



Publicly Funded Panorama™ Non-Invasive Prenatal Screening (NIPT)



PRENATAL SCREENING
DÉPISTAGE PRÉNATAL
ONTARIO

1-844-363-4357

Ask.Genetics@LifeLabs.com

MUST INCLUDE PSO eligibility checklist

1-833-351-6490

PSO@bornontario.ca

All fields are required; incomplete requisitions may result in testing delays

Testing performed in Canada

ORDERING HEALTHCARE PROVIDER	
Billing #	_____
Name	_____
Address	_____
	No Street

	City Province Postal Code
Telephone	_____ Fax _____
<p>Confirmation of patient consent: I confirm that this patient has been informed about the details associated with the genetic test(s) ordered below including its risks, benefits and limitations, and has given consent to testing as may be required by applicable law.</p>	
Healthcare Professional Signature _____	

LIFELABS LABELS

COPY TO HEALTHCARE PROVIDER	
<input type="checkbox"/> Other Healthcare Provider	<input type="checkbox"/> Genetic Counsellor
Billing #	_____
Name	_____
Address	_____
	No Street

	City Province Postal Code
Telephone	_____ Fax _____

PATIENT INFORMATION	
Last Name	_____
First Name	_____
Date of Birth	_____ MM / DD / YYYY
Health Card	_____
Address	_____
	No Street

	City Province Postal Code
Telephone	_____
Email	_____

REQUIRED CLINICAL INFORMATION	
Due Date	_____
Must be at least 9 weeks' gestation Month dd, yyyy ; e.g. July 6, 2022	
Pregnant Individual's weight	_____ <input type="checkbox"/> kg <input type="checkbox"/> lbs

TEST REQUESTED	COST	LL CODE
<input checked="" type="checkbox"/> Panorama™ Prenatal Test	No cost to patient	5518

Ongoing Twin Pregnancy?	<input type="checkbox"/> YES <input type="checkbox"/> NO	If yes: <input type="checkbox"/> Monochorionic <input type="checkbox"/> Dichorionic <input type="checkbox"/> Unknown	*Panorama™ does NOT accept twins conceived using a surrogate or egg donor, high order multiples (>2) or vanishing twins
Vanishing Twin	<input type="checkbox"/> YES* (Testing not possible) <input type="checkbox"/> NO		
IVF Pregnancy	<input type="checkbox"/> YES <input type="checkbox"/> NO	If yes, egg donor is: <input type="checkbox"/> SELF <input type="checkbox"/> NON-SELF	Egg age at retrieval: _____ years

Additional options (no cost):

Fetal Sex

Sex chromosome aneuploidies¹ (including Monosomy X)

1. Singletons and twins (identical) only

COLLECTION INFORMATION	
Date & Time	_____
Blood Collected	_____ MM / DD / YYYY _____ HH / MM
Collector Name	_____

PATIENT CONSENT	
<p>I have read or have had read to me the informed consent information about the Panorama™ Non-Invasive Prenatal Test (NIPT) (on reverse). I have had the opportunity to ask my healthcare provider about this test, including reliability of test results, risks, and alternatives prior to giving my informed consent. I understand that my personal health information and my blood samples will be sent to LifeLabs Genetics in Toronto, ON for testing. On rare occasion, my sample may be referred out of province or country to complete testing. I request and authorize LifeLabs to test my sample(s) for the chromosome conditions listed above as indicated on my test requisition. I acknowledge that LifeLabs will send the results to my ordering healthcare provider and other providers involved in my care. I understand that in rare instances, a high risk or no result may lead to investigations and diagnoses relating to my own health. If LifeLabs is asked to disclose information about me for any reason other than as required to complete this testing, I know that LifeLabs will ask for my consent. I understand that I must sign this consent form if I want testing performed, and that LifeLabs will retain a copy of this form in accordance with standard operational requirements.</p>	
<p>If you have questions about Panorama NIPT, pre-test counselling is available. Please contact our Genetic Counsellors at 1-844-363-4357.</p>	
Patient Name	_____
Patient Signature	_____ MM / DD / YYYY



