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

PRENATAL SCREENING
DÉPISTAGE PRÉNATAL
ONTARIO

1-844-363-4357
Ask.Genetics@LifeLabs.com

1-833-351-6490
PSO@bornontario.ca

Decisions about prenatal screening options should be made with your healthcare provider 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. On rare occasion, your sample may be referred out of province or country to complete testing. The Panorama™ Non-Invasive Prenatal Test (NIPT) screens for chromosome abnormalities in the fetus. It detects specific whole extra or missing chromosomes, fetal sex, and whether twins are identical or fraternal (zygosity). Panorama™ can be performed on a sample of maternal/pregnant individual's blood any time after 9 weeks of pregnancy. From the blood specimen, fragments of DNA from both the mother/pregnant individual 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
Add Sex Chromosome Abnormalities (including Monosomy X)**	Optional	√	√	X	X
Add Fetal Sex	Optional	√	√	√	√

* For more information about the disorders tested, visit https://www.lifelabsgenetics.com/product/non-invasive-prenatal-testing/
**Sex chromosome abnormalities (Monosomy X, XXY, XXX and XYY) will be reported if selected. Identification of a sex chromosome abnormality will also identify the sex of the fetus even if fetal sex is not opted in. By opting out of sex chromosome analysis, any abnormal/atypical findings on the sex chromosomes will not be reported.

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. Follow-up diagnostic testing is recommended. Your healthcare provider will explain the test results and optional/additional follow-up steps. If you have consented, 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/atypical finding is possible, your healthcare provider will be contacted to discuss recommendations for follow-up.
- **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/pregnant individual 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.

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. In alignment with accreditation standards, LifeLabs retains residual DNA samples from prenatal testing as well as downstream sequencing and PCR products for a period of up to two years. 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.