BC Prenatal Genetic Screening Program

harmony™ PRENATAL TEST performed in Canada

Dynacare®

Requisition for Funded NIPT in BC

PATIENT INFORMATION

Last Name _____

First Name _____

Date of Birth _____
Year / Month / Day

PHN/Carecard _____

Sex ☒ F ☐ M Weight _____ ☐ kg ☐ lbs

Address _____
No Street Apt.

_____
City Province Postal code

Tel _____

PATIENT CONSENT

My signature on this form indicates that I give permission to Dynacare to perform the laboratory tests 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. I know that my personal information is being collected and shared with the BC Prenatal Genetic Screening Program, as per BC's privacy and confidentiality policies.

Patient Signature _____

Date _____
Year / Month / Day

BLOOD DRAW INFORMATION

Collection Date Year | Month | Day

Is this a redraw? ☐ Yes ☐ No

Collection Centre _____

INDICATION FOR FUNDED NIPT

☐ Positive Screen from IPS/SIPS/Quad/FTS (Authorization code issued by C&W Prenatal Biochemistry Lab)

☐ Other (Authorization code issued by BCW or Victoria Medical Genetics)

Authorization Code _____

ORDERING 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) _____

Fax _____

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.

CLINICAL INFORMATION

Gestational age at date of ultrasound: _____ weeks _____ days

Date of ultrasound: 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 _____ MSP # _____
Year / Month / Day

1100 Bennett Road, Unit #4, Bowmanville, ON L1C 3K5 T 888.988.1888 F 450.663.4428

Rev. 2018AL06

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Patient Informed Consent

You are reading this consent form because you are eligible for funded NIPT as part of your prenatal care. Your health care provider will talk to you about why you are being offered funded NIPT. This consent form from Dynacare Next explains the Harmony NIPT test and how it is done.

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 able to use 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.

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, including the BC Prenatal Genetic Screening Program, 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. The BC Prenatal Genetic Screening Program collects, uses and discloses personal information only as authorized under section 26(c), 33 and 35 of the BC Freedom of Information and Protection of Privacy Act, other legislation and PHSA's Privacy and Confidentiality Policy.

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 in your area, go online to the BC Prenatal Genetic Screening Program (Perinatal Services BC) at **www.bcprenatalscreening.ca** to see a list of hospital out-patient lab collection sites or call Dynacare Next at **888.988.1888**.