

MaterniT® **Prenatal Test Requisition**

Patient Information Last name: First name: Date of birth: Health insurance #: Weight: Sex: M F Address: Province Postal code Telephone:

Test Menu Options MaterniT® 21 Plus - trisomy 21, trisomy 18, trisomy 13, fetal sex (MAT1) Do not include fetal sex on the report Additional options: Sex Chromosome Aneuploidies (SCA)¹ Enhanced Sequencing Series (ESS) - microdeletion panel, trisomy 22, trisomy 16 Microdeletion panel: 22q11.2 deletion syndrome, 11q23 (Jacobsen syndrome), 5p15 (Cri-du-chat syndrome), 8q24 (Langer-Giedion syndrome), 1p36 deletion syndrome, 4p16 (Wolf-Hirschhorn syndrome), 15q11 (Prader-Willi syndrome; Angelman syndrome) MaterniT® Genome¹ - genome-wide aneuploidies, copy number variants (CNV) ≥ 7Mb, microdeletion panel, fetal sex (MAT7) Do not include fetal sex on the report **Genome Flex**¹ - genome-wide sample reanalysis after completion of MaterniT® 21 Plus (MAT5) ¹ Singletons only. Please contact this patient for genetic counselling related to this test/clinical indication.

Blood Draw Information Collection date: Is this a redraw? Yes No Collection centre: ___ Collected by: _ Collection account #:___

Important: Patients must be of at least 9 weeks gestational age at the time of collection.

Prescriber Informa	tion	
Client #:		
Address:		
NO.	Street name	Office
City Telephone:	Province	Postal code
Fax:		
Copy results to:		
cc. Fax:	Last name, First name	

Clinical Information	
Gestation age: complete A or B	
A Gestational age at date of ultrasound:weeksdays	
Date of ultrasound:	
B LMP date; or MM DD IVF transfer date:	
No. of fetuses: 2 3 Other:	
IVF pregnancy: No Yes → Egg donor is: Self Non-self Donor age at retrieval: years	

Clinician Signa	ture	
3 1	ient has been fully informed about details, itations of the test(s).	
The patient has give	en full consent for this test.	
Clinician signature:		_
Licence #:	Date: YYYY MM DD	



Patient Informed Consent

Limitations of testing

While the results of these tests are highly accurate, discordant results, including inaccurate fetal sex prediction, may occur due to placental, maternal, or fetal mosaicism or neoplasm; vanishing twin; prior maternal organ transplant; or other causes. These tests are screening tests and not diagnostic; they do not replace the accuracy and precision of prenatal diagnosis with CVS or amniocentesis. The results of this testing, including the benefits and limitations, should be discussed with a qualified healthcare provider. Pregnancy management decisions, including termination of the pregnancy, should not be based on the results of these tests alone. The healthcare provider is responsible for the use of this information in the management of their patient.

Not all trisomic fetuses will be detected. Some trisomic fetuses may have LOW RISK results. Some non-trisomic fetuses may have HIGH RISK results. False negative and false positive results are possible. It is recommended that a HIGH-RISK result and/or other clinical indications of a chromosomal abnormality be confirmed through fetal karyotype analysis such as CVS or amniocentesis. It is recommended that results be communicated in a setting designated by your healthcare provider that includes appropriate counselling. A LOW-RISK result does not guarantee an unaffected pregnancy due to the screening limitations of the test. These tests provide a risk assessment, not a diagnosis, and results should be considered in the context of other clinical criteria. A negative or low risk test result also does not exclude the possibility of other chromosomal abnormalities or birth defects which are not a part of these tests.

An uninformative result may be reported, the causes of which may include, but are not limited to, insufficient sequencing coverage, noise or artifacts in the region, amplification or sequencing bias, or insufficient fetal fraction. For a variety of reasons, including biological, the test has a failure rate. As such, you may be requested to redraw a new sample. In a small number of cases, a result for fetal sex and/ or sex chromosome aneuploidy determination may not be obtained. This can be due to biological and technical factors influencing sex chromosome analysis that did not impact trisomy analysis. In these cases, we do not retest or redraw a new sample.

These tests are not intended to identify pregnancies at risk for neural tube defects or ventral wall defects. Testing for whole chromosome abnormalities (including sex chromosomes) and for subchromosomal abnormalities could lead to the potential discovery of both fetal and maternal genomic abnormalities that could have major, minor, or no, clinical significance. Evaluating the significance of a positive or a non-reportable result may involve both invasive testing and additional studies on the mother. Such investigations may lead to a diagnosis of maternal chromosomal or subchromosomal abnormalities, which on occasion may be associated with benign or malignant maternal neoplasms. These tests may not accurately identify fetal triploidy, balanced rearrangements, or the precise location of subchromosomal duplications or deletions; these may be detected by prenatal diagnosis with CVS or amniocentesis. The ability to report results may be impacted by maternal BMI, maternal weight, maternal systemic lupus erythematosus (SLE) and/or by certain pharmaceutical agents such as low molecular weight heparin (for example: Lovenox®, Xaparin®, Clexane® and Fragmin®).

Non-Invasive Prenatal Testing (NIPT) based on fetal cell-free DNA analysis is not a diagnostic test. No irrevocable obstetrical decision should be made on a positive result generated from a NIPT based on fetal cell-free DNA analysis, without confirmation by other invasive diagnostic testing. MaterniT® 21 Plus and MaterniT® Genome specimens will be sent to a laboratory in the United States. When samples are sent to the United States, personal information, including but not limited to name and date of birth, will accompany the sample. Personal information held in countries outside of Canada could be subject to disclosure to government or other authorities (whether of that country or of another country).

What is done with my sample after testing is complete?

No additional clinical testing will be performed on your blood sample other than those authorized by your healthcare provider. Dynacare will disclose the test results only to the healthcare provider(s) listed on the front of this form, or to his or her agent, unless otherwise authorized by you or as required by laws, regulations, or judicial order. Details on Dynacare's policies and procedures governing patient privacy and health information, including patient rights regarding such information, can be found at https://www.dynacare.ca/privacy-policy.aspx.

MaterniT® ordering options

MaterniT' 21 Plus Test	Sex Chromosome Aneuploidies (SCA)*	Enhanced Sequencing Series (ESS) Microdeletions*
Trisomy 21 (Down syndrome)	45, X (Turner syndrome)	22q (DiGeorge syndrome)
Trisomy 18 (Edwards syndrome)	47, XXY (Klinefelter syndrome)	5p (Cri-du-chat syndrome)
Trisomy 13 (Patau syndrome)	47, XXX (Triple X syndrome)	1p36 deletion syndrome
Fetal sex	47, XYY (Jacob syndrome)	15q (Angelman/Prader-Willi syndromes)
		11q (Jacobsen syndrome)
		8q (Langer-Giedion syndrome)
		4p (Wolf-Hirschhorn syndrome)
		Trisomy 22
		Trisomy 16

^{*}All MaterniT* tests report mosaicism ratio, if mosaicism detected, as additional findings.