

Patient Informed Consent for Panorama™ Non-Invasive Prenatal Test (NIPT)



Decisions about prenatal screening options should be made with your physician and results should be interpreted in context of other clinical factors specific to you and your pregnancy. You may be referred to a genetic counsellor or high risk pregnancy service as appropriate.

Test Description: Panorama™ was developed by Natera Inc., a laboratory certified under the Clinical Laboratory Improvement Act (CLIA). Two tubes of blood are required. All testing is performed by LifeLabs Genetics in Toronto ON in licensed, accredited, and regulated facilities. The Panorama™ Non-Invasive Prenatal Test (NIPT) screens for chromosome abnormalities in the fetus. It detects specific whole extra or missing chromosomes, fetal sex, microdeletions (loss of specific small regions of chromosomes), and whether twins are identical or fraternal (zygosity). Panorama can be performed on a sample of maternal blood any time after the start of 9 weeks of pregnancy. From the blood specimen, fragments of DNA from both the mother and the placenta are extracted and tested. The DNA fragments from the placenta are not directly from the fetus; the placental DNA provides the same result as true fetal DNA in ~98% of all pregnancies. Panorama™ has not been cleared or approved by the U.S. Food and Drug Administration or Health Canada.

Test Options: The test screens only for the chromosome abnormalities listed below:

Test Options*		Singleton (1 baby)	Identical twins (Monozygotic)	Fraternal twins (Dizygotic)	Egg donor (Singleton only)
Panorama™ Prenatal Test	Trisomies 21, 18, and 13	√	√	√	√
	Triploidy (3 copies of every chromosome)	√	X	X	X
	Sex chromosome abnormalities (including Monosomy X)**	√	√	X	X
Add 22q deletion syndrome	22q11.2 deletion syndrome	√	✓	X	X
Add Microdeletion Extended Panel	Microdeletions syndromes: Cri-du-chat, 1p36 deletion, Angelman, Prader-Willi, 22q11.2 deletion syndrome	√	X	X	X
Add Fetal Sex	Optional	√	√	√	√

^{*} For more information about the disorders tested, visit https://www.lifelabsgenetics.com/product/non-invasive-prenatal-testing/

Results: Your test results will be sent to the healthcare provider who ordered the test 7 to 10 days from sample receipt at the testing lab.

- A low risk result means a reduced chance that your baby has the chromosome abnormalities for which screening was done.
- A **high risk** result means that there is an **increased chance** your baby has a chromosome abnormality identified. Follow-up diagnostic testing is recommended. Your healthcare provider will explain the test results and optional/additional follow-up steps. LifeLabs may contact your healthcare provider to obtain follow-up diagnostic information to ensure quality and accuracy in reporting.
- A small proportion of samples do not provide conclusive results from the first specimen. In this case, LifeLabs will call your healthcare provider and you may be asked to provide a repeat blood sample; there is no charge for a repeat test. In rare cases where no result is possible, if you have self-paid for the NIPT you will receive a full refund. Refunds are not issued for partial or high risk triploidy/vanishing twin results.
- Panorama™ is not a diagnostic test. Decisions about your pregnancy should never be made based on these screening results alone, as they neither confirm nor rule out the presence of a chromosome abnormality in the fetus.

Limitations: No screening test is 100% accurate. Although the Panorama™ test will detect the majority of pregnancies in which the fetus has one of the above listed chromosome abnormalities, it cannot detect all pregnancies with these conditions. Results do not rule out other types of fetal chromosome abnormalities, genetic disorders, birth defects, or other complications in your fetus or pregnancy. Inaccurate test results or a failure to obtain test results may occur due to biological or technical issues.

This test cannot be performed on patients carrying more than two babies (triplets or more), on egg donor pregnancies with multiple babies, on pregnancies with a vanishing twin, or on pregnancies in which the mother had a prior bone marrow/solid organ transplant.

About 1 to 2% of all pregnancies have confined placental mosaicism, which means that the DNA fragments analyzed from the placenta may not match the fetal DNA for the chromosomes screened.

For microdeletion testing: testing may show that you are at high risk for carrying a 22q11.2 deletion. If so, the Panorama™ report will state that you have a 1 in 2 or 50% chance for an affected pregnancy (as fetal status cannot be determined in this case). Women who do not wish to risk finding out whether they carry this microdeletion should consider opting out of the microdeletion portion of the screening test. If the mother of the pregnancy is found to be a carrier of one of the other microdeletions on this panel, this screen will not be able to return results on the fetus. If you know you carry one of the microdeletions on this screen, it is recommended that you use another form of testing if you wish to determine the presence or absence of that microdeletion in your fetus. If the percentage of fetal (placental) DNA in the sample is below 7%, screening for Angelman syndrome will not be performed and the results will be reported as "risk unchanged". A redraw will not be recommended and, if so chosen by the ordering healthcare provider, the cost will be borne by the patient.

Confidential Reporting Practices: LifeLabs and Natera comply with applicable American and Canadian privacy laws. Test results will be reported to the ordering healthcare provider(s) or genetic counsellor(s) involved. You must contact your provider to obtain the results of the test. Additionally, your personal information could be released to others, as permitted or required by law (e.g. the BORN registry).

Cancellation, Disposition, or Retention of Samples: If a test is cancelled prior to test set-up, LifeLabs will send a cancellation report free of charge. Once testing is initiated, the full price of the analysis will be charged. LifeLabs may also keep your leftover de-identified samples for ongoing test development. You and your heirs will not receive any payments, benefits, or rights to any resulting products or discoveries. If you do not want your de-identified sample and/or data used for the purposes listed above, you may send a request in writing to LifeLabs at 175 Galaxy Boulevard, Toronto ON, M9W 0C9 within 60 days after test results have been issued and your sample will be destroyed. You may also make this request by email to ask.genetics@lifelabs.com and indicate "Sample Retention" in the subject line.

^{**} Sex chromosome trisomies (XXY, XXX, and XYY) will also be reported, if identified