Dynacare®

For test information, to inquire about sample collection or to speak to a genetic counsellor call **1.888.988.1888**

Prenatal Test Requisition

Important:

Harmony: Patients must be of at least 10 weeks gestational age at the time of collection.

MaterniT 21 Plus/MaterniT Genome: Patients must be of at least 9 weeks gestational age at the time of collection.

Patient Information

Last name: _____

First name: _____

Date of birth: YYYY MM DD

Health insurance no.: _____

Sex: ☐ M ☐ F Weight: _____ ☐ kg ☐ lbs

Address: _____
No. Street name Apt/Unit

_____
City Province Postal code

Telephone: _____

Clinical Information

Gestation age: complete A or B

A Gestational age at date of ultrasound: _____ **weeks** _____ **days**

Date of ultrasound: YYYY MM DD

B ☐ LMP date; **or**
☐ IVF transfer date: YYYY MM DD

No. of fetuses: ☐ 1 ☐ 2 ☐ **other:** _____

IVF pregnancy:
☐ No ☐ Yes → Egg donor is: ☐ **Self** ☐ **Non-self**
Donor age at retrieval: _____ **years**

Blood Draw Information

Collection date: YYYY MM DD

Is this a redraw? ☐ **Yes** ☐ **No**

Collection centre: _____

Collected by: _____

Prescriber Information

Last name: _____

First name: _____

Clinic: _____

Address: _____
No. Street name Office

_____
City Province Postal code

Telephone: _____

Fax: _____

Copy results to: _____
Last name, First name

cc. Fax: _____

Test Menu Options

MaterniT 21 PLUS + GENOME

☐ **MaterniT® 21 Plus (MAT1)**
(T21, T18, T13, Fetal sex)

Additional options:

- ☐ ESS **(MAT3)**
- ☐ SCA[1] **(MAT2)**
- ☐ ESS + SCA[1] **(MAT4)**
- ☐ MaterniT® Genome[1] **(MAT7)**
  Genome-wide fetal aneuploidies
- ☐ Genome Flex[1] **(MAT5/MAT6)**
  Specimen re-sequencing after MaterniT® 21 PLUS
- ☐ Opt out of fetal sex

harmony performed in Canada

☐ **Harmony® Prenatal Test**
(T21, T18, T13)

Additional options:

- ☐ Fetal Sex
- ☐ Monosomy X[1,2]
- ☐ Sex Chromosome Aneuploidy Panel[1,2]
- ☐ 22q11.2[1]

[1] Singletons only. [2] Fetal sex not reported.

☐ Please contact this patient for genetic counselling related to this test/ clinical indication

Clinician Signature

I attest that my patient has been fully informed about details, capabilities, and limitations of the test(s).

The patient has given full consent for this test.

Clinician Signature: _____

License no.: _____ Date: YYYY MM DD

Dynacare Cell-Free Fetal DNA Non-Invasive Prenatal Testing Informed Consent

Harmony® | MaterniT® 21 Plus | MaterniT® Genome

Limitations of the 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 mosaicismor 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 as 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.

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.

Harmony® Prenatal Test Ordering Options

Who is eligible for the Harmony® Prenatal Test?

Patients must be of at least 10 weeks gestational age for any of the Harmony Test offerings. Patients with a twin pregnancy are not eligible for monosomy X, sex chromosome aneuploidy, or 22q deletion syndrome options. The Harmony® Prenatal Test is not for patients with a history of or active malignancy; a pregnancy with fetal demise; a pregnancy with more than two fetuses; or a history of bone marrow or organ transplants. Please see below for additional eligibility criteria:

	Harmony (Trisomy 21, 18, 13) + or - Fetal Sex Option	Harmony + Sex Chromosome Aneuploidy (SCA) Panel or Monosomy X	Harmony + 22q Deletion Syndrome + or – Fetal Sex	Harmony + 22q Deletion Syndrome + or – Fetal Sex + or – SCA or Monosomy X
Singleton pregnancies including IVF	X	X	X	X
Twin pregnancies including IVF	X	Not eligible	Not eligible	Not eligible
More than 2 fetuses	Not eligible	Not eligible	Not eligible	Not eligible
Pregnancies with vanished twin	Not eligible	Not eligible	Not eligible	Not eligible

What are the limitations specific to the Harmony Prenatal Test?

The Harmony® Prenatal Test is not validated for use in pregnancies with more than two fetuses, fetal demise, mosaicism, partial chromosome aneuploidy, translocations, maternal aneuploidy, transplant, malignancy, or in women under the age of 18. For twin pregnancies, HIGH RISK test results apply to at least one fetus; male test results apply to one or both fetuses; female results apply to both fetuses.

MaterniT® Ordering Options

Who is eligible for the MaterniT® 21 Plus and MaterniT® Genome Tests?

Patients must be of at least 9 weeks gestational age for any of the MaterniT® test offerings. Patients who have received bone marrow or organ transplants or those who have metastatic cancer are not eligible for the MaterniT® 21 Plus or MaterniT® Genome tests. Please see below for additional eligibility criteria:

	MaterniT® 21 Plus Core (Trisomy 21, 18, 13 + or - Fetal Sex Options)	MaterniT® 21 Plus Core + Fetal Sex Chromosome Abnormalities (SCA)	MaterniT® 21 Plus Core + Fetal Sex Chromosome abnormalities (SCA) + Extended Sequencing Series	MaterniT® 21 Plus Core + Extended Sequencing Series (ESS)	MaterniT® Genome	Genome Flex
Singleton pregnancies including IVF	X	X	X	X	X	X
Twin pregnancies including IVF	X	Not eligible	Not eligible	X	Not eligible	Not eligible
More than 2 fetuses	X	Not eligible	Not eligible	X	Not eligible	Not eligible
Pregnancies with vanished twin	X	X	X	X	X	X

MaterniT® Ordering Options Continued...

MaterniT® 21 Plus Test	Sex Chromosome Aneuploidies (SCA)*	Extended Sequencing Series (ESS) - Microdeletions and Esoteric Chromosomal Aneuploidy*
Trisomy 21 (Down syndrome) **Trisomy 18** (Edwards syndrome) **Trisomy 13** (Patau syndrome) **Fetal sex**	**45, X** (Turner syndrome) **47, XXY** (Klinefelter syndrome) **47, XXX** (Triple X syndrome) **47, XYY** (Jacob syndrome)	**22q** (DiGeorge syndrome) **5p** (Cri-du-chat syndrome) **1p36** deletion 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.

*Reported as additional findings.

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 **http://dynacare.ca/privacy-policy.aspx**.

Harmony® Prenatal Test specimens will be tested in Canada. 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).

Patient Instructions for Sample Collection

To know the location of the nearest collection centre, call us at **888.988.1888** or visit **Dynacare.ca**.
You also have the option of having your sample collected in the comfort of your own home at no extra charge.*
One of our specially trained medical technicians will come to your home to perform the blood draw.
To book your home collection appointment, contact Dynacare at **888.988.1888**.

*Depending on distance, additional charges may apply.