Panorama™ Prenatal Screening Test
Funded by MOH

Must include MOH CHECKLIST

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

Certified Lab

natera | Panorama™ Next-generation NIPT

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

ORDERING HEALTHCARE PROVIDER

Billing # _____

Name _____

Address _____
No Street

_____
City Province Postal Code

Telephone _____ Fax _____

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.

Healthcare Professional Signature _____

COPY TO HEALTHCARE PROVIDER

☐ Other Healthcare Provider ☐ Genetic Counsellor

Billing # _____

Name _____

Address _____
No Street

_____
City Province Postal Code

Telephone _____ Fax _____

REQUIRED CLINICAL INFORMATION

Due Date _____

Must be at least 9 weeks gestation Month dd, yyyy ; e.g. July 6, 2022

Patient's weight _____ ☐ kg ☐ lbs

Ongoing Twin Pregnancy? ☐ YES ☐ NO **If yes:** ☐ Monochorionic ☐ Dichorionic ☐ Unknown

Vanishing Twin ☐ YES ☐ NO

Panorama™ does NOT accept twins conceived using a surrogate or egg donor, high order multiples (>2) or vanishing twins

IVF Pregnancy ☐ YES ☐ NO **If yes,** egg donor is: ☐ SELF ☐ NON-SELF Egg age at retrieval: _____ years

COLLECTION INFORMATION

Date & Time Blood Collected _____ MM / DD / YYYY _____ HH / MM

Collector Name _____

Panorama_PP Eng_JAN2023

LIFELABS LABELS

PATIENT INFORMATION

Last Name _____

First Name _____

Date of Birth _____
MM / DD / YYYY

Health Card* _____

Address _____
No Street

_____
City Province Postal Code

Telephone _____

Email _____

TEST REQUESTED (choose one)	COST	LL CODE
☐ **Panorama™ Prenatal Test**	No cost to patient	5518
☐ **Panorama™ Prenatal Test + 22q11.2 deletion**	$100	5518 + 3037
☐ **Panorama™ Prenatal Test + Microdeletion Extended Panel (5)**	$245	5518 + 3071

OPTIONS Choose none, one, or both

☐ **INCLUDE the sex of the baby on the report** (no cost)

☐ **DO NOT INCLUDE results related to sex chromosome aneuploidies** (no cost)

PATIENT CONSENT

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. On rare occasion, my sample may be referred to another province or the United States. 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. In the event of a high risk or no result, I acknowledge that LifeLabs may contact my healthcare provider to obtain follow- up diagnostic information to ensure quality and accuracy in reporting. 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.

Patient Name _____

Signature _____ _____
MM / DD / YYYY

Panorama™ Prenatal Screening Test Funded by MOH Checklist

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The Provincial Council for Maternal and Child Health (PCMCH) has recommended specific indications for NIPT funding.
Please complete either Category I or II and attach to page 1 of the Panorama™ Funded by MOH requisition. Confirm that your patient meets the following indications by checking the appropriate boxes. Ordering physician on page 1 must match physician information/signature on page 2 CHECKLIST.

PATIENT NAME _____ PATIENT HEALTH CARD _____

CATEGORY I

For investigation of trisomy 21, 18 or 13 ONLY, with appropriate pre-test counselling including a discussion of the limitations of the test.

- ☐ A maternal multiple marker screening test (eg. eFTS/MSS/Quad etc.) positive for aneuploidy.
- ☐ Women of advanced maternal age, defined as ≥ 40 years of age at expected time of delivery.
  In the context of in vitro fertilization, the maternal age is guided by the age of egg at retrieval (whether own egg or donor egg)
- ☐ Fetal nuchal translucency (NT) ≥ 3.5mm
- ☐ Previous pregnancy or child with Trisomy 21, 18, or 13
- ☐ Twins with ultrasound demonstration of fetal heart activity in both

Healthcare professional signature _____ Date: _____ Billing # _____

CATEGORY II

There are several situations where additional specialist consultation is necessary to determine whether NIPT is warranted and to provide appropriate pre and post- test counselling.
NIPT funding for the following criteria must be submitted by a genetics or maternal fetal medicine (MFM) specialist.

Risk indicators:

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

Specify _____

OR:

B/ ☐ Risk of aneuploidy for trisomy 21, 18 or 13 greater than that of a positive maternal multiple marker screen.

- Women less than 40 years of age at expected date of delivery must have at least one other risk factor noted.
- The risk of aneuploidy can be calculated by including any combination of risk indicators including soft markers, biochemistry, maternal age, etc.

Please indicate all risk factors present

☐ Soft markers (check all that apply):

☐	Absent nasal bone	☐	Hyperechogenic bowel	☐	Intracardiac echogenic focus / foci
☐	Choroid plexus cysts	☐	Hypoplastic nasal bone	☐	Short femur
☐	Clinodactyly	☐	Increased nuchal fold / edema	☐	Short humerus
☐	Cystic hygroma	☐	Increased nuchal translucency	☐	Ventriculomegaly

☐ Maternal age: _____

☐ Other, specify: _____

OR:

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

- ☐ Risk of a sex-limited disorder
- ☐ Ultrasound findings suggestive of a sex chromosome aneuploidy
- ☐ Ultrasound findings suggestive of a disorder of sex determination (DSD)

Genetics or MFM Specialist's Name _____ Billing # _____

Specialist Signature _____ Date _____

Genetics or MFM Centre _____

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

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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. On rare occasion, my sample may be referred to another province or the United States. 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 pregnant individual's blood any time after the start of 9 weeks of pregnancy. From the blood specimen, fragments of DNA from both the 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
	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/

**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.

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 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.

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). Pregnant individuals 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 pregnant individual 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 detemine 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.