Is Panorama™ right for me?

IF YOU WOULD LIKE TO KNOW whether your baby is at risk for certain genetic conditions, Panorama may be the right option for you. The first step is to talk with your healthcare provider.

Some women have a higher chance of their baby being affected with certain chromosome conditions, like Down syndrome, especially if they:

- Are over the age of 35
- Have certain family histories
- Have abnormal ultrasound findings
- Have abnormal blood test results

The likelihood of having a baby with a microdeletion syndrome is the same for all pregnancies, regardless of age.

Panorama is designed for all pregnant women, regardless of age. We accept samples from:

- Singleton pregnancies
- Twin pregnancies
- Pregnancies that are using an egg donor or surrogate

Unfortunately, we cannot accept samples from women who are bone marrow transplant recipients, women with pregnancies where there has been a vanishing twin, or women with twin pregnancies who conceived using an egg donor or surrogate.

When will I get my Panorama™ results?

Your healthcare provider will get your results back in 7-10 calendar days from receipt of your sample at our testing laboratory.

Visit www.lifelabsgenetics.com to find out more about getting tested

START THE CONVERSATION

If you are interested in learning more, speak to your healthcare practitioner. They may choose to refer you to a genetics professional in your area. A genetics professional – either a genetic counsellor or a medical geneticist - can discuss genetic conditions in more detail, tell you about follow-up testing to confirm or rule out genetic conditions in your baby, and answer any questions you may have about your results.

Additional Resources

Canadian Organization for Rare Disorders (CORD)
www.raredisorders.ca

Canadian Directory of Genetic Support Groups
www.lhsc.on.ca/Patients_Families_Visitors/Genetic_Support_Directory/index.htm

Canadian Down Syndrome Society
www.cdss.ca

Chromosome 22 Central
www.c22c.org

Canadian Association of Genetic Counsellors
www.cagc-accg.ca

Genetics Education Canada - Knowledge Organization
www.geneticseducation.ca

[1] Benn, P. Non-invasive prenatal testing using cell free DNA in maternal plasma: recent developments and future prospects. J Clin Med, 2014; 3:537-565.

[2] Pergament E et al. Single-nucleotide polymorphism-based noninvasive prenatal screening in a high-risk and low-risk cohort. Obstet & Gynecol 2014; 124(2 Pt 1): 210-218.

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

LifeLabs GENETICS™

V.2 | JAN 2018 PANORAMA™ PATIENT PAMPHLET

Panorama™ Prenatal Screen

Non-invasive DNA screening that lets you know more about your baby's health

LifeLabs GENETICS™ | panorama™ NEXT GENERATION NIPT

What is Panorama™?

Panorama is a non-invasive test performed through a simple blood draw from the mother's arm. This test can look at the baby's DNA to see if there is evidence of genetic conditions that could affect the baby's health.

Chromosome conditions tested:

- Trisomy 21
- Trisomy 18
- Trisomy 13
- Triploidy
- Monosomy X
- Sex-chromosome aneuploidies
- Microdeletions
- Fetal sex (optional)

Timing:	≥ 9 weeks
Detection of Down syndrome:	>99%
False positive rate for Down syndrome:	<1%
Risk of miscarriage:	None

Panorama always screens for the extra or missing chromosomes listed above. Screening for fetal sex and/or microdeletions are optional. Unlike the more common genetic conditions (ex: Down syndrome) that occur more frequently in mothers who are 35 years and older, microdeletions occur in pregnancies at the same rate, regardless of age.

What are Microdeletions?

A small, missing piece of a chromosome is called a microdeletion. Panorama screens for five microdeletion syndromes associated with serious health and developmental problems:

- 22q11.2 deletion (DiGeorge) syndrome
- 1p36 deletion syndrome
- Angelman syndrome
- Prader-Willi syndrome
- Cri-du-chat syndrome

What do Panorama™ results tell me?

Panorama gives you a personalized risk score and tells you if your baby is at high or low risk for the conditions it screens for.

LOW RISK RESULT

A low risk result indicates that it is unlikely that your baby is affected by one of the conditions on the Panorama panel. Note, however, that a low risk result does not guarantee a healthy pregnancy, as Panorama is not a diagnostic test and only screens for certain conditions.

HIGH RISK RESULT

A high risk result means that there is an increased risk that your baby has the condition, but it is not certain. Invasive testing during the pregnancy, such as amniocentesis (amnio) or chorionic villus sampling (CVS), or testing after the baby is born, can tell you for certain if the baby has the condition. Speak with your healthcare provider about your follow-up options.

NO RESULT

In a small percentage of cases, Panorama may not be able to obtain sufficient information from your blood sample to determine an accurate result. If this occurs, a second blood sample may be requested.

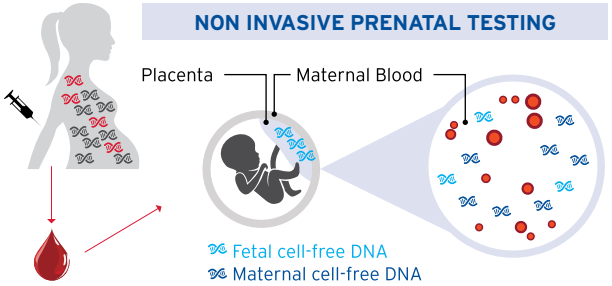
When can I get Panorama™?

You can have this test as early as 9 weeks gestation.

Other NIPTs cannot tell the difference between mom and baby's DNA.

Panorama™ can!

Because of its unique technology, Panorama is the only NIPT that can distinguish between the mom's DNA and the baby's DNA from the placenta. This enables Panorama to be a highly accurate screen.



How is Panorama™ different?

FEWER FALSE POSITIVES

Because Panorama analyzes the baby's DNA separately, it has a lower false positive and negative rate than other NIPTs.

HIGHEST FETAL SEX ACCURACY

Panorama has the highest reported accuracy in determining the fetal sex[2], and reporting is optional.

TRIPLOIDY

Panorama is the only NIPT that can detect triploidy, a severe chromosomal abnormality that can result in serious pregnancy complications if unmonitored.

ZYGOSITY

Panorama is the only NIPT that can determine zygosity (fraternal or identical twins).

LifeLabs GENETICS®

Panorama™ Private Pay

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panorama™ natera prenatal screen

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.

Physician 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 MM / DD / YYYY

Maternity 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

Indication: ☐ Abnormal serum screen ☐ Ultrasound findings ☐ Pregnancy history ☐ Family history ☐ Other: _____

COLLECTION INFORMATION

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

Collector Name _____

LIFELABS LABELS

PATIENT INFORMATION

Last Name _____

First Name _____

Date of Birth _____
MM / DD / YYYY

Address _____
No Street

_____
City Province Postal Code

Telephone _____

TEST REQUESTED	COST	LL CODE	
☐ **Panorama™ Prenatal Test**	$550	5517	NIP
☐ **Panorama™ Prenatal Test + 22q11.2 deletion**	$745	5517 + 3037	22Q
☐ **Panorama™ Prenatal Test + Microdeletion Extended Panel (5)**	$795	5517 + 3071	MD5

☐ **YES, include the sex of the baby on the report** (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. 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. 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 Signature _____ _____
MM / DD / YYYY

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/

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

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 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.