

Launch of the Panorama Non-Invasive Prenatal Test (NIPT) in Canada

Frequently Asked Questions

What is happening?

On October 5, 2015 LifeLabs Genetics began performing the Panorama Non-Invasive Prenatal Test (NIPT) at its genetics laboratory in Toronto. LifeLabs is the first Canadian laboratory to perform NIPT in Canada. Pregnant women, their families and their healthcare professionals will receive information about their fetus faster and with more accuracy than with existing pregnancy screening tests and at less risk than the alternative, more invasive tests.

Why is this important?

- By conducting the testing in Canada, LifeLabs is:
 - Providing better and faster access to critical health information for Canadian women and their families
 - Improving the overall experience and safety for women through a non-invasive blood test
 - Delivering material cost savings to Ontario which we estimate in the range of 40% per test
 - Attracting, developing and retaining a highly skilled workforce in genetic testing – in Ontario
 - Creating a ‘hub of excellence’ in Ontario for one of the fastest growing and actively anticipated advancements in healthcare delivery in many years.

What is Panorama NIPT?

Panorama NIPT is a safe way for expectant mothers to learn about the health of their baby without an invasive diagnostic procedure. It also delivers the most accurate results of any prenatal screening test.

Panorama uses a simple blood test to examine fetal DNA circulating in the mother’s blood to determine whether there are any chromosome abnormalities, including trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome), trisomy 13 (Patau syndrome), monosomy X (Turner syndrome), and triploidy. Panorama also screens for five clinically relevant conditions that are the result of missing pieces of DNA on specific chromosomes (referred to as ‘microdeletions’). (See more information under ‘Diseases’)

The test can be performed as early as nine weeks into a pregnancy without risk to the mother or the fetus. The test has a false positive rate of less than 1%. By comparison, the standard maternal serum screening has a 5% false positive rate.

LifeLabs provided access to NIPT prior to October 5th, so what changed?

LifeLabs has been a distributor of the Panorama NIPT in Canada since September 2013. The significant change is that now LifeLabs is the first lab to perform this or any other NIPT in Canada at our genetics laboratory in Toronto (using Natera technology).

By performing testing in Canada, LifeLabs is able to offer the test at greater value for money to taxpayers and individuals, and deliver results faster.

Is Panorama covered by provincial healthcare plans?

In Ontario, the Ministry of Health and Long-Term Care covers the cost of performing NIPT testing at LifeLabs for expectant mothers who are considered high-risk and meet one of the following criteria:

- 40 years of age or older at the time of delivery
- Positive maternal serum screen results
- Nuchal translucency (NT) \geq 3.5mm
- Previous pregnancy with a chromosome abnormality

(OHIP does not cover the cost of microdeletions)

- Additional criteria may also be considered for patients seen by a genetics or maternal fetal medicine (MFM) specialist.

Now that NIPT is covered by OHIP, how does that change how healthcare providers order the test?

- Starting October 5, 2015 Ontario doctors will complete a simple checklist to accompany the requisition instead of a much more complicated process when the doctor would need to apply for out of country funding to have the test performed.
- Healthcare providers who want more information about ordering Panorama should visit www.LifeLabsGenetics.com or contact LifeLabs Genetics at 1-844-363-4357 or Ask.Genetics@LifeLabs.com.

How much does Panorama cost for those who do not live in Ontario or who do not meet the criteria for coverage in Ontario?

- Any woman in Canada can have NIPT performed now by LifeLabs in our genetics lab. We are licensed to deliver this test for any patient in Canada.
- For women who do not meet the Ontario criteria for funding or live in other provinces, the cost of the test is approximately \$550 CAD.
- Some private insurance plans may cover this test and women should check with their insurer.
- **Microdeletion testing:**
 - Microdeletion testing costs between \$195 and \$245 depending on which test is chosen at the recommendation of a woman's doctor. Microdeletion is not covered by OHIP in Ontario.
- Women should check with their private insurer for potential coverage.

How much is the Ontario government saving as a result of this change?

By performing the NIPT test in Canada, the Ontario government will see an estimated savings of over 40 per cent per test.

Who is this test recommended for?

Panorama is a recommended screening test for women at increased risk of chromosome problems in the fetus. Indications for an increased risk include:

- 35 years of age or older
- A positive maternal serum screen result
- An ultrasound abnormality suggestive of a fetal chromosome problem
- A previous pregnancy with a chromosome abnormality
- Personal history of a chromosome abnormality

Leading professional associations such as the Society of Obstetricians and Gynaecologists of Canada (SOGC) and the American College of Obstetricians and Gynecologists (ACOG) have recommended that NIPT be offered as a test option to women with increased risk factors for fetal DNA abnormalities.

