PRENATAL SCREENING
DÉPISTAGE PRÉNATAL
ONTARIO

Dynacare®

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Publicly Funded Harmony Non-Invasive Prenatal Testing (NIPT) Requisition

Instructions: Healthcare provider to complete pages 1 and 2. Harmony can only be performed for singleton pregnancies and viable twin pregnancies. Harmony cannot be performed for higher order multiples nor pregnancies with a co-twin demise (i.e. vanishing twin). Pregnant individuals to take requisition to Dynacare for blood draw on or after 10 weeks' gestation.

PATIENT INFORMATION

Last Name _____

First Name _____

Date of Birth _____
Year / Month / Day

Health Ins. No. (OHIP #) _____

Sex ☐ F ☐ M Weight _____ ☐ kg ☐ lbs

Address _____
No Street Apt.

_____
City Province Postal code

Tel _____

CLINICAL INFORMATION

Gestational age: complete A or B

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

Date of ultrasound: Year | Month | Day

B ☐ LMP Date; or
☐ IVF Transfer Date
Year | Month | Day

# of Fetuses ☐ 1 ☐ 2

IVF Pregnancy ☐ No ☐ Yes
→ Egg Donor is: ☐ Self ☐ Non-self
Donor Age at Retrieval: _____ years

Vanishing Twin ☐ No ☐ Yes → Note: Harmony cannot be done for vanishing twin pregnancies.

BLOOD DRAW INFORMATION

Collection Date Year | Month | Day

Is this a redraw? ☐ Yes ☐ No

Collection Centre _____

Collected by _____

HEALTHCARE PROVIDER INFORMATION

Last Name _____

First Name _____

Clinic _____

Address _____
No Street Office

_____
City Province Postal code

Tel _____

Fax _____

Copy results to _____
Last Name, First Name

CC Fax _____

TEST MENU OPTIONS

☒ Harmony for T21, T18, T13

Additional options (no cost):

☐ Fetal Sex
☐ Monosomy X[1,2]
☐ Sex Chromosome Aneuploidy Panel[1,2]

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

HEALTHCARE PROVIDER 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.

Healthcare Provider Signature _____

Date _____ Licence No. _____
Year / Month / Day

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Publicly Funded Non-Invasive Prenatal Testing (NIPT)
PSO Eligibility Criteria Form

The following criteria for publicly funded NIPT have been established by Prenatal Screening Ontario. Please confirm that the pregnant individual in your care has a valid OHIP card and meets at least one of the following criteria by checking the appropriate boxes. Healthcare provider on page 1 must match provider information/signature on page 2. Note: If your patient does not currently meet the publicly funded eligibility criteria, private-pay NIPT is available. However, your patient may become eligible for publicly funded NIPT later in the pregnancy; reimbursement for private-pay NIPT can only be provided if your patient qualified for publicly funded NIPT at the time of blood draw. For more information on private-pay NIPT, visit dynacare.ca.

PATIENT INFORMATION

Last Name _____

First Name _____

Health Ins. No. (OHIP #) _____

Date of birth (Year/Month/Day) _____

CATEGORY I CRITERIA

Select all that apply:

- ☐ A multiple marker screening test (e.g. eFTS, STS) positive for aneuploidy.
- ☐ The age of the pregnant individual will be 40 years or older at the expected date of delivery. In the context of *in vitro* fertilization (IVF), this is defined as the oocyte (egg) age at retrieval being 39 years or older (whether self- or donor-provided oocyte).
- ☐ Previous pregnancy or child with trisomy 21, 18 or 13.
- ☐ Twin pregnancy with ultrasound demonstration of fetal heart activity in both fetuses.
- ☐ Increased nuchal translucency (NT) ≥3.5mm*

  *NT ≥3.5mm can be associated with genetic conditions and fetal congenital anomalies not detected by NIPT. **Prompt referral to a Genetics/Maternal Fetal Medicine specialist is indicated regardless of NIPT order or result.**

Healthcare Provider Signature _____ Billing # _____

Healthcare Provider Name (please print) _____ Date (Year/Month/Day) _____

CATEGORY II CRITERIA

The following situations require specialist consultation to determine whether NIPT is warranted and to provide appropriate pre- and post-test counselling. Select all that apply (must be completed by a Genetics or Maternal Fetal Medicine (MFM) specialist).

Risk indicators for trisomy 21, trisomy 18, trisomy 13 (select all that apply):

- ☐ Fetal congenital anomalies identified on ultrasound that are suggestive of trisomy 21, 18, or 13.

  Please specify: _____
- ☐ Cystic hygroma
- ☐ Isolated soft marker with moderate likelihood ratio for trisomy 21 (must check one or more):
  - ☐ Absent/hypoplastic nasal bone
  - ☐ Increased nuchal fold (≥6mm)
- ☐ Multiple soft markers with low likelihood ratio for trisomy 21 (must check two or more):
  - ☐ Aberrant right subclavian artery
  - ☐ Clinodactyly
  - ☐ Hyperechogenic bowel
  - ☐ Echogenic intracardiac focus/foci
  - ☐ Pyelectasis
  - ☐ Short femur
  - ☐ Short humerus
  - ☐ Ventriculomegaly
- ☐ Other indication, specify: _____

NIPT for sex chromosome determination (select at least one):

- ☐ Risk of sex-linked condition
- ☐ Ultrasound findings suggestive of a sex chromosome aneuploidy
- ☐ Ultrasound findings suggestive of a difference/disorder of sex development (DSD)

Genetics or MFM Specialist Signature _____ Billing # _____

Genetics or MFM Specialist Name (please print) _____ Date (Year/Month/Day) _____

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Patient Informed Consent

Limitations of the Testing

While the results of these tests are highly accurate, discordant results, including inaccurate fetal sex prediction, may occur due to mosaicism or neoplasm in the placenta, fetus or pregnant individual; vanishing twin; prior organ transplant of the pregnant individual; 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 genomic abnormalities in both the fetus and the pregnant individual 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 pregnant individual. Such investigations may lead to a diagnosis of chromosomal or subchromosomal abnormalities in the pregnant individual, which on occasion may be associated with benign or malignant 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 the pregnant individual's BMI, weight, 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.

Note: Options for Fetal Sex, Monosomy X, and Sex Chromosome Aneuploidy Panel can only be added up to a maximum of 30 days following initial reporting.

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. Your sample will be destroyed in accordance with Dynacare standard operating procedures 14 days after the test has been completed and the results have been sent to your healthcare provider. Dynacare will disclose the test results only to the healthcare provider(s) listed on 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 www.dynacare.ca/privacy-policy.aspx.