

- Dar P et al. Am J Obstet Gynecol. 2022. doi: https://doi.org/10.1016/j.ajog.2022.01.019
- DiNonno W et al. J Clin Med. 2019. 26;8(9):1311. doi: 10.3390/jcm8091311
- Nicolaides KH et al. Fetal Diagn Ther. 2014. 35(3):212-7. doi: 10.1159/000355655
- Curnow KJ et al. Am J Obstet Gynecol. 2015. 212(1):79.e1-9. doi: 1.1016/j.ajog.2014.10.012
- Martin K et al. ISPD 25th International Conference: June, 2021

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

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