What is the value of a prenatal diagnosis of chromosome abnormality?

When a woman learns her baby has a chromosome abnormality she can be counselled about the condition, the possibility of fetal loss, and the potential risks to her, if any. It allows her and her family to learn about support resources and discuss pregnancy options with their healthcare provider.

Is Panorama accurate?

Panorama delivers the most accurate results of any prenatal screening test. The test has a false positive rate of less than 1%. By comparison, the standard maternal serum screening has a 5% false positive rate.

How early can a pregnant woman take the Panorama test?

The Panorama NIPT test can be done as early as 9 week gestation. This is very appealing to pregnant women who are at an increased risk of a chromosome abnormality. Amniocentesis is not available until 16 weeks gestation. Chorionic villus sampling (CVS) can be done at 10 weeks but is not widely available.

How quickly are Panorama NIPT results available?

Panorama results are available within 7-10 business days.

What are the limitations of Panorama NIPT?

Panorama is not valid for women:

- Who are carrying more than one fetus (twins or multiple gestations)
- Who have used an egg donor or surrogate

- Who have had a bone marrow transplant

Although highly accurate, NIPT is still considered a screen, so an abnormal result should be confirmed through a diagnostic test like chorionic villus sampling (CVS) or amniocentesis.

How do I order Panorama?

Patients should consult with their healthcare provider to determine if Panorama is right for them.

The test can be ordered by healthcare providers across Canada and consists of a simple blood draw collected at any LifeLabs, CML HealthCare or BC Biomedical collection centre in British Columbia or Ontario.

LifeLabs has many collection options outside of these two provinces as well. Patients or healthcare providers should visit www.lifelabsgenetics.com for more information or contact LifeLabs Genetics at 1-844-363-4357 (1-84-GENE-HELP) or Ask.Genetics@LifeLabs.com.

Where can a patient get genetic counselling?

A searchable database of genetic counselling clinics across Canada can be found on the website of the Canadian Association of Genetic Counsellors (CAGC) - www.cagc-accg.ca

About the Diseases

What is a Trisomy?

Trisomy refers to an extra copy of a specific chromosome. Chromosomes come in pairs. Humans normally have 23 pairs, for a total of 46 chromosomes. People with Down syndrome, for example, have an extra chromosome 21.

What are the common features of Trisomy 21 (Down syndrome)?

Individuals with trisomy 21, also called Down syndrome, have some degree of intellectual disability and characteristic facial features. They are also at risk for heart defects and weak muscle tone. Lifespan is dependent on each individual's medical problems, but these individuals can live into their 60s and beyond.

What are the common features of trisomy 18 (Edwards syndrome) and 13 (Patau syndrome)?

Most pregnancies with Trisomy 18 and 13 will miscarry. Those that survive through the pregnancy do not live beyond a few days or weeks of life although there is a small percentage that lives longer than 1 year of age. These are very severe conditions and these babies require a great deal of special medical care, particularly for breathing and feeding. Other features include severe intellectual disability and birth defects involving the heart, brain, and spinal cord.

What is Monosomy X (Turner syndrome)?

Monosomy refers to a single copy of a chromosome. Females with Monosomy X, which is also known as Turner syndrome, are missing a second copy of an X chromosome. The features of Monosomy X can vary from mild to severe, including heart and kidney problems, short in height,

learning difficulties, and hearing loss with age. Typically fertility is affected due to problems with the ovaries.

What is Triploidy?

Triploidy is a condition in which the fetus has 3 copies of each chromosome instead of two (a total of 69 chromosomes rather than 46). It most often happens when 2 sperm fertilize an egg. Most pregnancies with triploidy will miscarry in the early part of the first trimester, although later miscarriage or stillbirth can occur. The majority of those that survive die shortly after birth. Triploidy also puts the mother's health at risk from pregnancy complications like pre-eclampsia, postpartum hemorrhage and molar pregnancy with the potential for malignancy.

Features include brain and craniofacial abnormalities, neural tube defects, heart defects and GI abnormalities.

For more information about Panorama NIPT at LifeLabs, including detailed information about the testing process and how healthcare providers can order the test, please visit www.lifelabsgenetics.com or contact **1-844-363-4357 (1-84-GENE-HELP)** or Ask.Genetics@LifeLabs.com.