Patient Information
Patient Name:
Date of Birth:
Maternal Age at EDD:
Gestational Age:
Maternal Weight:
Collection Kit:
Case File ID:

Test Information
Ordering Physician:
Clinic Information:

Additional Reports:
Report Date:
Samples Collected:
Samples Received:

natera™ | Panorama™ Next-generation NIPT

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

Result	*Fetal Sex*	*Fetal Fraction(s)*
LOW RISK	**Female**	**11.2%**

RESULT DETAILS: ANEUPLOIDIES

Condition Tested [1]	*Result*	*Risk Before Test* [2]	*Risk After Test* [3]
Trisomy 21	Low Risk	1/140	<1/10,000
Trisomy 18	Low Risk	1/284	<1/10,000
Trisomy 13	Low Risk	1/905	<1/10,000
Monosomy X	Low Risk	1/255	<1/10,000
Triploidy	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 [DiNonno et al.J.Clin.Med.2019.Aug 26; 8(9):1311.doi:10.3390/jcm8091311] and are reported as PPVs (high risk) and NPVs (low risk). Maternal age and fetal fraction are utilized in this calculation; however, the "risk after test" may not reflect the actual PPVs for this patient, as additional risk factors, including but not limited to: results of other screening, ultrasound findings, and personal/family history, are not included in the risk assessment.

Testing Methodology: DNA isolated from maternal blood, which contains placental DNA, is amplified at specific loci using a targeted PCR assay and is sequenced using a high-throughput sequencer. Fetal fraction is determined using a proprietary algorithm incorporating data from single nucleotide polymorphism-based (SNP-based) next-generation sequencing [Pergament E et al. Obstet Gynecol. 2014 Aug;124(2 Pt 1):210-8]. If there is sufficient fetal fraction, sequencing data is analyzed using a proprietary SNP-based algorithm to determine the fetal copy number for chromosomes 13, 18, 21, X and Y. If ordered, specific microdeletions will be evaluated using similar methodology [Wapner RJ et al. Am J Obstet Gynecol. 2015 Mar;212(3):332.e1-9]. If the fetal fraction is insufficient, fetal signal enhancement and/or an additional algorithm to determine whether there is an increased risk for triploidy, trisomy 18, and trisomy 13 may be utilized [McKanna et al. Ultrasound Obstet Gynecol 2019; 53:73-79]. However, some samples will not produce a result due to failure to meet the necessary quality thresholds.

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. 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 for deletions ≥0.5 Mb 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 clinical and familial data with the availability of genetic counseling when appropriate.

Reviewed By: Wenbo Xu, M.D., Ph.D., FACMG, Senior Laboratory Director

CLIA Laboratory Director: J. Dianne Keen-Kim, Ph.D., FACMG

IF THE ORDERING PROVIDER HAS QUESTIONS OR WISHES TO DISCUSS THE RESULTS, PLEASE CONTACT US AT 844-778-4700, option 2. 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 (PPV) 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 95% chance that the fetus is affected by Trisomy 21. In other words, 5% of the time, you may get a high-risk result when the fetus is not affected by Trisomy 21.

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

Condition	*Sensitivity (95% CI)*	*Specificity (95% CI)*	*PPV*	*NPV*
Trisomy 21 [1,2]	99.0% (CI 97.1-100)	>99% (CI 99.93-99.99)	95%	>99.99% *
Trisomy 18 [1,2]	94.1% (CI 82.9-100)	>99% (CI 99.96-100)	91%	>99.99% *
Trisomy 13 [1,2]	>99% (CI 73.5-100)	>99% (CI 99.6-100)	68%	>99.99% *
Monosomy X [2,3]	94.7% (CI 74.0-99.9)	>99% (CI 99.7-100)	78%	>99.99% *
Triploidy [4,5]	>99% (CI 66.4-100)	>99% (CI 99.5-100)	7.5%	>99.99% *
XXX, XXY, XYY [6] **	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)		

1 Dar P et al. Am J Obstet Gynecol. 2022. doi: https://doi.org/10.1016/j.ajog.2022.01.019
2 DiNonno W et al. J Clin Med. 2019. 26;8(9):1311. doi: https://doi.org/10.3390/jcm8091311
3 Martin et al. ISUOG World Congress 2022: September, 2022
4 Nicolaides KH et al. Fetal Diagn Ther. 2014. 35;(3):212-7. doi: https://doi.org/10.1159/000355655
5 Kantor et al. Prenat Diagn. 2022. 42;(8): 994-999. Doi: 10.1002/pd.6169
6 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 trisomies are only reported when clearly identified. At lower fetal fractions, identification of sex chromosome trisomies may not be possible.

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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Understanding Your Results

Low risk

What do my results mean?

Your results show that there is a low risk to your baby for the chromosome conditions listed on the report. These results cannot tell with certainty that your baby does not have these conditions. The specific chance that your baby has each condition can be found on page 1 of your test report under "Risk after test." Most people with low risk results do not choose to have further testing for these chromosome conditions.[1]

What should I do next?

You should talk to your healthcare provider about these results and continue with the prenatal care recommended for you. Although the chance that your baby has these chromosome conditions is low, you have the option of doing further testing during pregnancy to find out for sure if your baby has these conditions. These tests are called CVS (chorionic villus sampling) and amniocentesis, and both have a small risk of miscarriage. Please talk to your healthcare provider if you have questions about further testing.

NEVA* is always available to help you learn about your results. You can connect with Natera's Educational Virtual Assistant (NEVA) by logging into the patient portal at my.natera.com.

*NEVA is available only in the United States.

If you would like to discuss your results with a Natera genetic counselor, you can schedule a free information session at naterasession.com, by texting SESSION to 636363*, or by calling +1.877.476.4743. Please select **Panorama Non-Invasive Prenatal Chromosome Screening Post-Test** as the appointment type.

You can find a local genetic counselor through the National Society of Genetic Counselors at findageneticcounselor.nsgc.org.

*Text scheduling is available only in the United States.

1. van Schendel RV, et al; Dutch NIPT Consortium. Women's Experience with Non-Invasive Prenatal Testing and Emotional Well-being and Satisfaction after Test-Results. J Genet Couns. 2017 Dec;26(6):1348-1356. doi: 10.1007/s10897-017-0118-3. Epub 2017 Jun 30. PMID: 28667567; PMCID: PMC5672853.

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