

Prenatest®

Prenatal Screening Service



Providing the best solution for prenatal screening



Prenatal Screening

There are many ways your healthcare provider can check on the health of your fetus. This pamphlet describes a prenatal screening service that offers the highest level of accuracy for determining your risk of carrying a fetus with trisomy 21 or trisomy 18. This test does not provide a final diagnosis on the health of the fetus you are carrying. The results will inform you of your risk of carrying a fetus affected by some of the most common birth anomalies.

Performed early, in the **first trimester**, the Prenatest® screen will provide results rapidly to give you time to consider your options. Depending on your risk result, our service includes the option of a non-invasive prenatal test **free of charge** before proceeding with an invasive diagnostic test.

WHAT IS TRISOMY 21?

Trisomy 21, also called Down syndrome, is a genetic condition that occurs at conception when the fetus receives three copies of chromosome 21 instead of two. Trisomy 21 gives rise to intellectual and physical disabilities for which it is impossible to predict the degree of severity. Trisomy 21 occurs in about 1 in 800 births¹, however the incidence rate varies significantly with age. As a woman gets older, her risk of having a pregnancy with a chromosome abnormality increases. However, any woman, regardless of her age, has a risk of having an affected pregnancy.

WHAT IS TRISOMY 18?

Trisomy 18, also called Edwards syndrome, is a genetic condition that occurs at conception when the fetus receives three copies of chromosome 18 instead of two. In most cases, the fetus does not survive to birth. It is estimated that trisomy 18 occurs in approximately 1 out of every 6,000 births². The incidence rate of trisomy 18 also increases with maternal age.

¹Canadian Down Syndrome Society
²Ontario Ministry of Health and Long-Term Care

Prenatest® Screen

The Prenatest® Prenatal Screening Test is performed during your first trimester of pregnancy. It lets you know your risk of carrying a fetus that may be affected by one of the most common birth anomalies: trisomy 21 and trisomy 18.

Quick and straightforward, the Prenatest® method requires a few drops of blood taken from the tip of your finger and a fetal ultrasound. The test is designed for all pregnant women, regardless of their age, and does not pose any danger to the mother or to the fetus. It is also available for twin pregnancies.

WHEN CAN I GET TESTED?

The Prenatest® Screening Test should be performed during the first trimester, between the 11th and 14th weeks of your pregnancy. If you consult your doctor at a later date, a second trimester Prenatest® screen can be performed between the 15th and 22nd weeks of pregnancy. This second trimester screening test is also useful in detecting open neural tube defects.

WHAT DOES THE TEST MEASURE?

	Measurements
Blood draw (finger prick)	<ul style="list-style-type: none">• PAPP-A• Free Beta-hCG
Ultrasound	<ul style="list-style-type: none">• Nuchal translucency• Nasal bone

Nuchal translucency: The amount of fluid accumulation at the back of the fetal neck. Fetuses affected by certain conditions may have an increased nuchal translucency.

Nasal bone: 70% of fetuses affected by trisomy 21 have an absent nasal bone during the first trimester of pregnancy¹.

¹Cicero, S. et al., 2003.

Medical Requisition

PATIENT

Last name: _____

First name: _____

Date of birth: _____
YYYY / MM / DD

Prenatest® Prenatal Screening Test

1st trimester (11^{1/7} to 13^{6/7} weeks)

2nd trimester (15 to 22 weeks)

Prenatest® Plus Prenatal Screening Test

1st trimester (11^{1/7} to 13^{6/7} weeks)

PRESCRIBER

Last name: _____

First name: _____

Telephone: (____) _____

Prescriber's information

Signature: _____

Licence #: _____

Date: _____
YYYY / MM / DD

Why Choose Prenatest®?

- It is the best choice for prenatal screening in the first trimester
- It does not pose any danger to the mother or the fetus
- It includes a free non-invasive prenatal test for high risk and intermediate risk* results
- It offers the highest detection rate and lowest false-positive rate of any first trimester screen on the market
- It is available to pregnant women of all ages

*With the Prenatest® Plus service.

