harmony™ PRENATAL TEST
performed in Canada

Dynacare®

MOH-Funded Harmony Prenatal Test Requisition

PATIENT INFORMATION

Last Name _____

First Name _____

Date of Birth _____
Year / Month / Day

Health Ins. No. _____

Sex ☒ F ☐ M Weight _____ ☐ kg ☐ lbs

Address _____
No Street Apt.

_____
City Province Postal code

Tel _____

PRESCRIBER INFORMATION

Last Name _____

First Name _____

Clinic _____

Address _____
No Street Office

_____
City Province Postal code

Tel _____

Fax _____

PATIENT CONSENT

My signature on this form indicates that I have read, or had read to me, the informed consent on the back of this form. I understand the informed consent and give permission to Dynacare to perform the laboratory test(s) selected. I have had the opportunity to ask questions and discuss the capabilities, limitations, and possible risks of the test(s) with my healthcare provider or someone my healthcare provider has designated. I know that if I wish, I may obtain professional genetic counselling before signing this consent.

Patient Signature _____

Date _____
Year / Month / Day

TEST MENU OPTIONS

☒ Harmony Prenatal Test (T21, T18, T13)

Additional options:

- ☐ Fetal Sex
- ☐ Monosomy X*
- ☐ Sex Chromosome Aneuploidy Panel*

*Singletons only. Fetal sex not reported.

BLOOD DRAW INFORMATION

Collection Date Year | Month | Day

Is this a redraw? ☐ Yes ☐ No

Collection Centre _____

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

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 _____

Date _____ Licence No. _____
Year / Month / Day

1100 Bennett Road, Unit#4, Bowmanville, ON, L1C 3K5 T 888.988.1888 F 450.663.4428 DynacareNext@dynacare.ca

Rev.2018AL06

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Patient Informed Consent

The Harmony Prenatal Test and the available test options are laboratory-developed screening tests that analyze cell-free DNA (cfDNA) in maternal blood. The tests aid in the risk determination of fetal chromosomal or genetic conditions, and fetal sex determination, if selected. In some cases, follow-up confirmatory testing based on these test results could uncover maternal chromosomal or genetic conditions.

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 who have received bone marrow or organ transplants or those who have metastatic cancer are not eligible for the Harmony Prenatal Test. Please see below for additional eligibility criteria:

	Harmony (Trisomy 21, 18,13) with or without Fetal Sex Option	Harmony with Sex Chromosome Aneuploidy Panel or Monosomy X
Singleton Pregnancies including IVF	✓	✓
Twin Pregnancies including IVF	✓	Not eligible
More than 2 Fetuses	Not eligible	Not eligible

What are the limitations of the Harmony Prenatal Test?

The Harmony Prenatal Test is not intended nor validated for diagnosis or detection of mosaicism, partial trisomy, or translocations. Certain rare biological conditions may also affect the accuracy of the test. Limited numbers of aneuploidy twin and egg donor pregnancies have been evaluated because these conditions are rare. Results for twin pregnancies reflect the probability that the pregnancy involves at least one affected fetus. For twin pregnancies, male results apply to one or both fetuses, and female results apply to both fetuses.

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. A LOW RISK result does not guarantee an unaffected pregnancy due to the screening limitations of the test. Harmony provides a risk assessment, not a diagnosis, and results should be considered in the context of other clinical criteria. 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 amniocentesis. It is recommended that results be communicated in a setting designated by your healthcare provider that includes appropriate counselling. For a variety of reasons, including biological, the test has a failure rate. As such, you may be requested to redraw a new sample.

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 www.dynacare.ca/privacy-policy.aspx.

Your specimen will be tested in Canada, however, in some cases your sample may be sent to a laboratory in the United States for testing. In this case, 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).

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. Data have not been submitted or evaluated by Health Canada or other federal regulatory agencies and the test is not for sale as an In Vitro Diagnostic test in Canada.

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 Next at 888.988.1888.

*Depending on distance, additional charges may apply.

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MOH Criteria for Eligibility Form

Instructions: The Provincial Council for Maternal and Child Health (PCMCH) has recommended specific indications for NIPT funding. Please complete Patient Information and Indication Category I **or** II sections of the form, and attach to the completed Harmony™ Prenatal Test requisition.

PATIENT INFORMATION

Last Name _____

First Name _____

Health Ins. No. (OHIP #) _____

Date of birth (Year/Month/Day) _____

INDICATION CATEGORY I

For investigation of trisomy 21, 18 or 13 ONLY.

Singleton gestation (NIPT in the context of twin pregnancies requires consultation with a geneticist or maternal fetal medicine specialist (see Indication Category II)) with appropriate pre-test counselling including a discussion of the limitations of the test.

And any one of the following:

- ☐ A maternal multiple marker screening test (eg. FTS/IPS/Quad etc.) positive for aneuploidy
- ☐ Women of advanced maternal age, defined as ≥ 40 years of age at expected time of delivery
- ☐ Fetal nuchal translucency (NT) ≥ 3.5mm
- ☐ Pregnancy history of aneuploidy / previous child with aneuploidy

Physician Signature _____ Date (Year/Month/Day) _____ CSN# _____

INDICATION CATEGORY II

There are several situations where additional specialist consultation is necessary to determine whether NIPT is warranted and to provide appropriate pre and post-test counselling. **NIPT funding for the following indications must be submitted by a genetics or maternal fetal medicine (MFM) specialist.**

Risk Indicators:

A/

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

Specify: _____

OR:

B/

☐ Risk of aneuploidy for trisomy 21, 18 or 13 ≥ than that of a positive maternal multiple marker screen.

- Women less than 40 years of age at expected date of delivery must have at least one other risk factor noted.
- The risk of aneuploidy can be calculated by including any combination of risk indicators including soft markers, biochemistry, maternal age, etc.

Please indicate all risk factors present

☐ Twin pregnancy (if additional risk factors are identified, submit one checklist per fetus)

☐ Soft markers (check all that apply):

☐ Absent nasal bone	☐ Hyperechogenic bowel	☐ Intracardiac echogenic focus / foci
☐ Choroid plexus cysts	☐ Hypoplastic nasal bone	☐ Short femur
☐ Clinodactyly	☐ Increased nuchal fold / edema	☐ Short humerus
☐ Cystic hygroma	☐ Increased nuchal translucency	☐ Ventriculomegaly

☐ Maternal age _____

☐ Other, specify: _____

OR:

C/

☐ NIPT for sex chromosome determination (at least one of the following):

- ☐ Risk of a sex-limited disorder
- ☐ Ultrasound findings suggestive of either a sex chromosome aneuploidy
- ☐ Ultrasound findings suggestive of a disorder of sex determination (DSD).

Genetics or MFM specialist's name (Please print) _____

Specialist's Signature _____ Date (Year/Month/Day) _____ CSN# _____

Genetics or MFM Centre _____