Dynacare®

harmony®
performed in Canada

Harmony®
Prenatal Test Requisition

Patient Information

Last name: _____

First name: _____

Date of birth: YYYY MM DD

Health insurance #: _____

Sex: ☐ M ☐ F Weight: _____ ☐ kg ☐ lbs

Address: _____
No. Street name Apt/Unit

_____
City Province Postal code

Telephone: _____

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

Test Menu Options

☒ **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.

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: _____

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

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: _____

License no.: _____ Date: YYYY MM DD

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Patient Informed Consent

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, sex chromosome aneuploidy, or 22q11.2 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, sex chromosome aneuploidy or 22q11.2 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 are the limitations of the Harmony® Prenatal Test for 22q11.2?

In addition to the limitations discussed above, the 22q11.2 option is not validated for use in pregnancies with more than one fetus or for women with a 22q11.2 duplication or deletion.

A 22q11.2 deletion may not be detected in all fetuses. Due to the limitations of the test, a LOW PROBABILITY result does not guarantee that a fetus is unaffected by a chromosomal or genetic condition. Some fetuses with a 22q11.2 deletion may receive a test result of LOW PROBABILITY. Some fetuses without the 22q11.2 deletion may receive a test result of HIGH PROBABILITY. In cases of HIGH PROBABILITY results and/or other clinical indications of a chromosomal condition, confirmatory testing is necessary for diagnosis.

Note: The 22q11.2 option 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, 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 **https://www.dynacare.ca/privacy-policy.aspx**.

Harmony® Prenatal Test is a trademark of Roche.

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NL Health Services

Dynacare®

Criteria for Eligibility Form

Instructions: 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. (MCP #) _____

Date of birth (Day/Month/Year) _____

INDICATION CATEGORY I

For investigation of trisomy 21, 18 or 13 ONLY, 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. MSS/Quad etc.) positive for aneuploidy
- ☐ Women of advanced maternal age, defined as ≥ 37 years of age at expected time of delivery. In the context of in vitro fertilization, the maternal age is guided by the age at egg retrieval (whether own egg or donor egg)
- ☐ Twins with ultrasound demonstration of fetal heart activity in both
- ☐ Previous pregnancy or child with aneuploidy

Healthcare Professional Signature _____ Date (Day/Month/Year) _____

INDICATION CATEGORY II - ORDERING RESTRICTED TO GENETICS/MATERNAL FETAL MEDICINE

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 greater than that of a positive maternal multiple marker screen.

- Women less than 37 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:

☐ Soft markers (check all that apply):

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

☐ Maternal age at EDC: _____

☐ 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 a sex chromosome aneuploidy
- ☐ Ultrasound findings suggestive of a disorder of sex determination (DSD)

OR:

D/

☐ Unfavourable diagnostic test (e.g. anhydramnios, active HIV/hepC)

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

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