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PSO eligibility checklist

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Eligibility Criteria for publicly funded Non-Invasive Prenatal Testing (NIPT)

Publicly funded NIPT can only be performed for singleton pregnancies and viable twin pregnancies. Publicly funded NIPT cannot be performed for higher order multiples nor pregnancies with a demise of a co-twin ("vanishing twin"). The following criteria for publicly funded NIPT have been established by Prenatal Screening Ontario. Please confirm that the pregnant individual in your care has a valid OHIP card and meets at least one of the following criteria by checking the appropriate boxes. Ordering provider on page 1 must match provider information/signature on page 2.

Note: If your patient does not currently meet the publicly funded eligibility criteria, private-pay NIPT is available. However, your patient may become eligible for publicly funded NIPT later in the pregnancy; reimbursement for private-pay NIPT can only be provided if your patient qualified for publicly funded NIPT at the time of blood draw. For more information on private-pay NIPT, visit lifelabsgenetics.com/product/non-invasive-prenatal-testing/.

PATIENT NAME _____ PATIENT HEALTH CARD _____

CATEGORY I

Select all that apply:

- A multiple marker screening test (e.g. eFTS/STS) positive for aneuploidy.
- The age of the pregnant individual will be 40 years or older at the expected date of delivery.
In the context of *in vitro* fertilization, this is defined as the oocyte (egg) age at retrieval being 39 or older (whether self-provided or donor oocyte).
- Previous pregnancy or child with trisomy 21, 18 or 13.
- Twin pregnancy with ultrasound demonstration of fetal heart activity in both fetuses.
- Increased nuchal translucency (NT) $\geq 3.5\text{mm}^*$.

*NT $\geq 3.5\text{mm}$ can be associated with genetic conditions and fetal congenital anomalies **not** detected by NIPT. **Prompt referral to a Genetics / Maternal Fetal Medicine (MFM) specialist is indicated regardless of NIPT order or result.**

Healthcare Professional Signature _____ Date _____ Billing # _____

CATEGORY II

The following situations require specialist consultation to determine whether NIPT is warranted and to provide appropriate pre- and post-test counselling.

Select all that apply (must be completed by a Genetics or Maternal Fetal Medicine (MFM) specialist):

Risk indicators for trisomy 21, trisomy 18, trisomy 13 (select all that apply):

- Fetal congenital anomalies identified on ultrasound, which are suggestive of trisomy 21, 18 or 13.

Specify: _____

- Cystic hygroma
- Isolated soft marker with moderate likelihood ratio for trisomy 21 (must check one or more):
 - Increased nuchal fold ($\geq 6\text{mm}$)
 - Absent/Hypoplastic nasal bone
- Multiple soft markers with low likelihood ratio for trisomy 21 (must check two or more):

<input type="checkbox"/>	Aberrant right subclavian artery	<input type="checkbox"/>	Intracardiac echogenic focus / foci	<input type="checkbox"/>	Short humerus
<input type="checkbox"/>	Clinodactyly	<input type="checkbox"/>	Pyelectasis	<input type="checkbox"/>	Ventriculomegaly
<input type="checkbox"/>	Hyperechogenic bowel	<input type="checkbox"/>	Short femur	<input type="checkbox"/>	

- Other indication, specify: _____

NIPT for sex chromosome determination (at least one of the following):

- Risk of a sex-linked condition
- Ultrasound findings suggestive of a sex chromosome aneuploidy
- Ultrasound findings suggestive of a difference/disorder of sex development (DSD)

Genetics or MFM Specialist's Name _____ Billing # _____

Specialist Signature _____ Date _____

Genetics or MFM Centre _____

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)	✓	✗	✗	✗
Add Sex Chromosome Abnormalities (including Monosomy X)**	Optional	✓	✓	✗	✗
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.