Talk to your healthcare provider to decide if the Prenatest® screening test is appropriate for you.

GENETIC COUNSELLING

Dynacare Next offers genetic counselling services to support both patients and physicians by identifying genetic risks, explaining appropriate genetic testing options, discussing the implications of the test results, and helping patients make better healthcare decisions. Genetic counselling is included in the price of Prenatest® services.

Customer Care
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Two Prenatest® Options: Higher Accuracy and Added Value

Prenatest® Prenatal Screening Test

The Prenatest® Prenatal Screening service will inform you of your risk of carrying a fetus with trisomy 21 or 18. Patients with a high risk result will be offered the option of a non-invasive

prenatal test free of charge. In the first trimester, the detection rate of trisomy 21 is **90-95%**¹ and the false-positive rate is **less than 0.1%**².

Prenatest® Results	
LOW RISK	HIGH RISK
This means that your risk of having a fetus with trisomy 21 is lower than the established threshold value of 1/250. This does not guarantee that the fetus is not affected, but it tells you that you are at lower risk.	This means that your risk of having a fetus with trisomy 21 is greater than or equal to the established threshold value of 1/250. However, this does not necessarily mean that your fetus is affected. Your physician or a genetic counsellor will discuss your options with you, including diagnostic testing. Before proceeding with an invasive diagnostic test, you have the option of undergoing a non-invasive prenatal test free of charge.

Prenatest® Plus Prenatal Screening Test

The Prenatest® Plus Prenatal Screening service has an additional risk category (intermediate risk) to increase accuracy. Patients with intermediate risk or high risk results will be offered the option of a non-invasive prenatal test

free of charge. The detection rate of trisomy 21 is **greater than 98%**³ and the false-positive rate is **less than 0.1%**². Prenatest® Plus is only available in the first trimester of pregnancy.

Prenatest® Plus Results		
LOW RISK	INTERMEDIATE RISK	HIGH RISK
This means that your risk of having a fetus with trisomy 21 is lower than 1/2,500. This does not guarantee that the fetus is not affected, but it tells you that you are at lower risk.	This means that your risk is between 1/2,500 and 1/251. While your result is not high risk, the Prenatest® Plus service allows you to undergo a non-invasive prenatal test free of charge if you wish to pursue further testing. Your physician or a genetic counsellor will discuss this option with you.	This means that your risk of having a fetus with trisomy 21 is greater than or equal to 1/250. However, this does not necessarily mean that your fetus is affected. Your physician or a genetic counsellor will discuss your options with you, including diagnostic testing. Before proceeding with an invasive diagnostic test, you have the option of undergoing a non-invasive prenatal test free of charge.

Follow-Up Testing

NON-INVASIVE PRENATAL TEST

A non-invasive prenatal test (NIPT) is an advanced screening test that detects common fetal trisomies (21, 18 and 13) and sex chromosome aneuploidies by analyzing fetal cell-free DNA in a maternal blood sample.

DIAGNOSTIC TESTS*

The following diagnostic tests can determine if your pregnancy is affected by trisomy 21, trisomy 18 or other chromosomal anomalies. However, these invasive tests have an associated risk of pregnancy complications or miscarriage.

- **Chorionic villus sampling (CVS):** Procedure that takes a small amount of tissue from the developing placenta. The tissue is then sent to a laboratory to test the chromosomes. CVS is typically performed between 10 and 12 weeks of pregnancy.
- **Amniocentesis:** Procedure that withdraws a small amount of fluid that surrounds the fetus. The fluid is then sent to the laboratory to test the chromosomes. An amniocentesis is usually performed around or after the 15th week of pregnancy.

*Dynacare does not offer these diagnostic tests.

TIME TO RESULTS

	Work days
Prenatest® - 1 st trimester	3
Prenatest® Plus - 1 st trimester	3
Prenatest® - 2 nd trimester	10
Non-invasive prenatal test	10

Prenatest® is a registered trademark of Dynacare.

¹Nikolaides, K.H., 2011. ²Norton, M.E. et al., 2012. ³Nikolaides, K.H. et al., 2014.