BC Prenatal Genetic Screening Program

harmony®

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

115 Midair Court, Brampton, ON L6T 5M3 T 888.988.1888 F 450.663.4428 DynacareGenetics@dynacare.ca

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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 explains the Harmony NIPT test and how it is done.

The Harmony® Prenatal Test is a prenatal screening test that analyzes cell-free DNA (cfDNA) in maternal blood. The test provides a risk assessment, not a diagnosis, of fetal chromosomal or genetic conditions, and fetal sex determination. Consider Harmony results in the context of other clinical criteria. Follow up confirmatory testing based on Harmony results for Trisomy 21, 18, 13 or sex chromosome aneuploidy could reveal maternal chromosomal or genetic conditions in some cases. Results from the Harmony Prenatal Test should be communicated in a setting designated by your healthcare provider that includes the availability of appropriate genetic counselling.

The Harmony non-invasive prenatal test is licensed in accordance with Health Canada regulation requirements for a class III license. The Harmony test is based on cell-free DNA analysis and is considered a prenatal screening test, not a diagnostic test. Harmony does not screen for potential chromosomal or genetic conditions other than those expressly identified in this document. All women should discuss their results with their healthcare provider who can recommend confirmatory diagnostic testing where appropriate.

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 or sex chromosome aneuploidy 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.

What are the limitations of the Harmony Prenatal Test for Trisomies 21, 18, and 13, sex chromosome aneuploidy, and fetal sex determination?

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. Harmony does not detect neural tube defects. Certain rare biological conditions may also affect the accuracy of the test. 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.

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. 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.

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. 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.

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 at **888.988.1888**.